UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND
EDWARDS LIFESCIENCES LLC

Petitioners

v.

COLIBRI HEART VALVE LLC

Patent Owner

Case IPR2020-01649

Patent No. 9,125,739

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,125,739

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EX1032	Pavcnik et al., *Aortic and Venous Valve for Percutaneous Insertion*, Min Invas Ther & Allied Technol 9(3/4) 287-92 (2000)

Edwards Lifesciences Corporation and Edwards Lifesciences LLC ("Petitioners" or "Edwards") respectfully request *inter partes* review of Claims 1-5[1] of U.S. Patent No. 9,125,739 (the "'739 Patent") under 35 U.S.C. §§311-319 and 37 C.F.R. §42.100. There is a reasonable likelihood at least one claim is unpatentable for the reasons herein, and Petitioners request review of, and judgment against, these claims under 35 U.S.C. §§102 and/or 103.

I. INTRODUCTION

The '739 Patent suffers from two over-arching, fatal flaws, both of which stem from claims that cover more than what the applicants allege to have invented. First, it broadly claims a prosthetic heart valve including a valve means with multiple leaflets. These leaflets are not limited in construction, and can thus be formed with a single sheet of pericardial tissue or multiple pieces of pericardial tissue. The specification, however, repeatedly and explicitly limits the purported invention to the use of a single sheet of tissue to form the leaflets of the valve. Because the full scope of the claims is not support by the specification, the '739 Patent is not entitled to claim priority to January 4, 2002. This break in the priority chain makes the publication of the '739 Patent's grandparent application, U.S.

[1] An element-by-element breakdown of Claims 1-5 is provided in the Appendix attached hereto.

Patent App. Pub. No. 2005/0113910 (EX1015 ("Paniagua")), with its identical specification, prior art that anticipates the '739 Patent. *See Dr. Reddy's Labs. S.A. v. Indivior UK Ltd.*, IPR2019-329, Paper 49 at 82-86 (PTAB June 2, 2020) (challenged claims invalid as anticipated by earlier, related application publication with identical disclosure, which patent owner could not properly claim priority to because it did not provide written description support for full scope of challenged claims).

Second, the '739 Patent tries to claim what was already in the prior art—almost verbatim. The specification of the '739 Patent includes well over 100 lines that were copied word-for-word (or nearly so) from U.S. Patent No. 5,855,601 ("Bessler" (EX1006)). The invention claimed in the '739 Patent is almost entirely disclosed by the copied portions of Bessler. The only element not copied from Bessler was the requirement that the "stent member include[] a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration." EX1001, Element 1[b]. Instead, the applicants copied that description from U.S. Patent No. 5,332,402 ("Teitelbaum" (EX1007)).[2] Thus, in addition to being invalid because the applicants claimed more than they described,

[2] The '739 Patent does not acknowledge that it extensively copied disclosures from Bessler and Teitelbaum.

the claims of the ’739 Patent are also invalid because the applicants described—and then claimed—what others had already invented.

II. BACKGROUND OF THE ART

The elements of the system claimed in the ’739 Patent were each well-known attributes in the field of designing and delivering transcatheter heart valves (THVs) as of January 4, 2002, the priority date listed on the face of the ’739 Patent.

The history of transcatheter heart valve technology begins in 1989 with the work of Dr. Henning Rud Andersen and colleagues. That year, Dr. Andersen’s team conceived of and built prototypes of a permanently implantable collapsible and expandable heart valve that could be implanted via a catheter. This technology was premised on providing a minimally invasive alternative to surgical heart valve replacement procedures. EX1020, ¶28. Dr. Andersen’s team proved their concept was feasible by successfully implanting their prototype in pigs. *Id.*, ¶29. The results of these studies, implanting “a foldable biological cardiac valve inside a balloon expandable metallic stent,” were first published in 1992. EX1003 at 1-5. Dr. Andersen and his team also patented their work, more broadly contemplating that their device could be either balloon expandable or self-expanding, made with a variety of different stent structures, and made with a

variety of different valve structures. EX1004 at 2:38-68, 3:13-62, 7:12-16; EX1020, ¶29.

In 1994, the Textbook of Interventional Cardiology included a chapter written by Dr. Steven R. Bailey devoted to percutaneous expandable prosthetic valves. EX1005 at 4-12. The Textbook described Dr. Andersen's work as "[t]he most exciting published work in this area to date" and noted that "[a]lthough the [Andersen] study presents only early data illustrating the large amount of work required before a device such as this can be used, it illustrates that such devices await only the focused evaluation and improvement of a few investigators." *Id.* at 12. In the following years, a host of other transcatheter heart valves of various designs were conceptualized, studied, and publicized, and reported studies continued to support the viability of the technology. EX1020, ¶30 (citing, *e.g.*, EX1031 (report from 2000 on Bonhoeffer first-in-human transcatheter pulmonary valve implant); EX1032 (Pavcnik report in 2000 on transcatheter aortic and venous valve implants in animals)).

By January 4, 2002, all of the elements claimed in the '739 Patent were well-known in the art. EX1020, ¶31. The specification of the '739 Patent itself supports this conclusion because it copies extensively from prior art references. The '739 Patent copies verbatim (or nearly so) over one hundred lines from Bessler (EX1006) and Teitelbaum (EX1007). There is no attribution, nor is

there any mention of either prior art reference in the background discussion in the '739 Patent. EX1001 at 1:19-4:59; *see generally id.* Several examples of such passages copied from Bessler are reproduced side-by-side with the original language from Bessler in the below table, with the identical portions in each bolded and italicized:

'739 Patent	**Bessler ('601 Patent)**
"***The stent member*** 100 ***of the artificial heart valve*** device ***of the present invention may be made from*** various metal alloys, ***titanium, titanium alloy, nitinol, stainless steel, or other resilient, flexible non-toxic, non-thrombogenic, physiologically acceptable and biocompatible materials. The configuration may be the zigzag configuration shown or a sine wave configuration, mesh configuration or a similar configuration which will allow the stent to be readily collapsible and self-***	"***The stent member***s ***of the artificial heart valve***s ***of the present invention may be made from*** Elgiloy alloy, ***titanium, titanium alloy, nitinol, stainless steel, or other resilient, flexible non-toxic, non-thrombogenic, physiologically acceptable and biocompatible materials. The configuration may be the zig-zag configuration shown or a sine wave configuration, mesh configuration or a similar configuration which will allow the stent to be readily collapsible and self-***

'739 Patent	**Bessler ('601 Patent)**
expandable. When a zigzag or sine wave configured stent member is used, the diameter of the wire from which the stent is made is preferably ***from about 0.010 to 0.035 inches*** and still, ***preferably from about 0.012 to 0.025 inches. The diameter of the stent member will be from about 1.5 to 3.5 cm, preferably from about 1.75 to 3.00 cm, and the length of the stent member will be from about 1.0 to 10 cm, preferably from about 1.1 to 5 cm.***" EX1001 at 7:39-7:54.	***expandable. When a zig-zag or sine wave configured stent member is used, the diameter of the wire from which the stent is made*** should be ***from about 0.010 to 0.035 inches, preferably from about 0.012 to 0.025 inches. The diameter of the stent member will be from about 1.5 to 3.5 cm, preferably from about 1.75 to 3.00 cm, and the length of the stent member will be from about 1.0 to 10 cm, preferably from about 1.1 to 5 cm.***" EX1006 at 6:3-18.
"***Preferably the stent member*** 100 ***carries a plurality of barbs extending outwardly from the outside surface of the stent member for fixing the heart valve device in a desired position. More preferably the barbs are disposed in***	"***Preferably the stent member carries a plurality of barbs extending outwardly from the outside surface of the stent member for fixing the heart valve in a desired position. More preferably the barbs are disposed in***

'739 Patent	**Bessler ('601 Patent)**
two spaced-apart, circular configurations with the barbs in one circle extending in an upstream direction and the barbs in the other circle extending in a downstream direction. It is especially preferable that the barbs on the inflow side of the valve point in the direction of flow and the barbs on the outflow side point in the direction opposite to flow. It is preferred that the stent be formed of titanium alloy wire or other flexible, relatively rigid, physiologically acceptable material arranged in a closed zigzag configuration so that the ***stent member will readily collapse and expand as pressure is applied and released, respectively.***" EX1001 at 8:11-25.	***two spaced-apart, circular configurations with the barbs in one circle extending in an upstream direction and the barbs in the other circle extending in a downstream direction. It is especially preferable that the barbs on the inflow side of the valve point in the direction of flow and the barbs on the outflow side point in the direction opposite to flow. It is preferred that the stent be formed of titanium alloy wire or other flexible, relatively rigid, physiologically acceptable material arranged in a closed zig-zag configuration.*** Such a configured ***stent member will readily collapse and expand as pressure is applied and released, respectively.***" EX1006 at 4:12-26.

'739 Patent	**Bessler ('601 Patent)**
"The delivery and implantation system of the replacement ***artificial heart valve*** of the present invention ***percutaneously and transluminally includes a flexible catheter*** 400 ***which may be inserted into a vessel of the patient and moved within that vessel*** as depicted in FIG. 8. ***The distal end*** 410 ***of the catheter*** 400, ***which is hollow and carries the*** replacement ***heart valve*** device ***of the present invention in its collapsed configuration, is guided to a site where it is desired to implant the*** replacement ***heart valve. The catheter has a pusher member*** 420 ***disposed within the catheter lumen*** 430 ***and extending from the proximal end*** 440 ***of the catheter to the hollow section at the distal end*** 410	"The system for implanting the above described ***artificial heart valve*** ***percutaneously and transluminally includes a flexible catheter which may be inserted into a vessel of the patient and moved within that vessel.*** ***The distal end of the catheter, which is hollow and carries the*** artificial ***heart valve of the present invention in its collapsed configuration, is guided to a site where it is desired to implant the*** artificial ***heart valve. The catheter has a pusher member disposed within the catheter lumen and extending from the proximal end of the catheter to the hollow section at the distal end***

’739 Patent	**Bessler (’601 Patent)**
of the catheter. Once the distal end 410 ***of the catheter is positioned as desired, the pusher mechanism*** 420 ***is activated and the distal portion of the*** replacement ***heart valve*** device ***is pushed out of the catheter and the stent member*** 100 ***partially expands. In this position the stent member*** 100 ***is restrained so that it doesn’t pop out and is held for controlled release, with the potential that the*** replacement ***heart valve*** device ***can be recovered if there is a problem with the positioning.*** ***The catheter*** 400 ***is then retracted slightly and the*** replacement ***heart valve*** device ***is completely pushed out of the catheter*** 400 ***and released from the catheter to allow the stent member*** 100 ***to fully expand. If the stent member***	***of the catheter. Once the distal end of the catheter is positioned as desired, the pusher mechanism is activated and the distal portion of the*** artificial ***heart valve is pushed out of the catheter and the stent member partially expands. In this position the stent member is restrained so that it doesn’t pop out and is held for controlled release, with the potential that the*** artificial ***heart valve can be recovered if there is a problem with the positioning*** or the like. ***The catheter is the[n] retracted slightly and the*** artificial ***heart valve is completely pushed out of the catheter and released from the catheter to allow the stent member to fully expand. If the stent member***

'739 Patent	**Bessler ('601 Patent)**
100 preferably ***includes two circles of barbs on its outer surface as previously described, the first push and retraction will set one circle of barbs in adjacent tissue and the second push and release of the*** replacement ***heart valve*** device ***will set the other circle of barbs in adjacent tissue and securely fix the*** replacement ***heart valve*** device ***in place when the*** device ***is released from the catheter.*** ***Alternatively, or in combination with the above, the*** replacement ***heart valve*** device ***could be positioned over a*** metallic ***guidewire*** that is advanced through the catheter." EX1001 at 11:40-12:5.	***includes two circles of barbs on its outer surface as previously described, the first push and retraction will set one circle of barbs in adjacent tissue and the second push and release of the*** artificial ***heart valve will set the other circle of barbs in adjacent tissue and securely fix the*** artificial ***heart valve in place when the*** valve ***is released from the catheter.*** ***Alternatively, or in combination with the above, the heart valve could be positioned over a guidewire.***" EX1006 at 4:53-5:14.

Compare also EX1001 at 6:51-7:5 *with* EX1006 at 3:47-64; EX1001 at 7:12-15 *with* EX1006 at 5:36-38; EX1001 at 7:18-25 *with* EX1006 at 5:44-51; EX1001 at 7:29-38 *with* EX1006 at 5:52-60; EX1001 at 8:27-28 *with* EX1006 at 6:19-20; EX1001 at 8:35-43 *with* EX1006 at 3:57-64; EX1001 at 10:56-66 *with* EX1006 at 4:28-36; EX1001 at 10:67-11:39 *with* EX1006 at 8:7-50; EX1001 at 12:31-36 *with* EX1006 at 8:1-6; *see* EX1020, ¶32.

Bessler discloses nearly all features of the '739 Patent's purported inventive disclosure. Bessler was filed on June 21, 1996, and as the title explains, is directed to an "Artificial Heart Valve and Method and Device for Implanting the Same." EX1006 at 1. Bessler teaches a replacement heart valve device, attached within a self-expanding "stent member," for percutaneous and transluminal implantation, comprising a "valve means that permit[s] flow in only one direction." EX1006 at, *e.g.*, 2:55-62. The stent member may be made from various known materials, including the alloy nitinol, and preferably includes two circles of barbs, which "anchor the expanded stent member at a desired site." EX1006 at, *e.g.*, 4:12-26, 2:63-64; EX1020, ¶33.

FIG. 1

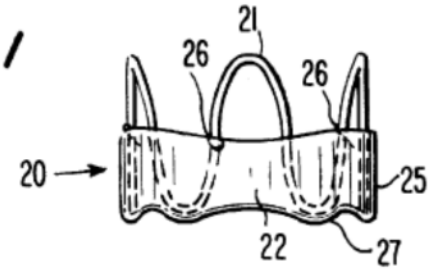
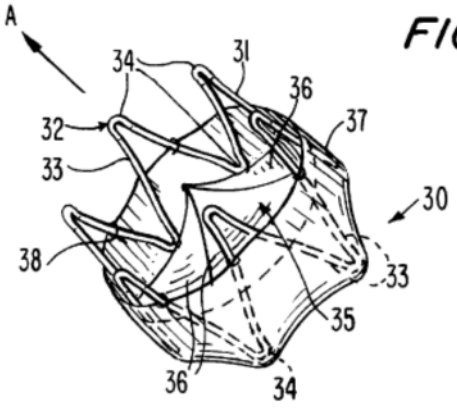


FIG. 4



The valve member that is attached within the stent member "is flexible, compressible, host-compatible, and non-thrombogenic" (EX1006 at 6:19-23; EX1020, ¶34) and can be formed either from pericardium or from synthetic material. EX1006 at 4:9-11 ("The flexible valve means preferably comprises porcine pericardium ...."), 6:20-24 ("The valve can be, for example, a glutaraldehyde fixed porcine aortic valve .... The valve can also be fresh, cryopreserved or glutaraldehyde fixed allografts or xenografts."); EX1020, ¶37. This structure is free of any added components sometimes used in prosthetic valves to reinforce the valve structure. *See generally* EX1006; EX1020, ¶37.

FIG. 2

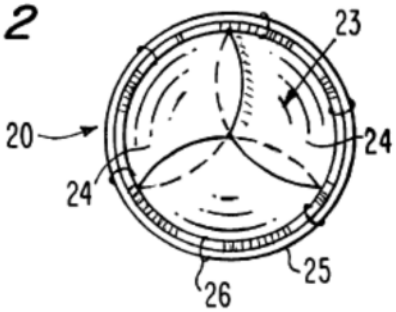
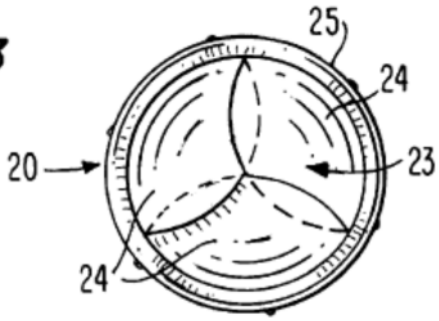


FIG. 3



Bessler further discloses a cuff portion that may extend along the internal or external surface of the stent. EX1006 at 4:4-9. Certain claims of Bessler broadly encompass embodiments where the cuff portion can be on the inside or outside surface of the stent, whereas other claims limit the cuff to the outer surface of the stent. *Compare*, *e.g.*, EX1006, claim 13 ("13. An artificial valve comprising ... said valve member comprising a circular portion, said circular portion having a plurality of leaflets extending from the periphery of said circular portion towards the center thereof … said valve member having a cuff portion extending from the periphery of said circular portion, said cuff portion being disposed downstream of said valve member and substantially parallel to the cylindrical surface of said stent member and said cuff portion being attached to said stent member with a plurality of sutures.") *with id.*, claim 1 ("1. An artificial heart valve comprising ... a self-expanding, cylindrical stent member having first and second ends and an outer surface ... and a cuff portion extending on said outer surface); EX1020, ¶¶35-36.

Bessler also teaches a system for implanting its replacement heart valve percutaneously and transluminally, comprising a flexible catheter with a pusher member and, optionally, a guidewire. EX1006 at 4:53-5:14. As noted above, the '739 Patent copied this teaching nearly verbatim. *Compare* EX1001 at 11:40-12:5 *with* EX1006 at 4:53-5:14. Bessler describes a delivery system and

method by which the catheter is positioned at the desired site of implantation of the artificial heart valve, and then activation of the pusher member mechanism pushes the artificial heart valve device partially out of the catheter, allowing the stent member to partially expand. EX1006 at 4:63-5:3. The delivery system includes means such as threads or sutures "looped through an opening [] in the pusher member [] and then passed about a portion of the heart valve" that holds the valve in place and makes it possible for the valve to be recovered before full deployment. EX1006 at 4:63-5:3, 7:55-57; EX1020, ¶38. Full deployment is achieved by retracting the catheter slightly, pushing the device out completely, and releasing it from the catheter so the stent can fully expand. EX1006 at 5:3-6; *see also* EX1020, ¶38.

Bessler demonstrated the feasibility of the valve he designed and described the results of that early research and the successful implantation of the valve in pigs in a 1996 article. EX1008. In the study, Bessler and his team implanted trileaflet valves made with a stainless steel stent and bovine pericardium tissue in pigs. EX1008 at 1. They reported that "[i]ntra-operative color echocardiography revealed minimal regurgitation, central flow, full apposition of all leaflets, and no interference with coronary blood flow." *Id.* This animal study demonstrated that the valve remained anchored, provided an effective seal and "effectively prevent[ed] regurgitation when the valve is anchored properly," and

provided unidirectional flow "with no turbulence and minimal transvalvular gradient and central flow." *Id.* at 4-5. A person of ordinary skill in the art ("POSITA") reading Bessler's article would recognize the success and feasibility for future development of Bessler's designs. EX1020, ¶39.

One of the few elements of the claims of the '739 Patent that was not copied nearly word-for-word from Bessler is the description of the stent member as "flar[ing] markedly at both ends in a trumpet-like configuration." EX1001 at 7:63. Instead, the description in the specification of the flared stent member was copied verbatim (or nearly so) from Teitelbaum (EX1007):

'739 Patent	**Teitelbaum ('402 Patent)**
"***A meshwork of nitinol wire of approximately 0.008 inch gauge*** is ***formed into a tubular structure with a minimum central diameter of 20 mm*** to make the stent.	"***[A] meshwork of nitinol wire of approximately 0.008 inch gauge formed into a tubular structure with a minimum central diameter of 20 mm***.
Away from its central portion, the tubular structure flares markedly at both ends in a trumpet-like configuration.	***Away from its central portion, the tubular structure flares markedly at both ends in a trumpet-like configuration****....*
The maximum diameter of the flared	***The maximum diameter of the flared***

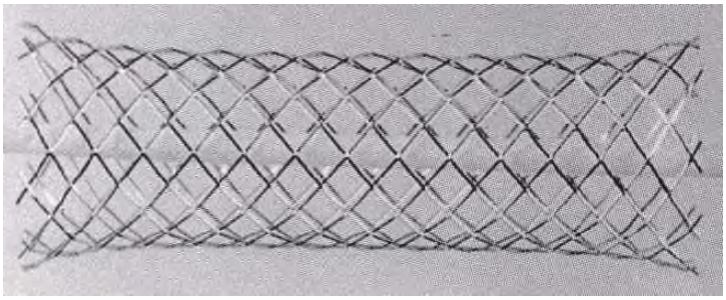
'739 Patent	**Teitelbaum ('402 Patent)**
ends of the stent is approximately 50 mm. ***The purpose of the stent is to maintain a semi-rigid patent channel through the diseased cardiac valve following its*** implantation." EX1001 at 7:59-67.	***ends of the stent is approximately*** 30 mm. ***The purpose of the stent is to maintain a semi-rigid patent channel through the diseased cardiac valve following its*** balloon dilation as shown in FIG. 2." EX1007 at 5:52-63; *see id.* at 2:21-36.

Compare also EX1001 at 7:55-59 *with* EX1007 at 5:34-38; EX1001 at 8:1-10 *with* EX1007 at 5:39-49; *see also* EX1020, ¶40.

Teitelbaum was not the only reference to disclose a stent that "flares at both ends in a trumpet-like configuration" before January 4, 2002. Indeed, such a stent shape was well-known to POSITAs at that time. Other examples included the Wallstent, U.S. Patent App. Pub. No. 2002/0032481 ("Gabbay") (EX1009), U.S. Patent No. 6,425,916 ("Garrison") (EX1010), U.S. Patent No. 6,652,578 ("Bailey") (EX1011), U.S. Patent No. 5,957,949 ("Leonhardt") (EX1012), and U.S. Patent No. 6,908,481 ("Cribier") (EX1017); *see* EX1020, ¶¶41-50.

The Wallstent was developed in the 1980s by Hans Wallstén and Christian Imbert. EX1016 at 7; EX1020, ¶42. Jacques Puel performed the first-in-human implant of a Wallstent on March 28, 1986. EX1020, ¶42. Thus, the

Wallstent was well-known to POSITAs by January 4, 2002. *Id.*; EX1016 at 7. The '739 Patent applicants were aware of the Wallstent—they referenced it in declarations submitted in support of the grandparent application to the '739 Patent. EX1018 at, *e.g.*, 167. The applicants explained that they used a Wallstent in their design and described the Wallstent as having flared ends ("We changed the attachment position of the valve to be closer to the proximal and wider part of the Wal[l]stent."). EX1018 at 167, 169; EX1020, ¶43. The flared configuration of the Wallstent (with the ends having a greater diameter than the central portion of the stent) can be seen in the below photograph:



Wallstent

In addition to Teitelbaum and Wallstén, many others in the field had already taught the use of a stent with a flared, trumpet-like configuration with a transcatheter heart valve by January 4, 2002. For example, Gabbay, which claims priority to September 12, 2000 (EX1009 at 1), discloses a flared stent, as the description and the below figure make clear: "The stent portion 14 [in Figure 2] also may include outwardly turned portions at the 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." *Id.*, ¶[0043]; EX1020, ¶45.

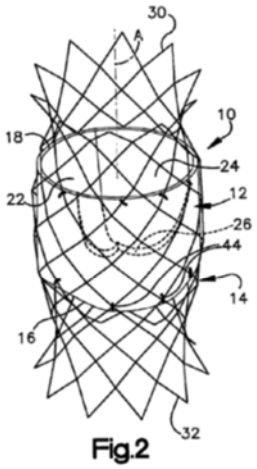


Fig.2

Gabbay (Ex. 1009)

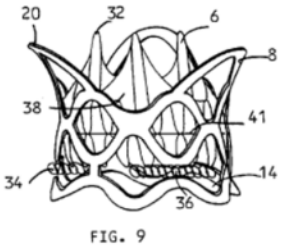


FIG. 9

Garrison (Ex. 1010)

Relatedly, Garrison, titled "Methods and Devices for Implanting Cardiac Valves" and filed on February 10, 1999, teaches a valve implantation system that uses a flared "valve displacer" to hold the native leaflets open. EX1010 at, *e.g.*, 2:8-2:10 ("The first and second ends [of the valve displacer] are preferably flared outwardly to form a circumferential recess around the central portion.").

Yet another example of prior art that teaches the use of a flared stent with a THV is Bailey ("Endoluminal Cardiac and Venous Valve Prostheses and Methods of Manufacture and Delivery Thereof"), which was filed on May 11, 2001. EX1011 at 1; *see id.* Fig. 2.

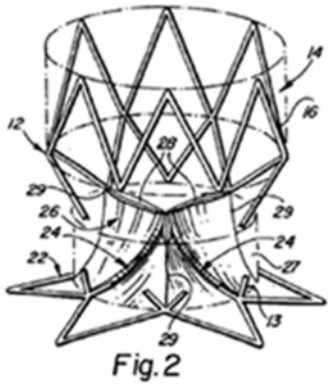


Fig.2

Bailey (Ex. 1011)

In its summary of the prior art, Bailey discusses Teitelbaum, describing Teitelbaum's stent as "comprised of a meshwork or braiding of nitinol wire similar to that described by Wallsten, U.S. Patent No. 4,655,771, with trumpet like distal a[nd] proximal flares.... The flared ends are intended to maintain the position of the stent component across the valve thereby anchoring the device." EX1011 at 2:33-42. Bailey's description of both Teitelbaum and the Wallstent confirms that multiple stent designs with trumpet-like flared ends were well-known to POSITAs before January 4, 2002, and that their utility in anchoring the device was a known benefit. EX1020, ¶47.

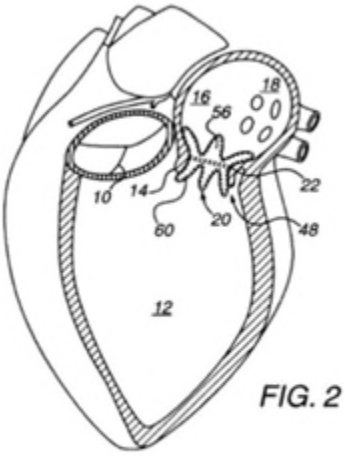


FIG. 2

Leonhardt (Ex. 1012)

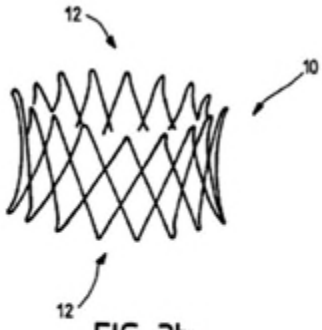


FIG_3b

Cribier (Ex. 1017)

Another example, Leonhardt ("Percutaneous Placement Valve Stent"), was filed on May 1, 1997. As illustrated in Figure 2 (excerpted above), Leonhardt teaches an artificial valve device, with a valve stent that "flair[s] at one or both ends." EX1012 at 6:11; *see also id.* at 4:60-65. The self-expanding (preferably nitinol (EX1012 at 5:11-13, 5:46-48)) stent is "pre-sized to open beyond the width of the natural valve mouth and will flair sufficiently to conform and seal to the tissue." EX1012 at 6:19-22; *see also id.* at 5:2-5, 4:60-65; EX1020, ¶48.

Drs. Alain Cribier and Brice Letac also developed several prosthetic valve designs in the mid-1990s, which formed the basis of a family of patents and applications, including U.S. Patent No. 6,908,481 ("Cribier"), which claims foreign priority to a European application with a filing date of December 31, 1996. Cribier teaches various options for valve structures, including the use of a collapsible and expandable frame that "[m]ore preferably ... has projecting curved

extremities and presents a concave shape. This is aimed at reinforcing the embedding and the locking of the implantable valve in the distorted aortic orifice." EX1017 at 5:64-67. This concave frame is illustrated in Figure 3b (excerpted above); EX1020, ¶49.

During prosecution of the '739 Patent, the Examiner cited each of Gabbay, Garrison, Bailey, and Cribier for their respective disclosures of a "stent member [that] includ[es] a tubular structure away from its central portion that flares at both ends in a trumpet-like configuration." EX1002 at 237 (Gabbay), 236 (Garrison), 388 (Garrison), 383 (Bailey), 385-86 (Bailey), 387 (Cribier). The applicants made amendments and arguments purportedly distinguishing each of Gabbay, Garrison, Bailey, and Cribier, and the '739 Patent was eventually allowed over these references, but applicants never disputed that these references disclose a stent with ends that flare in a trumpet-like configuration. *See generally* EX1002 at 307-21, 357-58, 412-26, 508-09.

As discussed below, the specification of the '739 Patent does not describe the full scope of the claims, because there is no disclosure of a valve means with leaflets constructed from multiple pieces of valve material. The first disclosure broadly permitting leaflets constructed from multiple pieces of material was in a Preliminary Amendment to the '650 Application filed on April 15, 2014. This later date is assumed to be the effective filing date of the Challenged Claims

for purposes of Ground 1. (Grounds 2-5 rely on art that predates January 4, 2002, which is assumed to be the priority date for purposes of those Grounds.) There were key advances in the state of the art in the THV field between January 4, 2002 and April 15, 2014.

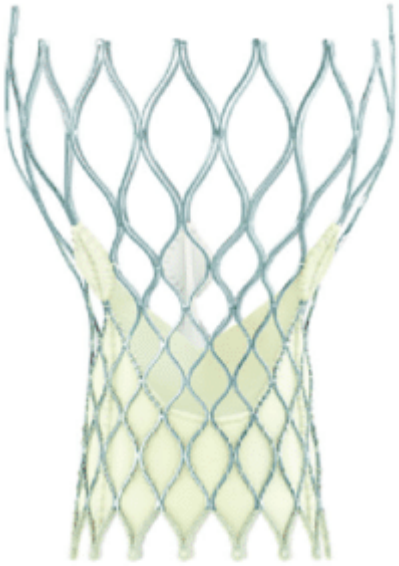
In 1999, Dr. Cribier and three others formed a company called Percutaneous Valve Technologies ("PVT"), whose work resulted in the device that was used by Dr. Cribier in the first ever implantation of a transcatheter aortic heart valve in a patient in April 2002. EX1020, ¶99. PVT patented its device along with a series of other THV embodiments, which are described, for example, in U.S. Patent No. 6,730,118. *Id.*; EX1023.

The PVT device was later commercialized by Edwards (which acquired PVT in 2004) as SAPIEN. EX1020, ¶100. SAPIEN was approved in Europe in September 2007 and in the U.S. in November 2011. EX1024; EX1029; EX1020, ¶100. Edwards had two other THVs in the SAPIEN product line, SAPIEN XT and SAPIEN 3, approved in Europe before April 15, 2014 (in March 2010 (EX1028) and January 2014 (EX1014), respectively). EX1020, ¶100.

Edwards Sapien Valve | Edwards Sapien XT | Edwards Sapien 3

Additionally, a company called CoreValve (later acquired by Medtronic, who Colibri has sued, alleging infringement of the '739 Patent by Medtronic's CoreValve devices[3]) received CE Mark approval for commercial sales of its original CoreValve device in May 2007 (EX1027) (and also FDA approval in January 2014 (EX1030)). EX1020, ¶101.

[3] *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, No. 8:20-cv-847-DOC-JDE (C.D. Cal.). *See* EX1022.



Medtronic
CoreValve

Thus, by April 15, 2014, multiple commercial THVs with various designs were well-known in the field.

III. MANDATORY NOTICES (§42.8)

A. Real Parties-In-Interest Under §42.8(b)(1): Edwards Lifesciences Corporation and Edwards Lifesciences LLC are the real parties-in-interest, and there are no other 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 Under §42.8(b)(2): Petitioners are aware that Patent Owner has asserted the '739 Patent against Medtronic CoreValve LLC in *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, No. 8:20-cv-847-DOC-

JDE (C.D. Cal.); Petitioners are not a party to that action. Medtronic CoreValve LLC filed IPR2020-1454 on September 2, 2020 challenging the validity of Claims 1-5 of the '739 Patent.

C. Lead and Back-Up Counsel Under §42.8(b)(3):

Edwards designates the following:

Lead Counsel	**Back-Up Counsel**
Brian P. Egan (Reg. No. 54,866) Morris, Nichols, Arsht & Tunnell LLP 1201 North Market Street P.O. Box 1347 Wilmington, DE 19899-1347 Email: began@mnat.com Telephone: 302-351-9454 Facsimile: 302-498-6216	Gregory S. Cordrey (Reg. No. 44,089) Jeffer Mangels Butler & Mitchell, LLP 3 Park Plaza, Suite 1100 Irvine, CA 92614 Email: gcordrey@jmbm.com Telephone: 949-623-7200 Facsimile: 949-623-7201

D. Service Information Under §42.8(b)(4)

Counsel's service information is provided above. Edwards consents to electronic service by email to began@mnat.com and gcordrey@jmbm.com.

E. 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. 100440.

IV. STANDING (§42.104(a))

Petitioners certify that the '739 Patent is eligible for, and Petitioners are not barred or estopped from requesting, *inter partes* review.

V. GROUNDS (§§42.22 and 42.104(b))

Claims 1-5 are unpatentable as follows: **Ground 1:** anticipated under §102(b) by Paniagua (EX1015); **Grounds 2 & 3:** obviousness under §103 over Bessler (EX1006) in view of Teitelbaum (EX1007) or Leonhardt (EX1012); **Grounds 4 & 5:** obviousness under §103 over Bessler (EX1006) in view of Teitelbaum (EX1007) + U.S. Patent Application Publication No. 2001/0044633 ("Klint") (EX1019); or Bessler (EX1006) in view of Leonhardt (EX1012) + Klint (EX1019).[4]

VI. THE '739 PATENT

A. The '739 Patent Overview

The '739 Patent's specification describes devices and methods for preparing and/or implanting devices in a minimally invasive fashion to replace diseased or defective native heart valves. *See generally* EX1001; EX1020, ¶¶51-54. The '739 Patent describes as "especially advantageous" procedures wherein the "defective heart valve [is] removed …." EX1001 at 2:64-3:1.

[4] Bessler, Teitelbaum, and Leonhardt are prior art under §§102(a), (b), and (e); Klint is prior art under §102(a) and (e).

Acknowledging that prosthetic heart valves were already known in the prior art as of the January 4, 2002 filing of the original application (U.S. Patent App. No. 10/037,266 (the "'266 Application")), the '739 Patent identifies purported shortcomings of those prior art replacement heart valves that the applicants sought to improve upon. In particular, the '739 Patent contends that the prior art devices did not "effectively simulate the exact anatomy of a native heart valve" (*id.* at 4:45-47), including because of "the presence of extensive suturing" in securing the individually cut leaflets to the stent (*id.* at, *e.g.*, 4:41-44, 51-55), because "the leaflets of most such tissue valves are constructed by cutting or suturing the tissue material, resulting in leaflets that do not duplicate the form and function of a real valve and are more susceptible to failure" (*id.* at 4:55-59). The applicants of the '739 Patent therefore set out to develop what they described as "a completely newly designed artificial biological tissue valve disposed within the inner space of [a stainless steel or nitinol] stent" where "[t]he cusp or leaflet portion of the valve means is formed by folding of the pericardium material preferably used to create the valve without cutting of slits to form leaflets or otherwise affixing of separate leaflet portions." *Id.* at 4:64-5:5.

Although not a requirement of any of the claims of the '739 Patent, the specification touts as the solution to these perceived shortcomings of prior art replacement heart valves the use of "***a single, continuous, uncut*** [sheet of

pericardium material]" (*id.* at 8:56 (emphasis added)), "unlike prior efforts that have involved suturing of three separate leaflet/cusp portions on to the main valve body portion" (*id.* at 8:58-60). Instead of forming separate valve leaflets by cutting and suturing a piece of valve material, the '739 Patent describes a method of forming a valve "by taking a flat sheet of the [valve] material and folding in such a way that forms a three-leaflet or other number of leaflet valve." *Id.* at 5:41-44; *see also id.* at, *e.g.*, 5:1-5, 5:53-55, 5:58-61, 8:44-9:6, 9:46-55, 9:56-10:3. "The folding of the pericardium material to create the cusps or leaflets reduces the extent of suturing otherwise required, and resembles the natural form and function of the valve leaflets. It also greatly reduces the risk of tearing of the cusps or leaflets, since they are integral to the valve rather than being attached by suturing." *Id.* at 9:50-55; *see also id.* at 5:64-67. That is, the '739 Patent describes its "newly designed artificial biological tissue valve" as formed by folding one single sheet of valve material. EX1020, ¶¶55-58.

The preferred method of forming the single sheet of valve material into the valve portion is illustrated in Figure 9. EX1001 at 7:16-18, 8:54-55, 8:61-9:6, 9:46-55. "[W]ith flat sheet on a table, a person facing the sheet would create a cuff at the upper border of sheet by folding the horizontal top edge away/downwardly (fold no. 1). The leaflet portion is formed by folding the sheet's lower half towards the fold[]/upwardly, as shown in FIG. 9A" (*id.* at 8:62-66):

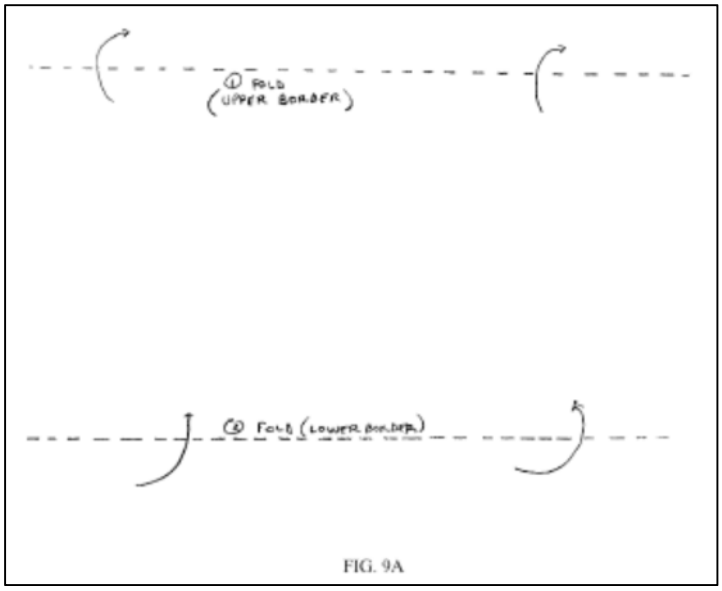


FIG. 9A

"The sheet, now with the upper cuff and bottom inward fold, is folded inwardly at two preferably equidistant vertical points as shown in FIG. 9B to create the leaflet/cusp portion (folds nos. 3 and 4)" (*id.* at 8:66-9:3):

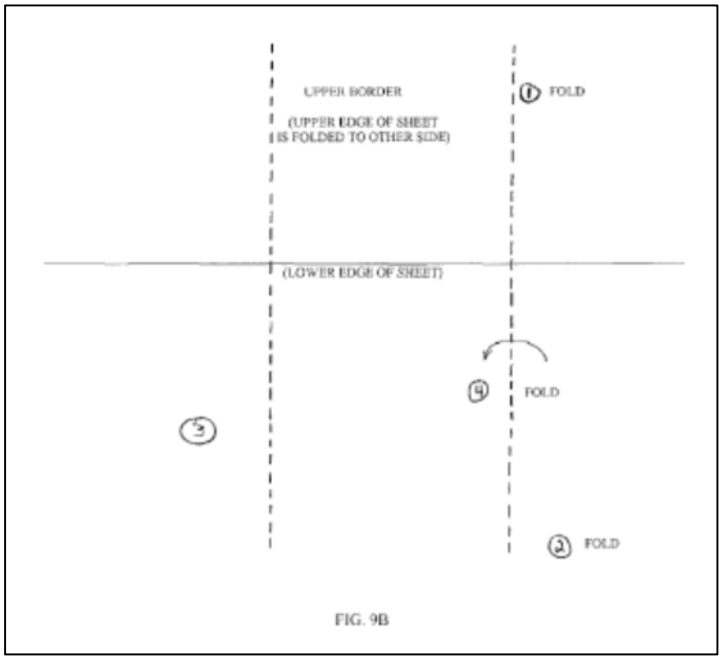


FIG. 9B

Finally, "[t]he leaflets/cusps are formed by folding fold nos. 6, 7 and 8 after the two opposite vertical edges of sheet are joined to create a cylindrical valve shape ...." (*id.* at 9:3-5):

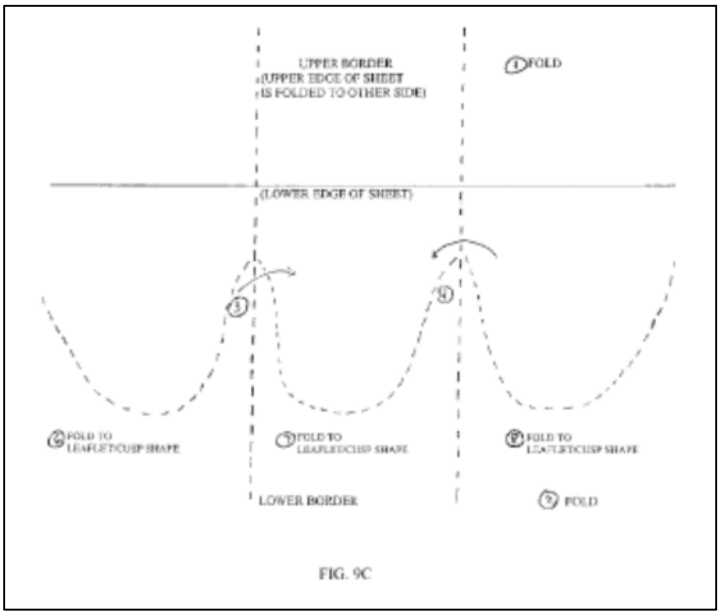


FIG. 9C

Although the specification of the '739 Patent allows for the possibility that the valve structure ***as a whole*** may be made from more than one piece of valve material, it is clear that ***the leaflet portion of the valve*** must be constructed from a single piece:

> Although a preferred embodiment of the invention comprises a single piece of valve material folded to create the valve body and a leaflet-forming portion that has no cuts or sutures, the inventors have discovered that ***as long as the leaflet portion of the valve itself is formed***

> ***from a single piece of biocompatible material***, the other portions of the valve can be formed by suturing of one or more separate pieces of material without losing the novel and improved qualities of the present invention. ... This alternate embodiment comprises a leaflet forming layer made of a single piece of valve material attached to a separate piece forming the valve body having a folded cuff portion. The single piece leaflet forming layer is preferably cylindrical in shape and can be formed with or without folding. In this embodiment the single piece leaflet layer can itself be attached to the stent with or without a cylindrical cuff portion.

Id. at 9:8-20 (emphasis added); EX1020, ¶58.

The sole independent claim of the ’739 Patent (Claim 1) claims an assembly comprising a stent member, a valve means, and a delivery system. Despite the clear description in the specification that the leaflet portion of the valve means must be constructed from a single piece of material, Claim 1 broadly claims “a valve means including two to four individual leaflets”; that is, the ’739 Patent claims ***both*** valve means with leaflets constructed from a single piece of material ***and*** valve means where the leaflets are formed from multiple, separate pieces of

material. EX1020, ¶¶59-60. As explained below, the other elements of Claim 1—including a stent that "flares at both ends in a trumpet-like configuration," a design that was already known from, *inter alia*, Teitelbaum, Leonhardt, Cribier, the Wallstent, Garrison, Gabbay, and Bailey (*supra* Section II), and a delivery system with a pusher member previously described nearly word-for-word by Bessler (*id.*)—were neither novel nor non-obvious. The four dependent claims (2-5) merely add properties that were already well-known in the percutaneous prosthetic heart valve field: that the stent be "self-expanding" (Claim 2); that the self-expanding stent of Claim 2 be comprised of nitinol (Claim 3); that Claim 1's stent "include[] two circles of barbs on an outer surface of the stent member" (Claim 4); or that the pusher member of Claim 1's delivery system "include[] a controlled release mechanism that can be activated" (Claim 5). EX1020, ¶61.

B. Prosecution Overview

The application (14/253,650) leading to the '739 Patent was filed on April 15, 2014. EX1001 at 1. The Preliminary Amendment filed on April 15, 2014 added new claim 34, which claimed "a valve means ... including ... two to four individual leaflets." EX1002 at 69. The claims of the Preliminary Amendment were the first appearance in the family of the '739 Patent of a description of a prosthetic heart valve that did not require the leaflets of the valve means to be constructed from a single sheet of material. EX1020, ¶¶62-63.

After several rounds of rejections and amendments, in the November 7, 2014 Final Office Action, the Examiner rejected all claims but suggested that including a limitation in the claims "requir[ing] [the] valve to reside entirely within the inner channel of the stent member when the prosthetic heart valve is collapsed on the pusher member *and* when the prosthetic heart valve is [] released from the delivery system" would overcome the rejection. EX1002 at 388 (emphasis original). In response, the applicants amended the independent claim to require that the valve means "resides entirely within the inner channel of the stent member" in both the collapsed and deployed configurations. EX1002 at 410-11; EX1020, ¶¶64-73.

To further distinguish Bailey and Cribier, the applicants argued that the pending claims did not require "valve arms or regulator struts" or "strengthening struts [], pleats [], or other reinforcing feature" to support the valve leaflets and prevent prolapse. EX1002 at 416-18. In response to this argument, an Examiner's Amendment was required to add the limitation "wherein no reinforcing members reside within the inner channel of the stent member." *Id.* at 447. With this amendment, to "more clearly overcome the previous Bailey rejection," the Examiner allowed the '739 Patent. *Id.*; EX1020, ¶¶74-80.

C. Priority Date

On its face, the ’739 Patent claims priority to the January 4, 2002 filing date of the ’266 Application. However, the specification of the ’739 Patent lacks written description support for the full scope of its claims,[5] because the specification is explicitly limited to a description of a valve leaflet portion made from a single sheet of tissue material. *Supra* Sections VI.A; EX1001 at 5:1-5, 5:41-44, 5:53-55, 5:58-61, 8:44-9:6, 9:46-55, 9:56-10:3. As discussed above, however, the claims of the ’739 Patent are not limited to a single-piece valve design but broadly cover “a valve means including two to four individual leaflets made of fixed pericardial tissue” (EX1001 at Claim 1); that is, the claims of the ’739 Patent cover ***both*** valve means where the leaflets are made from a single piece of tissue material ***and*** valve means where the leaflets are constructed from multiple, separate pieces of tissue material.

The ’739 Patent draws a real distinction between THVs where the valve leaflets are made from a single piece of tissue material and THVs where the leaflets are formed by cutting and suturing multiple separate pieces of tissue together. The ’739 Patent applicants touted a valve structure whose leaflet portion

[5] The ’739 Patent shares the same specification as its parent, U.S. Patent No. 9,610,158, and its grandparent, U.S. Patent No. 8,308,797.

is formed from a single piece as one of their purported advancements: "a completely newly designed artificial biological tissue valve" (EX1001 at 4:66-67) whose "design provides a number of advantages over prior designs, including improved resistance to tearing at suture lines" (*id.* at 5:7-9; *see also id.* at 5:64-67), "reduces the extent of suturing otherwise required, and resembles the natural form and function of the valve leaflets" (*id.* at 5:59-61). *See supra* Section VI.A.

Thus, the '739 Patent claims a broader scope of invention than the '266 Application supports. *See Liberty Mutual Insurance Co. v. Progressive Casualty Insurance Co.*, CBM2012-00003, Paper 78 at 41 (PTAB Feb. 11, 2014) ("For an application to be entitled to the earlier filing date of an ancestral application, under 35 U.S.C. § 120, one of the requirements is that the earlier-filed application contain a disclosure that complies with 35 U.S.C. § 112, first paragraph, for the claims in the later-filed application."); *Dr. Reddy's*, IPR2019-329, Paper 49 at 82-86.

As discussed above, the specification of the '739 Patent (which is identical to the specification of its parent and its grandparent) describes forming the valve leaflets only from a single sheet of valve material (EX1001 at 5:1-5, 5:41-44, 5:53-55, 5:58-61, 8:44-9:6, 9:46-55, 9:56-10:3), and makes clear that, while "other portions of the valve can be formed by suturing of one or more separate pieces of material without losing the novel and improved qualities of the

present invention" (*id.* at 9:13-16), "the leaflet portion of the valve itself is formed from a single piece of biocompatible valve material" (*id.* at 9:11-13).[6] The first

[6] The specification of the '739 Patent includes a single reference to "the individual leaflets": "The free edge of the leaflet layer may be straight or curved, and this free edge forming the free edges of the individual leaflets may be contoured in parabolic or curved shape." EX1001 at 10:22-25. In context, however, "the individual leaflets" are part of "the leaflet layer" (*id.*) which the '739 Patent's specification explicitly requires to be formed from "a single piece of valve material." *Id.* at 9:8-24 ("This alternate embodiment comprises a leaflet forming layer made of a single piece of valve material attached to a separate piece forming the valve body having a folded cuff portion.... In this embodiment, the single piece leaflet layer can itself be attached to the stent ...."); *see also*, *e.g.*, '797 Patent (EX1021), claim 1 ("***a single sheet*** of biocompatible pericardium tissue .... ***the single sheet*** of biocompatible pericardium tissue partitioned ... to form ***two individual valve leaflets*** ...." (emphasis added)). Thus, this single use of "the individual leaflets" in the specification of the '739 Patent describes the formation of more than one leaflet from the single sheet of tissue material (EX1001 at 5:1-5, 5:41-44, 5:53-55, 5:58-61, 8:44-9:6, 9:46-55, 9:56-10:3), and not leaflets made from multiple separate pieces of tissue material.

reference to "a valve means ... including ... two to four individual leaflets" that did not require the leaflets of the valve means to be constructed from a single sheet of material only appeared when the new claims were added on April 15, 2014. EX1002 at 69.

Like the ultimately issued claims of the '739 Patent, these claims from April 15, 2014 included "a valve means ... including ... two to four individual leaflets." *Id.* Thus, the earliest disclosure in the '739 Patent family of the full scope of the claims, including a valve means with leaflets that may be constructed from multiple pieces of valve material, is April 15, 2014.

D. Claim Construction

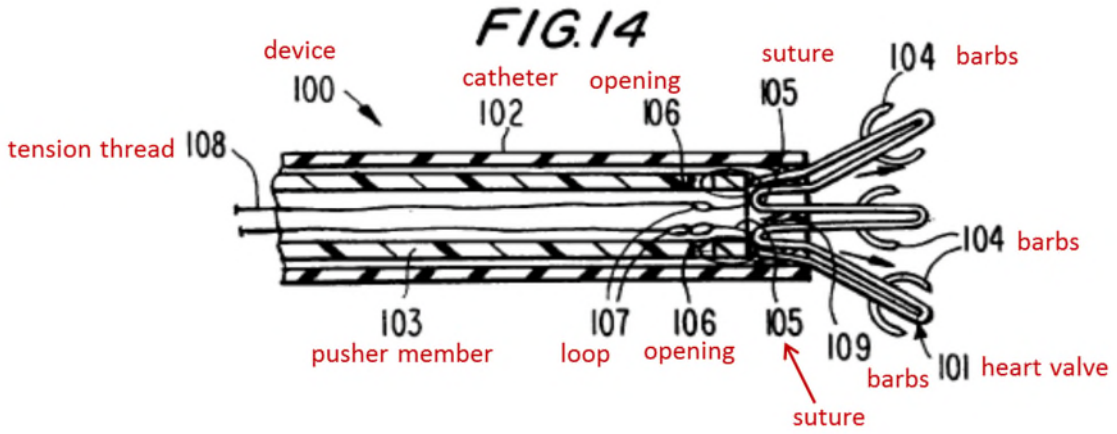
Petitioners construe the claims per *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*), and 37 C.F.R. §42.100(b), under which terms are presumed to have their ordinary and customary meaning as understood by a POSITA. For purposes of this IPR, Petitioners submit that nearly all terms can be given their plain and ordinary meaning as understood by a POSITA, except for the term "onto" in the phrase "wherein the prosthetic heart valve is collapsed onto the pusher member," which Petitioners request be construed as "in contact with."

"Pusher member" appears only once in the specification of the '739 Patent (and is referred to just one additional time (this time as a "pusher mechanism")). EX1001 at 11:48-55. As discussed above, this disclosure was

copied nearly word-for-word from Bessler. *Compare* EX1001 at 11:40-12:5 *with* EX1006 at 4:53-5:14. Therefore, the "pusher member" and the meaning of mounting the replacement heart valve device "onto" the "pusher member" must be what Bessler teaches. Indeed, in opposing a motion to dismiss in *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, No. 8:20-cv-847-DOC-JDE (C.D. Cal.), Patent Owner agreed that the description that appears at 11:40-12:2 of the '739 Patent (citing to U.S. Patent 8,900,294 (EX1026), which has the same specification), describes "an embodiment where the 'heart valve device is pushed out'" (EX1025 at 6:14-17), whereas the embodiment described at 12:3-30 is "one where the 'stented-valve device is released by pulling the cover sheath 460 of the delivery system.'" (*Id.*). That is, Colibri has argued that the only embodiment of a delivery system in the '739 Patent that describes using a pusher member to push out a prosthetic device is the one that was copied from Bessler.

Both Bessler and the '739 Patent describe the "pusher member" as "extending from the proximal end [] of the catheter to the hollow section at the distal end 410 of the catheter." EX1001 at 11:48-51; EX1006 at 4:60-63. This hollow section at the distal end of the catheter carries the replacement heart valve. EX1001 at 11:44-48; EX1006 at 4:56-60.

As Bessler depicts in Figure 14, the replacement heart valve (101, below) is just distal to, and is ***in contact with***, the pusher member (103):



The applicants never told the Examiner during prosecution of the '739 Patent that they had copied the description of the "pusher member" directly from Bessler. *See generally* EX1002.[7] Nor did they correct the Examiner when she noted that "Gabbay ... does not disclose the valve to be collapsed onto the pusher member" because "Gabbay's pusher member 210 or 716 is a plunger member with lumen, ending proximally to the valve, which pushes out the valve from behind" (EX1002 at 238), instead re-stating the Examiner's statement (without expressly adopting it) and then arguing that the cited combination of Gabbay with Garrison would be inoperative. *See id.* at 319-21. The applicants subsequently took their

[7] Bessler was identified in an Information Disclosure Statement ("IDS") as one of 300 U.S. patents. EX1002 at 160 (as part of range 150-77). (Eventually, over 600 references were identified. *See* EX1001 at 2-7.) But Bessler was not relied on by the Examiner in any Office Action, nor was it referenced by the applicants.

failure to correct the Examiner's error one step further, and embraced it in distinguishing the combination of Yang '525 in view of Yang '646:

> [A]s can be seen in Fig. 1 of Yang '646, the catheter shaft 24 *terminates* proximal (to the right in Fig. 1) of the valve 30.... Accordingly, the expandable heart valve 30 cannot be collapsed onto the catheter shaft 24 because the catheter shaft carries stabilization balloon 36 and the catheter shaft 24 terminates proximally of the valve 30.

Id. at 423-24. The applicants never explained to the Examiner that the only description of a "pusher member" in the specification describes the "pusher member" as extending to a "hollow section at the distal end [] of the catheter" where the replacement heart valve device is carried. EX1001 at 11:44-51. Thus, far from being distinguishable from a disclosure where the pusher member "terminates proximal" to the replacement heart valve device, the sole written description of a "pusher member" in the '739 Patent *requires* it.[8] For these

[8] Figure 8 of the '739 Patent is not to the contrary. First, the description in the specification is inconsistent with what is illustrated in Figure 8, as a POSITA would readily recognize. EX1020, ¶¶81-87. Additionally, to the extent Figure 8 is viewed in light of the specification, it identifies the "pusher member" as element

reasons, the proper construction of "onto" in the phrase "wherein the prosthetic heart valve is collapsed onto the pusher member," is "in contact with."

Additionally, pursuant to 37 C.F.R. §42.104(b)(3), Petitioners note that the challenged claims contain the phrase "valve means." Although this phrase contains the word "means," it provides sufficient structure to preclude application of 35 U.S.C. §112, sixth paragraph when read in light of the specification, as a POSITA would understand the term "valve means." *Mass. Inst. of Tech. v. Abacus Software*, 462 F.3d 1344, 1356 (Fed. Cir. 2006) (noting that to avoid §112(6), "it is sufficient if the claim term is used in common parlance or by persons of skill in the pertinent art to designate structure"); EX1020, ¶88. Nonetheless, should the claims be interpreted under 35 U.S.C. §112(6), the specification provides adequate structure. EX1001 at, *e.g.*, 5:1-5, 5:11-15, 6:55-57, 6:21-7:18, 8:26-9:25, 10:26-54, Figs. 1-3 & 9.

E. Level of Ordinary Skill

As proposed by Dr. Goldberg and adopted herein by Edwards, a POSITA as of either January 4, 2002 (Grounds 2-5) or April 15, 2014 (Ground 1) would have been an interventional cardiologist with a working knowledge of heart

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420, which is pictured as terminating adjacent to the stent 100. EX1001, Fig. 8; EX1020, ¶86, n.2.

valve designs, expandable stents, and intravascular delivery systems for stents. EX1020, ¶27. This POSITA would, where necessary, work as a team in combination with a medical device engineer. *Id.* A POSITA as of April 15, 2014 would have had the additional knowledge of the important developments in the art in the intervening 12 years discussed above. *Supra* 24-27; EX1020, ¶27.

VII. DETAILED REASONS FOR RELIEF

Pursuant to 37 C.F.R. §42.104(b)(1), (2), (4), and (5), an explanation of how Claims 1-5 of the '739 Patent are unpatentable, along with the exhibit numbers of supporting evidence, are provided below.

A. Ground 1: Claims 1-5 Are Invalid Under 35 U.S.C. §102(b) over Paniagua (EX1015)

As discussed above, *supra* Section VI.C, the specification of the '739 Patent fails to provide written description support for a valve means with two to four individual leaflets made from multiple separate pieces of valve material as claimed in each of the claims. The first disclosure in the family of the '739 Patent broadly permitting use of a multi-piece leaflet layer was on April 15, 2014. Therefore, for purposes of Ground 1, an effective filing date of April 15, 2014 is assumed. As a result, the '739 Patent's grandparent application (U.S. Patent Application No. 10/887,688), which published as U.S. Patent App. Pub. No. 2005/0113910 on May 26, 2005 ("Paniagua" (EX1015)), is prior art under 35 U.S.C. §102(b). Because the specification of Paniagua is identical to the '739

Patent's, it anticipates each and every limitation of Claims 1-5. *See, e.g.*, EX1015 at Figs. 1, 3B, 4-6 & 8; Abstract; ¶¶[0024]-[0026], [0028], [0030], [0032]-[0033], [0037]-[0038], [0040]-[0042], [0044], [0046]-[0047], [0049]-[0050], [0054], [0058]-[0059], [0061]; and claims 1, 33.

To be clear, although Claim 1 broadly includes THVs whose valve means include two to four individual leaflets made from multiple separate pieces of tissue material, a THV with a valve means whose leaflets are made from only a single piece of tissue material also falls within the scope of the claims. As such, Paniagua, which only discloses THVs with valve means leaflets made from a single piece of tissue material, reads on each of Claims 1-5. Although the specification of Paniagua is identical to the '739 Patent's specification, and therefore, is an exact, word-for-word prior art disclosure, a brief element-by-element analysis is provided below for completeness.

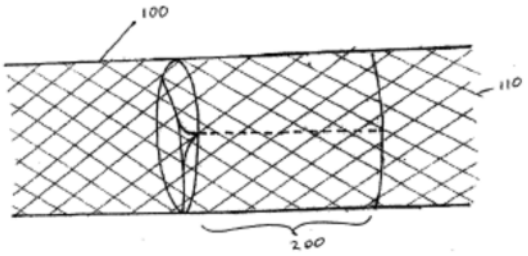
1. Claim 1 (Preamble)

Paniagua discloses an assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire. EX1015 at Abstract, ¶¶[0024], [0025], [0059], [0061]; EX1020, ¶102-03.

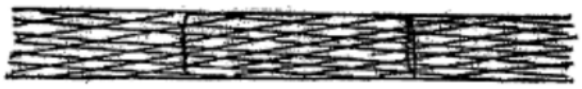
2. Element 1[a]

Paniagua discloses a prosthetic heart valve that includes a stent member having an inner channel, the stent member collapsible, expandable and

configured for transluminal percutaneous delivery. EX1015 at Figs. 5 & 6, ¶¶[0024]-[0025], [0032]-[0033], [0037]-[0038], [0040]-[0041], [0044], [0058]-[0059]; EX1020, ¶104.



Paniagua Fig. 5.



Paniagua Fig. 6

3. Element 1[b]

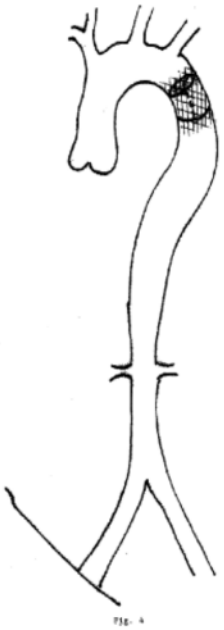
Paniagua discloses wherein the stent member includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration. EX1015 at ¶[0042]; EX1020, ¶105.

4. Element 1[c]

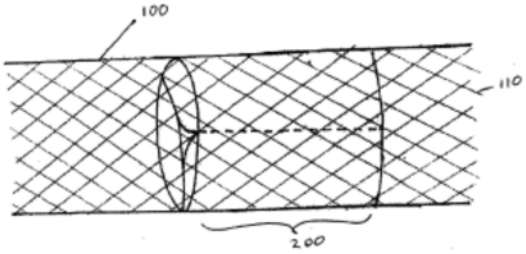
Paniagua discloses a valve means including two to four individual leaflets made of fixed pericardial tissue. EX1015 at Abstract, ¶¶[0025]-[0026], [0037], [0046]-[0047], [0049], [0054]; EX1020, ¶106.

5. Element 1[d]

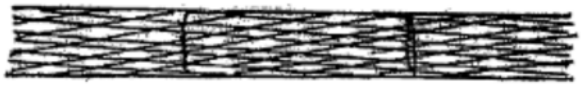
Paniagua discloses wherein the valve means resides entirely within the inner channel of the stent member. EX1015 at Figs. 4-6, Abstract, ¶¶[0024], [0032]-[0033], [0037], [0046], Claims 1 & 33; EX1020, ¶107.



Paniagua Fig. 4.



Paniagua Fig. 5.



Paniagua Fig. 6

6. Element 1[e]

Paniagua discloses a valve means with no reinforcing members residing within the inner channel of the stent member. EX1015 at Figs. 1 & 3B, Abstract, ¶¶[0024], [0026], [0028], [0030], [0037], [0046]-[0047], [0049]-[0050]; EX1020, ¶108.

7. Element 1[f]

Paniagua discloses a delivery system including a pusher member and a moveable sheath. EX1015 at ¶[0058]; EX1020, ¶109.

8. Element 1[g]

Paniagua discloses the pusher member including a guidewire lumen. EX1015 at Abstract, ¶¶[0025], [0059], [0061]; EX1020, ¶110.

9. Element 1[h]

Paniagua discloses that the pusher member is disposed within a lumen of the moveable sheath. EX1015 at ¶¶[0025], [0058]-[0059]; EX1020, ¶111.

10. Element 1[i]

Paniagua discloses that 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. EX1015 at ¶[0058]; EX1020, ¶112.

11. Element 1[j]

Paniagua discloses that a distal end of the prosthetic heart valve is located at a distal end of the moveable sheath. EX1015 at ¶[0058]; EX1020, ¶113.

12. Element 1[k]

Paniagua discloses wherein 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. EX1015 at Figs. 4-6, Abstract, ¶¶[0024], [0032]-[0033], [0037], [0046], claims 1 & 33; EX1020, ¶114.

13. Claim 2

Paniagua discloses wherein the stent member is self-expanding. EX1015 at Abstract, ¶¶[0024]-[0025], [0032]-[0033], [0037]-[0038], [0040]-[0041], [0059]; EX1020, ¶115.

14. Claim 3

Paniagua discloses wherein the stent member comprises nitinol. EX1015 at Abstract, ¶¶[0024], [0040]-[0042]; EX1020, ¶116.

15. Claim 4

Paniagua discloses wherein the stent member includes two circles of barbs on an outer surface of the stent member. EX1015 at ¶¶[0044] & [0058]; EX1020, ¶117.

16. Claim 5

Paniagua discloses wherein the pusher member includes a controlled release mechanism that can be activated. EX1015 at ¶[0058]; EX1020, ¶118.

B. Grounds 2 & 3: Claims 1-5 Are Invalid Under 35 U.S.C. §103 over Bessler (EX1006) in View of Teitelbaum (EX1007) (Ground 2) or Leonhardt (EX1012) (Ground 3)

As detailed above (Section VI.A), the '739 Patent's specification copied large portions of Bessler's specification. Bessler does not, however, explicitly disclose a stent that "flares at both ends in a trumpet-like configuration." EX1020, ¶¶119-20. Instead, the '739 Patent copied its description of the flared stent from Teitelbaum. EX1007 at 2:22-36, 5:51-68, Fig. 2; EX1020, ¶¶40, 123-

24. And, as discussed above, such flared stents were well-known in the art as an option to improve anchoring of the stent across the native valve. EX1020, ¶¶41-50, 124-27. The teachings of Bessler in view of Teitelbaum (EX1007) or Leonhardt (EX1012) render obvious each of the elements of Claims 1-5 of the '739 Patent. EX1020, ¶¶119-53.

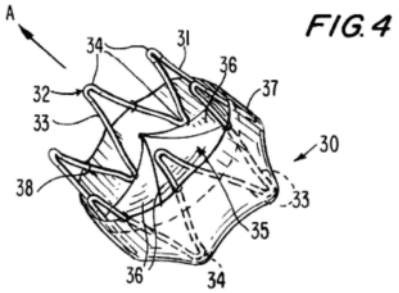
1. Claim 1 (Preamble)

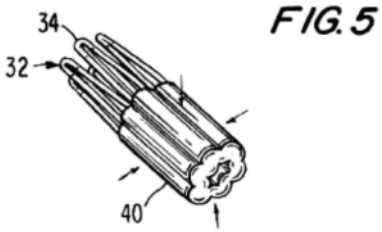
Bessler teaches "[a]n assembly to treat a native heart valve in a patient." EX1006 at 1:7-11 ("The present invention relates to novel artificial heart valves. More particularly, the present invention relates to novel heart valves that are especially adapted for placement using minimally invasive surgical techniques and to the method and device useful for such placement."); EX1020, ¶121. The assembly disclosed by Bessler is "for use in combination with a guidewire." EX1006 at 5:13-14 ("[T]he heart valve could be positioned over a guidewire."); *see also id.* at 7:35-38 ("A guidewire 94 having a blunt end 95 is disposed through a lumen 97 of the pusher member 93 and is used to guide the distal end of the catheter 91 to the desired site."); EX1020, ¶121.

2. Element 1[a]

Bessler teaches a prosthetic heart valve. EX1006 at 2:57-62 ("The invention includes a new heart valve ...."). That heart valve includes a stent member having an inner channel. *Id.* ("[The] heart valve comprises a stent

member ....”). Further, the stent member is collapsible, expandable, and configured for percutaneous transluminal delivery. *See id.* at Fig. 4 (Bessler’s stent in an expanded configuration), Fig. 5 (Bessler’s stent in a collapsed configuration) & at 2:57-62 (“The invention includes a new heart valve which may be implanted percutaneously and transluminally ....”).





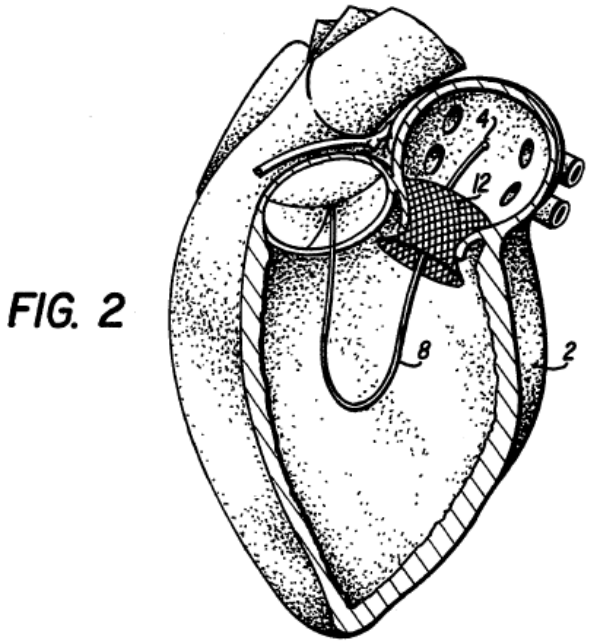
Bessler Fig. 4 Bessler Fig. 5

See also id. at 3:52-55, 4:21-26, 5:44-51, 5:58-60; EX1020, ¶122.

3. Element 1[b]

The combination of Bessler and Teitelbaum or Bessler and Leonhardt discloses “wherein the stent member includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration.” Bessler’s stent member is not explicitly taught as “includ[ing] a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration.” But Teitelbaum teaches a “tubular structure” that “[a]way from its central portion ... flares markedly at both ends in a trumpet-like configuration.” EX1007 at 2:21-29,

5:51-65 (citing Fig. 2); *see also id.* at 5:10-11 ("[a] compressed nitinol [], doubly-flared stent"); EX1020, ¶¶123-24.



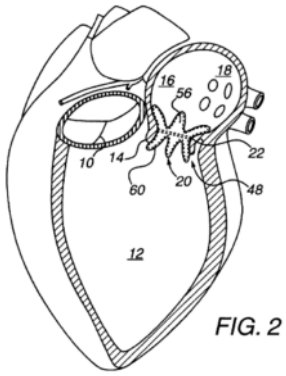
Teitelbaum Fig. 2

Both Teitelbaum and Bessler recognize the desirability of "anchor[ing] the expanded stent member at a desired site" (EX1006 at 2:62-63). Bessler teaches the optional use of barbs to aid in achieving this goal (*id.*); Teitelbaum explains that the purpose of the flared stent is to "maintain the position of this component across the native valve following deployment" (EX1007 at 2:34-36, 5:63-65). Thus, a POSITA would have been motivated to modify Bessler's device by using a flared stent as taught by Teitelbaum in conjunction with, or as an alternative to, Bessler's optional barbs in order to better anchor the device in place and improve sealing, reducing leakage of blood around the valve device (known as "paravalvular

leakage"). EX1020, ¶124. A POSITA would have found this slight modification of the stent member to change the shape at the ends to be a routine modification that would clearly work and yield predictable results. *Id.* In addition to Teitelbaum, other investigators had already taught the use and advantages of a flared stent structure, including Leonhardt (EX1012), Cribier (EX1017), the Wallstent (EX1016 at 7; EX1018 at 167, 169), Garrison (EX1010), Gabbay (EX1009), and Bailey (EX1011). Each of these prior art teachings provide further motivation to combine Bessler with Teitelbaum. Gabbay, for example, provides further confirmation that a person of ordinary skill in the art would have been motivated to combine the use of barbs with a trumpet-like stent structure for improved securement and engagement with the surrounding tissue. EX1009 at ¶[0048] ("[T]he spike portions 38' and 40' may extend radially outwardly from the stent in different directions. In addition, the inflow end 32' also may flare outwardly for engagement with surrounding tissue when implanted."). And Bailey notes that if the embodiment of Bessler without barbs is selected there is an increased risk of device migration, further bolstering the motivation to modify Bessler with a trumpet-like shape to secure the device in place. EX1011 at 4:17-18 ("the [Bessler] device is unstable and prone to migration if barbs are omitted"). Thus, the use of a stent with a trumpet-like configuration, including its

implementation and advantages, was well-known to a POSITA by January 4, 2002. EX1020, ¶124.

Alternatively (or additionally), Leonhardt teaches this element.[9] Leonhardt's "valve stent 20 flair[s] at one or both ends as is shown in FIG. 2." EX1012 at 6:10-11. This stent "is pre-sized to open beyond the width of the natural valve mouth and will flair sufficiently to conform and seal to the tissue." *Id.* at 6:19-22; *see also id.* at 4:60-65; 5:2-5 ("Each end [of the stent] is pre-sized in diameter to be approximately thirty percent (30%) larger in diameter than the largest diameter of the tissue against which the valve stent 20 (FIG. 3) will seal."); EX1020, ¶125.



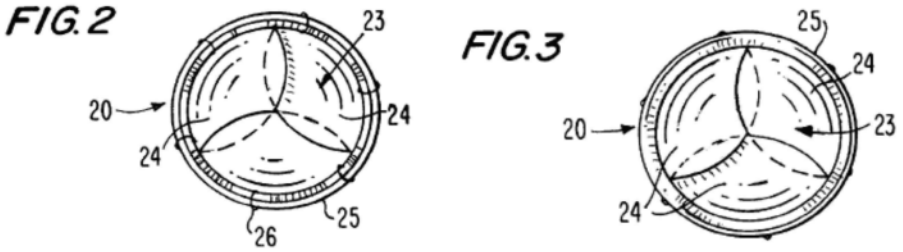
Leonhardt Fig. 2.

[9] Leonhardt was not the basis of any rejections made in the Office Actions—it was never cited by either the Examiner or the applicants. *See generally* EX1002. It was merely one of 300 U.S. patents identified in an IDS. EX1002 at 161 (as part of range 150-77).

Bessler describes a goal of its invention as "anchor[ing] the expanded stent member at a desired site." EX1006 at 2:62-63. A POSITA thus would have been motivated to combine Bessler's valve structure with the flared stent structure of Leonhardt because Leonhardt teaches that the advantage of its flared stent structure is that the "flair[s] ... conform and seal to the tissue" (EX1012 at 6:21-22; *see also id.* at 4:60-65, 5:2-5). Thus, Bessler and Leonhardt both recognize improved anchoring and sealing as desired results. A POSITA would have been motivated to combine Bessler with Leonhardt's flared stent to achieve improved embedding and anchoring of the stent and would have found this slight modification of the stent member to change the shape at the ends to be a routine modification that would clearly work and yield predictable results. EX1020, ¶126-27. In addition to Leonhardt, other investigators had already taught the use and advantages of a flared stent structure, including Cribier (EX1017), the Wallstent (EX1016 at 7; EX1018 at 167, 169), Teitelbaum (EX1007), Garrison (EX1010), Gabbay (EX1009), and Bailey (EX1011), each of which provide further motivation to combine the teachings of Bessler and Leonhardt for the same reasons discussed above with respect to the combination of Bessler and Teitelbaum. Thus, this modification, its implementation and advantages, was well-known to a POSITA by January 4, 2002. EX1020, ¶126-27.

4. Element 1[c]

Bessler's valve means includes "two to four individual leaflets made of fixed pericardial tissue." For example, Figures 2 and 4 both show three leaflets, "although it is understood that there could be from 2 to 4 leaflets." EX1006 at 5:21-24; *see also id.* at 3:65-4:3, 4:9-11 & Figs. 2 & 3; EX1020, ¶128.



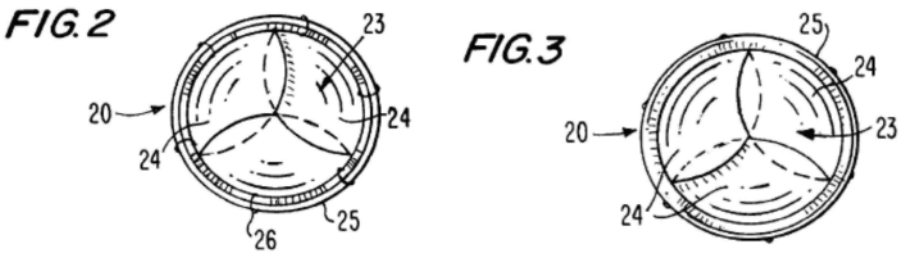
Bessler Figs. 2 & 3.

Bessler's valve means (which Bessler also refers to as the "valve member") is made of fixed pericardial tissue. EX1006 at 4:9-11 ("The flexible valve means preferably comprises porcine pericardium ...."); 6:20-24 ("The valve can be, for example, a glutaraldehyde fixed porcine aortic valve which has three cusps that open distally to permit unidirectional blood flow. The valve can also be fresh, cryopreserved or glutaraldehyde fixed allografts or xenografts."); EX1020, ¶129.

5. Element 1[d]

Bessler's valve means resides entirely within the inner channel of the stent member. A POSITA would recognize that it is the "generally arcuate center portion" of the device of Bessler that "open[s] in response to blood flow in one

direction and closes in response to blood flow in the opposite direction" (EX1006 at 3:65-4:1), that is the valve means. EX1020, ¶130-33. The center portion 23 of the valve member in Bessler is shown in Figures 2 & 3 as comprised of three leaflets 24; the valve member is attached to the stent member by sutures 26. EX1006 at 5:15-27.



Bessler Figs. 2 & 3.

To the extent that Patent Owner argues that Bessler's "cuff portion" is a part of the "valve means" of the '739 Patent, as discussed above (*supra* Section II), Bessler discloses a cuff portion that can be, but is not required to be, on the outside of the stent. *Compare* EX1006 claim 13 with, *e.g.*, *id.*, claim 1; *see also id.* at 4:4-9; EX1020, ¶132-33.[10]

[10] Such an argument is also inconsistent with positions that Patent Owner has taken both during prosecution and litigation of the '739 Patent. EX1020, ¶131. During prosecution, the applicant differentiated an external cuff or seal from the valve means: responding to an Office Action rejecting an earlier version of the claims that required "the valve means and all fixed pericardial tissue [to] reside entirely

6. Element 1[e]

There are no reinforcing members residing within the inner channel of the stent member in Bessler. No description of the valve means in Bessler includes a description of reinforcing members (nor any mention of valve arms, regulator struts, reinforcing pleats, or similar). *See* EX1006 at 3:55-64, 3:65-4:3, 5:15-24, 5:28-35, 5:36-38 and Figs. 2-4; and *see generally* EX1006. Therefore, a POSITA would recognize that there are no reinforcing members resid[ing] within the inner channel of the stent member" in Bessler. EX1020 at ¶¶135-136.[11]

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within the inner channel of the stent member" (EX1002 at 415), the applicant distinguished Bailey as "disclos[ing] that ***the tissue*** is located on the abluminal side of the frame" and argued that "Bailey teaches away from a configuration where ***tissue*** is limited to the interior of the stent member." *Id.* (emphasis added). During litigation in *Colibri Heart Valve LLC v. Medtronic CoreValve LLC,* No. 8:20-cv-847-DOC-JDE (C.D. Cal.), in which Patent Owner has accused Medtronic's CoreValve devices of infringing the '739 Patent, Patent Owner states in claim charts attached to the Amended Complaint that CoreValve's "outer skirt is not part of the 'valve means.'" EX1022 at 7.

[11] Bessler does not explicitly recite this negative limitation, but neither does the '739 Patent, which only mentions "reinforcing members" in Claim 1.

7. Element 1[f]

As discussed above (*supra* Section II), the '739 Patent copies its disclosure of the delivery system including a pusher member almost word-for-word from Bessler: "The system for implanting the above described artificial heart valve percutaneously and transluminally includes ***a flexible catheter*** which may be inserted into a vessel of the patient and moved within that vessel.... ***The catheter has a pusher member disposed within the catheter lumen*** ...." EX1006 at 4:53-63 (emphasis added); *compare id. with* EX1001 at 11:40-49. Bessler thus discloses a delivery system that includes a pusher member and a moveable sheath. To be clear, the "moveable sheath" of Bessler is the "catheter" or "flexible catheter," "which is hollow and carries [at its distal end] the artificial heart valve … in its collapsed configuration." EX1020, ¶137; s*ee* EX1006 at 4:56-58 ("The distal end of the catheter, which is hollow and carries the artificial heart valve of the present invention in its collapsed configuration …"),[12] 5:3-6 ("The catheter is the[n] retracted slightly and the artificial heart valve is completely pushed out of the catheter and released from the catheter to allow the stent member to fully

[12] This language was copied into the '739 Patent. *Compare with* EX1001 at 11:44-47.

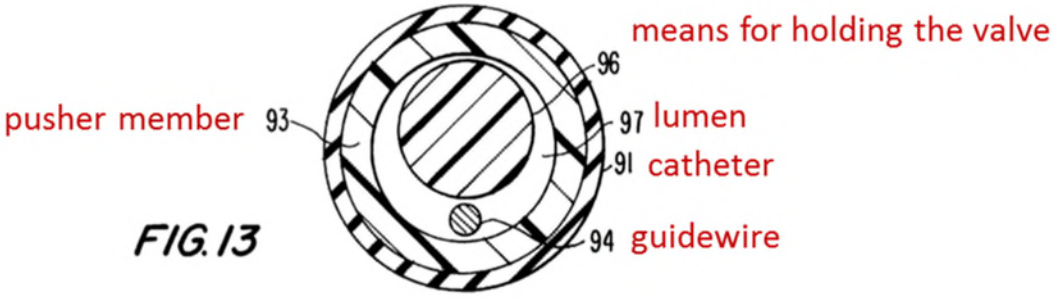
expand."),[13] 5:46-51 ("The artificial heart valve will not stay in its collapsed configuration without being restrained. Once the restraint is removed, the self-expanding stent member 32 will cause the artificial heart valve to take its expanded configuration …"),[14] 7:33-35 ("Disposed within the catheter 91 is a hollow flexible pusher member 93, which is movable longitudinally with respect to the catheter 91."), Claim 17 ("moving the leading half of said valve out of the distal end of the catheter ... and retracting the catheter slightly to remove the trailing half of said valve from the hollow end of said catheter"), Figs. 12 & 13; EX1020, ¶¶137-39.

8. Element 1[g]

Bessler's pusher member includes a guidewire lumen. EX1006 at 7:35-38 ("A guidewire 94 having a blunt end 95 is disposed through a lumen 97 of the pusher member 93 and is used to guide the distal end of the catheter 91 to the desired site." (referring to Figs. 12 & 13)); *see also id.* at 4:53-5:14; EX1020, ¶140.

[13] This language was copied into the '739 Patent. *Compare with* EX1001 at 11:59-62.

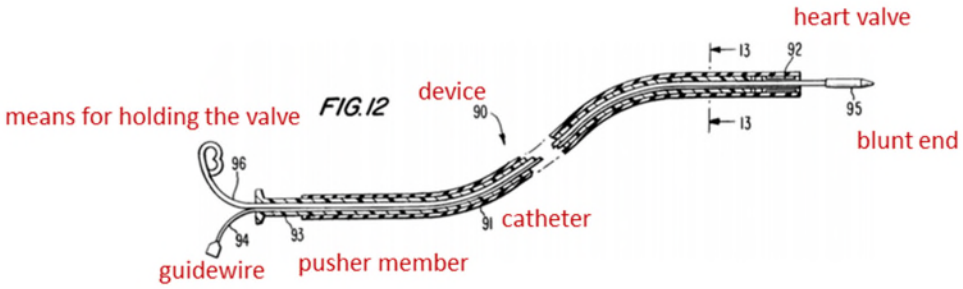
[14] This language was copied into the '739 Patent. *Compare with* EX1001 at 7:21-25.

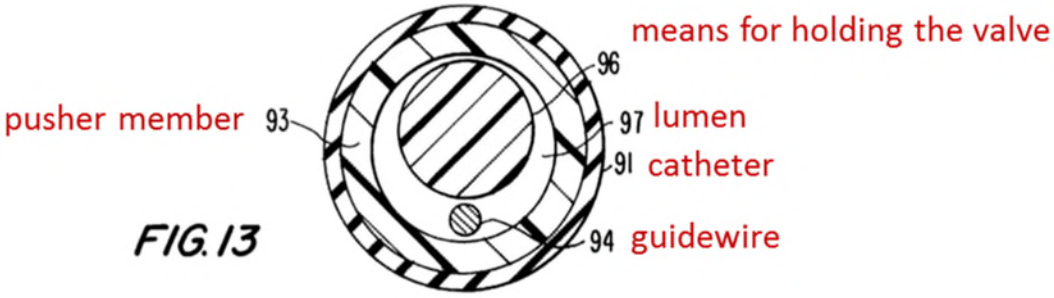


Bessler, Fig. 13.

9. Element 1[h]

Bessler's pusher member is disposed within a lumen of the moveable sheath (what Bessler refers to as a "catheter"). EX1006 at 4:60-63 ("The catheter has a pusher member disposed within the catheter lumen and extending from the proximal end of the catheter to the hollow section at the distal end of the catheter."); *see also id.* at 7:33-35 and Figs. 12 & 13; *see also supra* Element 1[f]; EX1020, ¶141.





Bessler, Figs. 12 & 13.

10. Element 1[i]

The ’739 Patent copied its only disclosure of a “pusher member” from Bessler. *Compare* EX1001 at 11:40-12:5 *with* EX1006 at 4:53-5:14. Therefore, whatever the ’739 Patent is argued to describe as the pusher member, Bessler must disclose. Bessler’s 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:

> The distal end of the catheter, which is hollow and carries the artificial heart valve of the present invention in its collapsed configuration, is guided to a site where it is desired to implant the artificial heart valve. The catheter has a pusher member disposed within the catheter lumen and extending from the proximal end of the catheter to the hollow section at the distal end of the catheter. Once the distal end of the catheter is positioned as desired, the pusher mechanism is activated and the distal portion of the artificial heart valve is pushed out of the catheter and the stent member partially expands. In this position the stent member is restrained so that it doesn’t pop out and is held for controlled release, with the potential that the

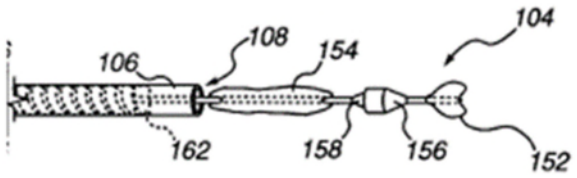
> artificial heart valve can be recovered if there is a problem with the positioning or the like. The catheter is them retracted slightly and the artificial heart valve is completely pushed out of the catheter and released from the catheter to allow the stent member to fully expand.

EX1006 at 4:63-5:6; *see also id.* at 5:46-51 ("The artificial heart valve will not stay in its collapsed configuration without being restrained. Once the restraint is removed, the self-expanding stent member 32 will cause the artificial heart valve to take its expanded configuration, as seen in FIG. 4."); *see also* EX1020, ¶¶142-43.

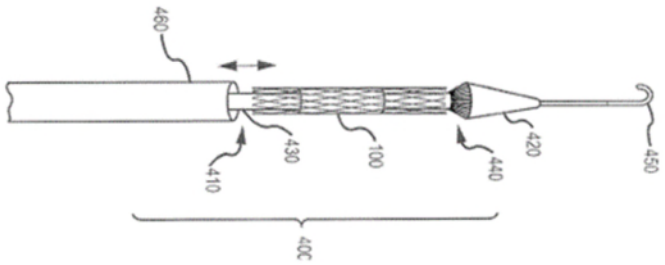
To the extent that the term "onto" in the phrase "wherein the prosthetic heart valve is collapsed onto the pusher member" is construed narrowly such that it requires the pusher member to pass through the interior of the prosthetic valve (contrary to the only use of "pusher member" described in the specification (EX1001 at 11:40-12:5)), Leonhardt has a delivery system with a "push rod" with an inner passage through which an "inner catheter" extends. EX1012 at 6:45-49; EX1020, ¶144. That "inner catheter" "pass[es] through valve 22 prior to and during deployment." EX1012 at 7:15-17; *see also id.* at 7:21-29, 8:23-31; EX1020, ¶145. Leonhardt further describes deploying the valve by "withdrawing outer sheath 106." EX1012 at 10:53-11:22; EX1020, ¶145. And to the extent Patent Owner attempts to rely upon Figure 8 of the '739 Patent to

support a narrow construction of "onto," the arrangement of Leonhardt's delivery system parallels that depicted in Figure 8 of the '739 Patent:

Leonhardt Fig. 5



'739 Patent Fig. 8



Compare EX1001, Fig. 8 *with* EX1012, Fig. 5 (excerpted); EX1020, ¶145. Although not depicted, Teitelbaum teaches a similar arrangement. Teitelbaum's delivery system includes a "pusher rod" with a "delivery sheath," wherein the stent is deployed by holding the pusher "steady while the sheath is withdrawn," allowing the stent to expand. EX1007 at 5:10-22; 3:46-61; EX1020, ¶146.

A POSITA would have been motivated to modify Bessler's delivery system with features taught by Leonhardt and Teitelbaum because a POSITA would recognize that collapsing the prosthesis onto a pusher member with an inner catheter extending through the pusher member permits the operator to hold the

apparatus steady, such as in the deployment method Teitelbaum describes (EX1007 at 5:15-19, 3:54-59), increasing the precision of device placement over pushing a device out of a catheter. EX1020, ¶147. A POSITA would have had a reasonable expectation of success in making these combinations, because these combinations represent a simple substitution of one known prior art delivery system element (a pusher member adjacent to the collapsed prosthesis) with another (a pusher member that includes an inner catheter that extends through the interior of the collapsed prosthesis). *Id.*

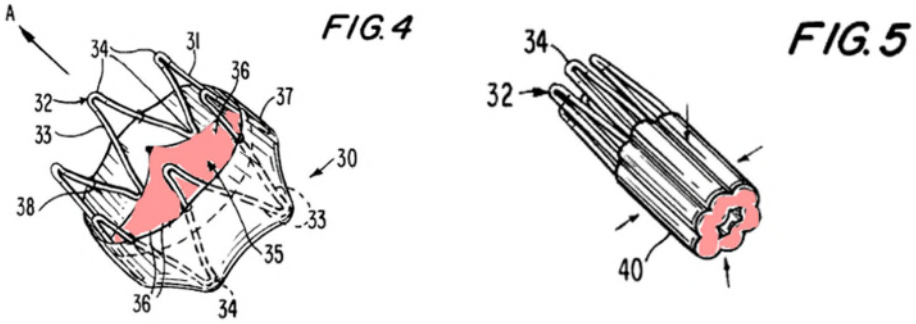
11. Element 1[j]

In Bessler, a distal end of the prosthetic heart valve is located at a distal end of the moveable sheath. EX1006 at 4:63-66; *see also id.* at 7:30-33, 7:48-53 (describing the distal end of the valve being the first end ejected from the distal end of the catheter and referring to Fig. 14); EX1020, ¶148.

12. Element 1[k]

For the same reasons Bessler discloses "wherein the valve means resides entirely within the inner channel of the stent member," *supra* Section VII.B.5. (Element 1[d]), Bessler discloses "wherein the valve means resides entirely within the inner channel of the stent member in said collapsed configuration and is configured to reside entirely within the inner channel of the stent upon deployment in the patient." EX1006 at 3:65-4:1, 4:4-9, 5:15-23, Figs. 2

& 3; EX1020, ¶¶130-33, 149. This can likewise be seen in Figures 4 and 5 of Bessler:



EX1006, Figs. 4 & 5 (valve means in red).

Leonhardt provides additional evidence that valve means "resid[ing] entirely within the inner channel of the stent member" (in both the collapsed and deployed states) without reinforcing members (Elements 1[d]-[e], 1[k]) were known in the art. EX1012 at 6:24-32; EX1020, ¶¶134, 136, 150.

13. Claim 2

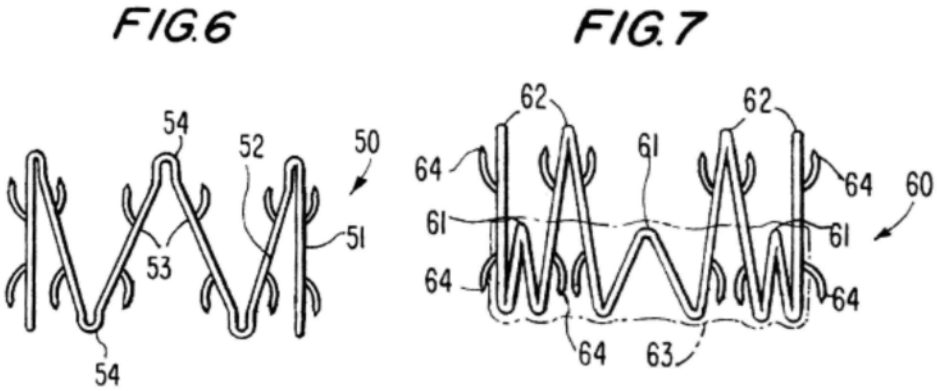
Bessler discloses a self-expanding stent member. EX1006 at 2:60-62 ("The stent member is self-expanding ...."); *see also id.* at Abstract, 3:52-55, 5:47-50, 5:58-60, 6:7-11, and claims 1, 13, 17, 19 & 20; EX1020, ¶151.

14. Claim 3

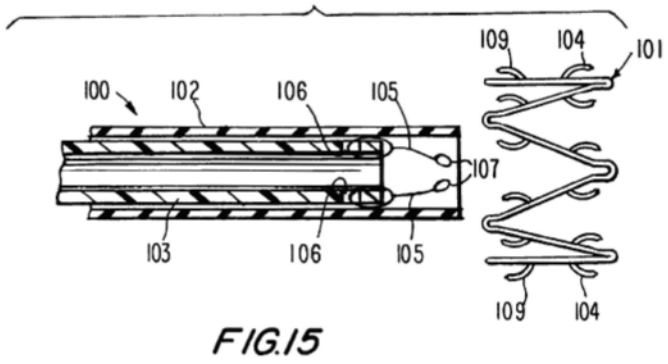
Bessler discloses making the stent member out of nitinol. EX1006 at 6:3-7 ("The stent members of the artificial heart valves of the present invention may be made from … nitinol …."); *see also id.* at claim 7 ("The artificial valve of claim 6, wherein the material is Elgiloy alloy or nitinol."); EX1020, ¶152.

15. Claim 4

Bessler teaches embodiments where the stent member comprises two circles of barbs on an outer surface of the stent member, as depicted in Figures 6, 7, and 15:



Bessler Figs. 6 & 7.



Bessler Fig. 15.

See also EX1006 at 4:12-18 ("Preferably the stent member carries a plurality of barbs extending outwardly from the outside surface of the stent member for fixing the heart valve in a desired position. More preferably the barbs are disposed in two spaced-apart, circular configurations with the barbs in one circle extending in an upstream direction and the barbs in the other circle extending in a downstream

direction."); s*ee also id.* at 2:62-63, 5:6-12, 5:61-62, 7:61-67, and claims 1, 4-5, 13, & 15-20; EX1020, ¶¶33, 153. The '739 Patent's description of the barbs on the stent member is copied nearly word-for-word from Bessler. *Compare* EX1001 at 8:11-25 *with* EX1006 at 4:12-26.

16. Claim 5

Bessler discloses a delivery system wherein the pusher member includes a controlled release mechanism that can be activated. EX1006 at 7:38-42, 7:53-67 and Figs. 14 & 15; EX1020, ¶¶38, 154. Indeed, the description of the controlled release mechanism in the '739 Patent was copied nearly word-for-word from Bessler's description. *Compare* EX1001 at 11:51-59 *with* EX1006 at 4:63-5:3.

C. Grounds 4 & 5: Claims 1-5 Are Invalid Under 35 U.S.C. §103 over Bessler (EX1006) in View of Teitelbaum (EX1007) + Klint (EX1019) (Ground 4); or Bessler (EX1006) in View of Leonhardt (EX1012) + Klint (EX1019) (Ground 5)

As discussed above (Section VII.B), the combinations of Bessler and Teitelbaum, or Bessler and Leonhardt, disclose at least Claim 1's Preamble and Elements 1[a]-1[h], 1[j]-[k], and Claims 2-5 of the '739 Patent. Those sections (*supra*) are incorporated into the Grounds in this section by reference. To the extent that Patent Owner argues that the combinations of Bessler and Teitelbaum, or Bessler and Leonhardt, do not disclose Element 1[i] because of a narrow construction of the term "onto" in the phrase "wherein the prosthetic heart valve is

collapsed onto the pusher member," Klint (EX1019) additionally teaches this element and it would have been obvious to a POSITA to combine (1) Bessler with Teitelbaum and Klint; or (2) Bessler with Leonhardt and Klint. EX1020, ¶¶155-62.

Klint, which was filed in the U.S. on January 26, 2001 and published on November 22, 2001, broadly teaches "a delivery system for a prosthesis, such as a stent, a stent graft, a valve member, or a filter, wherein the prosthesis is compressible to be placed within a receptacle at the distal end of the delivery catheter and is then radially expandable upon delivery to a treatment site after being urged from receptacle." EX1019 at ¶¶[0021], [0091]; EX1020, ¶157. Klint's delivery system includes a shaft portion with a lumen extending along its length, wherein a self-expandable prosthesis is arranged in a receptacle at the distal end of the delivery device, and a pusher member with engagement means extends through the lumen of the delivery device. Below, Klint's delivery system is depicted (Figure 13) along with a depiction of the distal end of the delivery system and a partially deployed prosthesis (Figure 16):

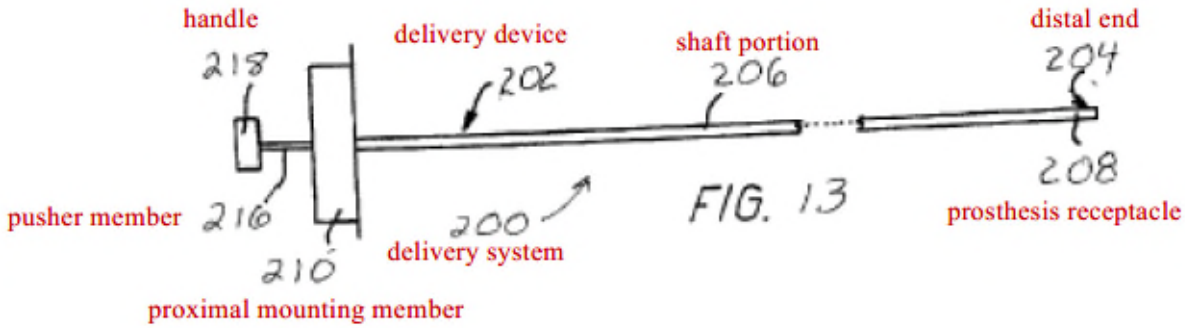


FIG. 13

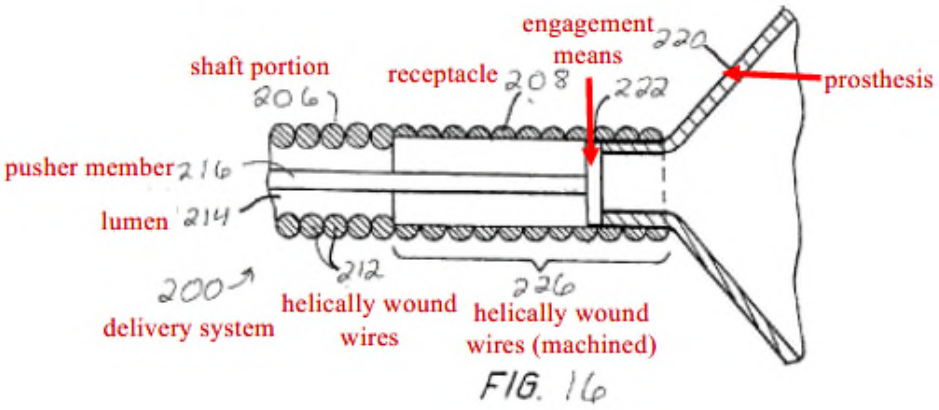


FIG. 16

EX1019, Figs. 13, 16; *id.* at ¶¶[0091]-[0103]; EX1020, ¶158.

Klint discloses embodiments with two alternative designs for the engagement of the pusher member with the prosthesis: (1) delivery systems where the pusher member is adjacent to and in contact with the prosthesis; and (2) delivery systems where the pusher member passes through the collapsed prosthesis. EX1019, ¶ [0094]; EX1020, ¶159. Klint explains that the latter arrangement "can be an advantage if the prosthesis has an extensive length, and in particular if it has a construction having a tendency to buckle when pushed upon." EX1019, ¶[0094]; EX1020, ¶160.

A POSITA would have been motivated to modify Bessler and Teitelbaum (Ground 4) or Bessler and Leonhardt (Ground 5) in light of the teachings of Klint, because a POSITA would recognize the advantage of this design, as explained by Klint (reducing the risk that the prosthesis will buckle or be damaged during delivery from having force applied to it by a pusher member located adjacent to the device). EX1019, ¶[0094]; EX1020, ¶162. A POSITA would also have been motivated to make these combinations because a POSITA would recognize that collapsing the prosthesis onto the pusher member permits the operator to hold the apparatus steady, such as in the deployment method Teitelbaum describes (EX1007 at 5:15-19, 3:54-59), increasing the precision of device placement over pushing a device out of a catheter. EX1020, ¶161.

A POSITA would have had a reasonable expectation of success in making these combinations, because these combinations represent a simple substitution of one known prior art delivery system element (a pusher member adjacent to the collapsed prosthesis) with another (a pusher member that extends through the interior of the collapsed prosthesis). EX1020, ¶161. Indeed, Klint's use of these two delivery systems as alternatives (EX1019, ¶[0094]) demonstrates that a POSITA would have recognized their interchangeability. And the results of these combinations would be predictable as "[c]atheters for medical diagnostic or therapeutic use [were] [ ] well known", including catheters that include "a pusher

to push a device such as a stent from the distal end of the catheter." EX1019, ¶¶[0007]-[0009]; EX1020, ¶¶161-62.

Leonhardt provides further evidence that a POSITA would have had a reasonable expectation of success in making the combination of Bessler, Teitelbaum, and Klint; or Bessler, Leonhardt, and Klint, because as discussed above, Leonhardt teaches embodiments in which portions of the delivery system pass through the interior of the prosthetic heart valve. EX1020, ¶160; EX1019, ¶[0027]; EX1012 at 6:46-49, 7:11-17, 7:21-29, 8:23-31. And similarly, Teitelbaum teaches the use of a "pusher rod" that is "held steady while the sheath is withdrawn." EX1007 at 5:15-19, 3:54-59; EX1020, ¶160.

VIII. OBJECTIVE INDICIA OF NON-OBVIOUSNESS

Petitioners are not aware of any evidence that supports any objective indicia of non-obviousness, but reserve the right to respond to any such purported evidence by Patent Owner. *Petroleum Geo-Servs. Inc. v. WesternGeco LLC*, IPR2014-1475, Paper 18 at 28 (PTAB Mar. 17, 2015) (evidence of objection indicia "must be first developed ... by Patent Owner); EX1020, ¶163.

IX. THE BOARD SHOULD NOT EXERCISE §314(a) OR §325(d) DISCRETION

Neither §314(a) and *General Plastic*[15] or *Apple/Fintiv*[16] nor §325(d) support

[15] *See Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-1357,

discretionary denial of this Petition.

A. §314(a)

1. The *General Plastic* Factors Do Not Favor Denial

Factor 1: Petitioners and Medtronic are different, unrelated petitioners. Petitioners are not a co-defendant in the district court litigation between Patent Owner and Medtronic, and Petitioners' and Medtronic's products do not overlap. *See Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-0062, Paper 11 (PTAB Apr. 2, 2019) (precedential).

Factors 2, 4 & 5: Petitioners filed their petition "at or around the time of" the first-filed petition on the '739 Patent. *Valve Corp.*, IPR2019-0062 at 14. Thus, here, unlike in *Valve Corp.*, there is no delay to be explained or excused. *See id.* at 10-11, 13-14.

Factor 3: Here, this petition was filed only two weeks after Medtronic filed the first petition. Patent Owner has not filed a preliminary response to that petition nor has the Board issued an institution decision on the first petition.

Factors 6 & 7: The second petition was filed "at or around the same time" as the first-filed petition, and the first petition has not yet been instituted and was

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Paper 19 at 16 (PTAB Sept. 6, 2017) (precedential).

[16] *See Apple Inc. v. Fintiv, Inc.*, IPR2020-0019, Paper 11 at 5-16 (PTAB Mar. 20, 2020) (precedential).

filed by an unrelated petitioner. *See id.* at 15. Thus, the concerns for inefficiency from serial, repetitive patent challenges that applied in *Valve Corp.* are not implicated here. *See id.*

2. The *Apple/Fintiv* Factors Do Not Favor Denial

Factors 1 & 2: Petitioners are not a party to the co-pending district court litigation between Patent Owner and Medtronic, but Petitioner understands that Medtronic moved to stay those proceedings on September 4 and that a decision on that motion is pending. If the stay is not granted, Petitioner understands that the court set a trial date of September 14, 2021. This trial date is earlier than a final written decision would be expected in this case, but Medtronic has filed two motions that may alter that date—a motion to dismiss, as well as the previously noted motion to stay.

Factor 3: Petitioners are not parties to the co-pending district court litigation, and thus have not and will not invest resources in that case. To date, it does not appear that the parties or the court have invested substantial resources in that case, either—Medtronic has filed, and the parties have briefed, a motion to dismiss, and a scheduling order was recently entered. Medtronic's motion to stay would eliminate additional expenditure of resources by the court and the parties if it is granted.

Factors 4 & 5: Petitioners are not a party to the co-pending district court

litigation, which weighs against denying institution. *See Nalox-1 Pharms., LLC v. Opiant Pharms., Inc.*, IPR2019-685, Paper 11 at 6 (PTAB Aug. 27, 2019). The co-pending district court litigation is currently in its early stages and as a non-party, Petitioners have no control over or insight into what art and arguments may be raised in that case.

Factor 6: The arguments in this case are unusual, making the merits of this Petition particularly strong and counseling against discretionary denial. Here, Ground 1 is based on a challenge to the priority claim of the '739 Patent, which would make the publication of its own grandparent prior art. Because Paniagua and the '739 Patent have identical specifications, if the Board finds that there is a written description defect, then the publication of the grandparent application anticipates its own grandchild. And for Grounds 2-5, the challenge is primarily based on the applicants' copying of portions of two pieces of prior art nearly word-for-word into the specification and then, twelve years later, filing a continuation application with claims that covered the copied references. For these reasons, the Grounds raised in this Petition are unusual and unusually strong.

B. §325(d)

With respect to §325(d), the art and arguments presented in this Petition were not previously considered because none of the references presented were substantively considered during prosecution. Klint was not even cited; the others

were only included as line items in IDSs listing hundreds of refences (EX1002 at 157, 160, 161, 185; *see generally* EX1002 at 150-77, 181-204; EX1001 at 2-7). *See Hobbico, Inc. v. Traxxas, L.P.*, IPR2018-00010, Paper 8 at 19 (PTAB Apr. 18, 2018) (mere citation of a reference in an IDS and consideration without comment was insufficient to indicate the examiner substantively considered the references); *Zip-Top LLC v. Stasher, Inc.*, IPR2018-01216, Paper 14 at 35–36 (PTAB Jan. 17, 2019) (similar). And the Examiner of the '739 Patent was not made aware that the applicants copied portions of Bessler and Teitelbaum and did not consider whether the '739 Patent could claim priority to January 4, 2002. Thus, under step 1 of the *Advanced Bionics*[17] analysis, *Becton, Dickinson*,[18] Factors (a), (b), and (d) demonstrate that the art relied on in this Petition is not the same or substantially the same as what was considered by the Examiner because the art raised here was never considered and is uniquely situated over other prior art references.

If, however, the inclusion of these references on IDSs is found to constitute previous presentation to the Office, the analysis under step 2 of *Advanced Bionics*

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[17] *See Adv. Bionics LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-1469, Paper 6 at 8-9 (PTAB Feb. 13, 2020) (precedential).

[18] *See Becton Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-1586, Paper 8 at 17-18 (PTAB Dec. 15, 2017) (informative).

counsels against denial, because Factors (c), (e), and (f) support a finding that the Examiner erred by failing to consider these references. Under Factor (c), the asserted art was not evaluated at all during examination. Because the Examiner did not consider these references at all, under Factor (e), the error committed was failure to evaluate references that disclose the claimed invention essentially word-for-word: the identical specification of Paniagua and the description from Bessler that was copied into the '739 Patent. Finally, for Factor (f), as discussed above with respect to *Apple/Fintiv* Factor 6, these are unusual and unusually strong facts that warrant reconsideration of this prior art.

Nor are Petitioners' art and arguments substantially the same as those presented by Medtronic in IPR2020-1454. Petitioners' Grounds are based on (1) the argument that the publication of the '739 Patent's grandparent is anticipatory prior art and (2) that the applicants copied large portions of Bessler into their specification and then attempted to claim the teachings of Bessler but with a flared stent. Medtronic's petition does not make these arguments and relies almost entirely on different art.[19]

[19] One exception: both use Leonhardt as a secondary reference for at least the flared stent. But Petitioner's arguments with respect to its primary reference, Bessler, are distinct from Medtronic's arguments with respect to its primary reference, Garrison.

X. CONCLUSION

Petitioner submits that the substantial evidence presented in this Petition demonstrates that there is a reasonable likelihood that Claims 1-5 of the '739 Patent would have been anticipated and obvious to a person of ordinary skill in the art. Accordingly, Petitioner respectfully requests that the Board grant *inter partes* review pursuant to 35 U.S.C. §314.

Respectfully submitted,

/s/ Brian P. Egan

Brian P. Egan (Reg. No. 54,866)
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
Email: began@mnat.com
Telephone: 302-351-9454
Facsimile: 302-498-6216

Gregory S. Cordrey (Reg. No. 44,089)
Jeffer Mangels Butler & Mitchell, LLP
3 Park Plaza, Suite 1100
Irvine, CA 92614
Email: gcordrey@jmbm.com
Telephone: 949-623-7200
Facsimile: 949-623-7201
Attorneys for Petitioners
Edwards Lifesciences Corporation and
Edwards Lifesciences LLC

Date: September 18, 2020

APPENDIX

APPENDIX

U.S. Patent No. 9,125,739 Claims 1-5
Element-by-Element Breakdown

Claim No.	'739 Patent Claim Element
1 (Preamble)	An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising:
1[a]	a prosthetic heart valve including: a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery,
1[b]	wherein the stent member includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration; and
1[c]	a valve means including two to four individual leaflets made of fixed pericardial tissue,
1[d]	wherein the valve means resides entirely within the inner channel of the stent member, and
1[e]	wherein no reinforcing members reside within the inner channel of the stent member;

Claim No.	'739 Patent Claim Element
1[f]	a delivery system including a pusher member and a moveable sheath,
1[g]	the pusher member including a guidewire lumen,
1[h]	wherein the pusher member is disposed within a lumen of the moveable sheath,
1[i]	wherein 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,
1[j]	wherein a distal end of the prosthetic heart valve is located at a distal end of the moveable sheath, and
1[k]	wherein 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.
2	The assembly of claim 1, wherein the stent member is self-expanding.

Claim No.	'739 Patent Claim Element
3	The assembly of claim 2, wherein the stent member comprises nitinol.
4	The assembly of claim 1, wherein the stent member includes two circles of barbs on an outer surface of the stent member.
5	The assembly of claim 1, wherein the pusher member includes a controlled release mechanism that can be activated.

37 C.F.R. § 42.24(D) CERTIFICATION

The undersigned hereby certifies that this submission, excluding the table of contents, table of authorities, exhibit list, mandatory notices under §42.8, certificate of word count, certificate of service, and appendix of claim listing, contains 13,984 words, as determined using the standard word counting feature of the Microsoft Word program.

*/s/ Brian P. Egan*_____
Brian P. Egan (Reg. No. 54,866)

Attorney for Petitioners Edwards Lifesciences Corporation and Edwards Lifesciences LLC

Date: September 18, 2020

CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(E), 42.105(A))

I hereby certify that, on September 18, 2020, I caused a true and correct copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 9,125,739 ("the '739 Patent") and all associated supporting materials to be served via Fedex delivery at the correspondence address of record for the '739 Patent:

FOX ROTHSCHILD LLP
Princeton Pike Corporate Center
997 Lenox Drive
BLDG. #3
Lawrenceville, NJ 08648

/s/ Gregory S. Cordrey
Gregory S. Cordrey (Reg. No. 44,089)

Attorney for Petitioners
Edwards Lifesciences Corporation and
Edwards Lifesciences LLC

Date: September 18, 2020