

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES
LLC, AND EDWARDS LIFESCIENCES AG
Petitioners

v .

BOSTON SCIENTIFIC SCIMED, INC.
Patent Owner

Case IPR2017-_____
Patent 8,992,608

PETITION FOR *INTER PARTES* REVIEW OF

U.S. PATENT NO. 8,992,608

UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42

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EXHIBIT LIST

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EXHIBIT 1104	WO 03/047468 to Spenser <i>et al.</i>
EXHIBIT 1105	U.S. Patent App. Pub. No. 2003/0236567 to Elliot
EXHIBIT 1106	U.S. Patent App. Pub. No. 2004/0082989 to Cook <i>et al.</i>
EXHIBIT 1107	First Declaration of Dr. Nigel Buller, Originally Submitted in IPR2017-00060
EXHIBIT 1108	Alain Cribier <i>et al.</i> , “Early experience with percutaneous transcatheter implantation of heart valve prosthesis for the treatment of end-stage inoperable patients with calcific aortic stenosis,” J. Am. Coll. Cardiol., 43(4): 698-703 (2004).
EXHIBIT 1109	U.S. Patent App. Pub. No. 2001/0039450 to Pavcnik <i>et al.</i>
EXHIBIT 1110	U.S. Patent App. Pub. No. 2004/0033364 to Spiridigliozzi <i>et al.</i>
EXHIBIT 1111	U.S. Patent No. 3,365,728 to Edwards
EXHIBIT 1112	Charles T. Dotter, “Transluminally-Placed Coilspring Endarterial Tube Grafts,” Investigative Radiology, 329-32 (1969).
EXHIBIT 1113	Frank Ing, “Stents: What’s Available to the Pediatric Interventional Cardiologist?” Catheterization and Cardiovascular Interventions 57:274-386 (2002).
EXHIBIT 1114	U.S. Patent No. 6,206,911 to Milo
EXHIBIT 1115	Excerpts from Vossoughi et al., Stent Graft Update (2000)
EXHIBIT 1116	Excerpts from Dolmatch et al., Stent Grafts: Current Clinical Practice (1999)
EXHIBIT 1117	Andersen et al., “Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs,” European Heart Journal, 13:704-08 (1992).
EXHIBIT 1118	U.S. Patent No. 5,411,552 to Andersen <i>et al.</i>
EXHIBIT 1119	U.S. Patent No. 6,015,431 to Thornton <i>et al.</i>
EXHIBIT 1120	U.S. Patent App. Pub. No. 2001/0021872 to Bailey <i>et al.</i>

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EXHIBIT 1121	U.S. Patent No. 6,352,554 to De Paulis
EXHIBIT 1122	European Patent 2 749 254 B1 to Salahieh <i>et al.</i>
EXHIBIT 1123	American Heritage College Dictionary, 4th Ed. 2002 (definition of “flaps”)
EXHIBIT 1124	Merriam-Webster’s Collegiate Dictionary, 10th ed. (2001) (definitions of “flaps” and “pleats”)
EXHIBIT 1125	Charles S. Thompson et al., “Endoluminal stent grafting of the thoracic aorta: Initial experience with the Gore Excluder,” <i>Journal of Vascular Surgery</i> , 1163-70 (June 2002)
EXHIBIT 1126	Gore Excluder Instructions for Use (2002)
EXHIBIT 1127	U.S. Patent No. 5,957,949 to Leonhardt <i>et al.</i>
EXHIBIT 1128	Assignment record for U.S. Patent App. Pub. No. 2003/0236567 to Elliot
EXHIBIT 1129	Lawrence <i>et al.</i> , “Percutaneous Endovascular Graft: Experimental Evaluation,” <i>Radiology</i> , 163(2): 357-60 (May 1987).
EXHIBIT 1130	European Patent 2 926 766 B1 to Salahieh <i>et al.</i>
EXHIBIT 1131	Boston Scientific’s August 24, 2016 Response in Opposition Proceedings of EP 2 749 254 B1
EXHIBIT 1132	Boston Scientific’s August 24, 2016 Reply in German Infringement Proceeding 4a O 137/15
EXHIBIT 1133	U.S. Patent No. 5,855,601 to Bessler <i>et al.</i>
EXHIBIT 1134	U.S. Patent No. 5,476,506 to Lunn
EXHIBIT 1135	US 2005/0283231 to Haug <i>et al.</i>
EXHIBIT 1136	Second Declaration of Dr. Nigel Buller
EXHIBIT 1137	Textbook of Interventional Cardiology, 2d Ed., Chapter 75: Percutaneous Expandable Prosthetic Valves (1994)
EXHIBIT 1138	U.S. Patent No. 5,469,868 to Reger
EXHIBIT 1139	U.S. Patent No. 7,731,742 to Schlick <i>et al.</i>
EXHIBIT 1140	Pavcnik, <i>et al.</i> , “Aortic and venous valve for percutaneous insertion,” <i>Min. Invas. Ther. & Allied Technol.</i> 9(3/4) 287-292 (2000)
EXHIBIT 1141	Moazami <i>et al.</i> , “Transluminal Aortic Valve Placement: A Feasibility Study With a Newly Designed Collapsible Aortic Valve,” <i>ASAIO J.</i> Vol. 42:5, pp. M383-85 (Sept./Oct. 1996)

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EXHIBIT 1142	Prosecution History of U.S. Patent Application No. 10/972,287 [*]
EXHIBIT 1143	Prosecution History of U.S. Patent Application No. 10/870,340 to Haug <i>et al.</i> [*]
EXHIBIT 1144	Prosecution History of U.S. Patent Application No. 12/269,213 to Haug <i>et al.</i> [*]
EXHIBIT 1145	<i>Edwards Lifesciences LLC v. Boston Sci. SciMed, Inc.</i> EWHC (Pat), Claim No. HC-2015-004574, Boston Scientific's Closing Arguments (Jan. 26, 2017)
EXHIBIT 1146	<i>Edwards Lifesciences LLC v. Boston Sci. SciMed, Inc.</i> EWHC (Pat), Claim No. HC-2015-004574, Day 7 Trial Transcript (Jan. 27, 2017)
EXHIBIT 1147	U.S. Patent No. 5,693,088 to Lazarus
EXHIBIT 1148	Edwards' EPO Opposition to EP 2 749 254 (Mar. 16, 2017)
EXHIBIT 1149	U.S. Patent Application Publication No. 2003/0093145 to Lawrence-Brown <i>et al.</i>
EXHIBIT 1150	Certified English Translation of WO 03/003949 to Seguin
EXHIBIT 1151	Third Party EPO Opposition to EP 2 749 254 (Sept. 2, 2015)
EXHIBIT 1152	Edwards' EPO Opposition to EP 2 926 766 (June 23, 2016)
EXHIBIT 1153	WO 03/003949 to Seguin
EXHIBIT 1154	<i>Edwards Lifesciences LLC v. Boston Sci. SciMed, Inc.</i> EWHC (Pat), Claim No. HC-2015-004574, EP 2 749 254 Patent Fig. 23 with Boston's Annotations (Jan. 27, 2017)

^{*}These prosecution history exhibits do not include copies of the foreign references filed during prosecution of the identified application, which are not relevant to the issues raised in this Petition.

I. OVERVIEW OF PETITION

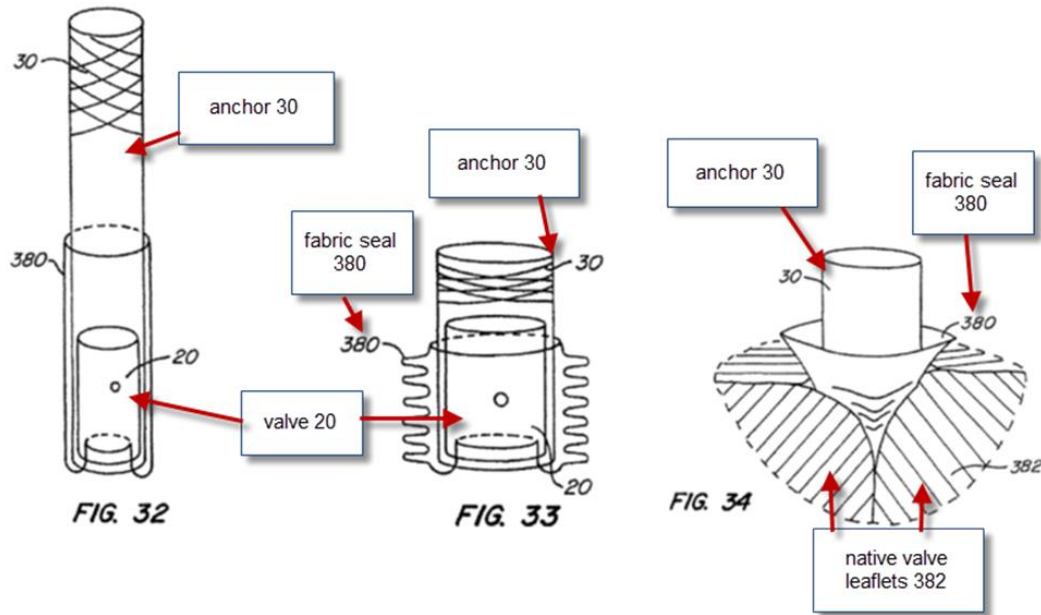
Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences AG (collectively, “Edwards”) respectfully request *inter partes* review of claims 1-9 of U.S. Patent No. 8,992,608 (“’608 Patent,” Ex. 1101) under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq.* This is Edwards’ second petition for *inter partes* review. Edwards’ first petition, IPR2017-00060, was instituted on claims 1-4 on March 29, 2017.

The ’608 Patent’s purported invention is directed to a collapsible and expandable prosthetic heart valve delivered via catheter (“transcatheter heart valve” or “THV”). Specifically, the ’608 Patent describes a THV implemented with a straightforward combination of 4 features already well-known in the art, including:

- a stent-based support structure (“anchor”);
- commissure support elements attached to the anchor;
- a replacement valve with commissure portions attached to the commissure support elements; and
- a fabric seal.

As pictured below, the fabric seal “extends from the distal end of the replacement valve and back proximally over the expandable anchor,” and has “flaps” and

“pockets” that purportedly prevent blood from flowing between the fabric seal and surrounding heart tissue (*i.e.*, paravalvular leak):

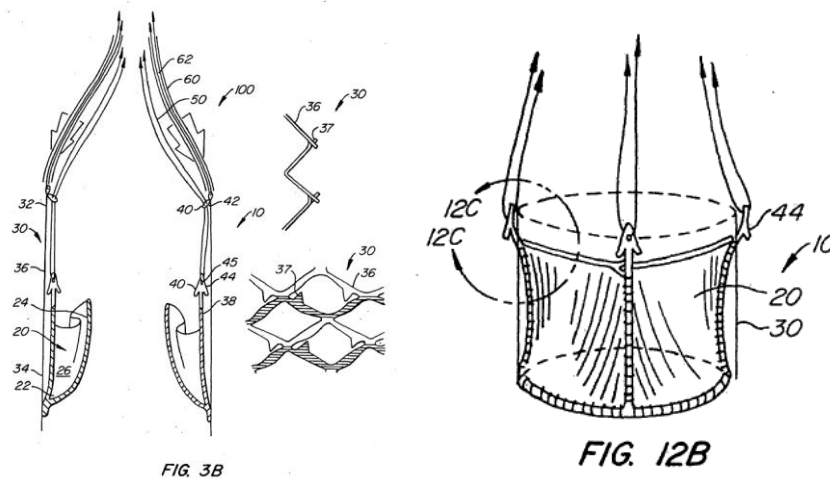


Ex. 1101 at 2:42-49, 14:21-29, Figs. 32-34. An element-by-element breakdown of Claims 1-9 is provided in the attached Appendix.

It is undisputed that THVs and this set of attributes—the anchor, fabric seal, commissure support elements attached to the anchor, and replacement valve commissure portions attached to the commissure support elements—were all well known before the '608 Patent's purported June 16, 2004 priority date. Indeed, even the claim limitation added to purportedly place the '608 Patent in condition for allowance—"the fabric seal extends from the distal end of the replacement valve and back proximally over the expandable anchor"—was a well-known feature adopted by numerous THV designs. As such, Claims 1-4 purport to claim

as Patent Owner's exclusive property a straightforward THV implementation that was, at minimum, obvious to any person of ordinary skill, and are accordingly unpatentable.

Moreover, the '608 Patent's claims cover both THVs with a plurality of "commissure support element[s]" and valve "commissure portion[s]," and THVs with only one "commissure support element" and one valve "commissure portion." But the grandparent application to which the '608 Patent claims priority (10/870,340 (Ex. 1143)) provides written description support only for the former (*i.e.*, plurality), thereby resulting in a break in the priority chain. As pictured below, the embodiments described in the grandparent application include a plurality of "posts 38" with commissure portions of a trileaflet valve attached thereto:

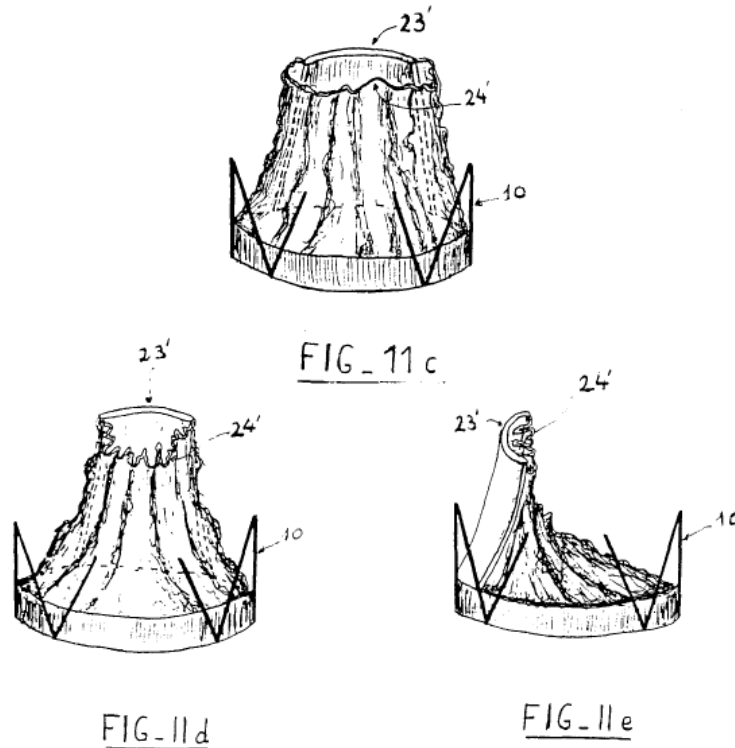


See, *e.g.*, Ex. 1143 at Figs. 3B (cross section of THV depicting two of three commissure support elements and two of three valve commissure portions), 12B

(three-dimensional representation of THV having three commissure support elements and three valve commissure portions); Ex. 1136 (Second Declaration of Dr. Nigel Buller), ¶ 41.¹ A valve with only a single commissure support element and a single valve commissure portion would require a completely different and unique design, which is neither described nor pictured in the grandparent application. Ex. 1136, ¶ 45. By way of example, other THV patents, including WO 1998/029057 (“Cribier,” Ex. 1103), include embodiments that, at a minimum, suggest to a person of ordinary skill in the art how a THV could be

¹ In support of this petition, Edwards submits the First Declaration (Ex. 1107) and Second Declaration (Ex. 1136) of Dr. Nigel Buller. The First Declaration is the same Declaration Dr. Buller submitted in support of IPR2017-00060. The Second Declaration adopts and incorporates Dr. Buller’s testimony from his First Declaration, and is intended to supplement Dr. Buller’s opinions for purposes of the instant petition. Moreover, Edwards resubmits all exhibits from its first petition (Exhibits 1001-1034, including Dr. Buller’s First Declaration at Ex. 1007), but has renumbered each of these Exhibits from 10XX to 11XX numbers in accordance with Patent Office practice for second petitions. All citations in Dr. Buller’s First Declaration to 10XX numbers are treated herein as made to the corresponding 11XX numbers. The remaining Exhibits (1135-1154, including Dr. Buller’s Second Declaration at Ex. 1136), are new.

designed with only a single commissure support element and valve commissure portion attached thereto:



See Ex. 1103 at Figs. 11c-e (detailing a valve structure with a semi-rigid part 24' akin to a commissure support element and a foldable part 23' that collapses into the semi-rigid part during diastole). Ex. 1136, ¶ 45. But there is nothing in the '608 Patent's grandparent application that contemplates or suggests in any way a single commissure support element design as suggested by Cribier or otherwise, and the '608 claims thus include a broader scope of invention than the grandparent application supports. *Id.*.

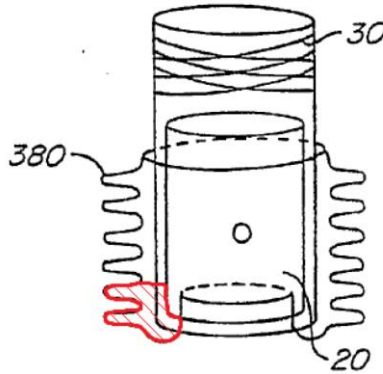
In view of this defect, the '608 Patent should only be afforded priority to the earliest disclosure of the full scope of its claims, which was lacking until at

least a November 24, 2008 preliminary claim amendment in its parent U.S. Application No. 12/269,213 (Ex. 1144). Claims 1-9 of the '608 Patent are therefore anticipated by earlier publications in its asserted priority chain, including the 2005 publication of the '608 Patent's grandparent application (Ex. 1135).

II. THE INSTANT PETITION IS DISTINCT FROM EDWARDS' FIRST IPR PETITION, AND SHOULD BE INSTITUTED

The instant Petition presents two new grounds of invalidity, neither of which is based on "substantially the same prior art or arguments previously ... presented to the Office." *See* 35 U.S.C. 325(d). Ground 1 presents a new ground of invalidity based on a break in the '608 Patent's priority chain, which results in the publication of the purported grandparent application becoming anticipatory prior art against each of Claims 1-9. This ground challenges five claims of the '608 Patent not previously raised in any prior petition (Claims 5-9), and because a challenge to these dependent claims necessarily requires addressing the substance of independent Claim 1, the inclusion of previously-challenged Claims 1-4 in this new ground does not add meaningfully to the burden on the Board or Patent Owner. Petitioner respectfully submits the interests of justice and efficiency are best served by reaching these significant questions together for all claims, and that for these reasons the Board should not exercise its § 325(d) discretion to deny institution in this regard.

Grounds 2 raises prior art and arguments different from those previously presented and rests on circumstances that have changed since the October 2016 filing of Edwards' first petition. This Ground is premised on claim construction positions asserted by Boston Scientific in a January 2017 trial in the United Kingdom involving a European counterpart patent to the '608 Patent. Despite the U.S. Patent Office's express conclusion during prosecution of the '608 Patent that the various embodiments of sealing structures described therein—*e.g.*, “sacs” (Figs. 15-16), “flaps and pockets” (Figs. 32-34), and “expandable foam” (Figs. 27-31)—are mutually exclusive (Ex. 1102 at 331-32), a position Boston Scientific conceded at the time by electing to prosecute “flaps and pockets” claims without traverse (*id.* at 337, 352), Boston Scientific now argues to the contrary. Boston's new position is that “flaps and pockets” and “sacs” are not mutually exclusive, and that embodiments described in the patent have both. *See* Ex. 1145, ¶ 137; Ex. 1146 at 1067:8-10 (“[Y]ou can be within both patents, or you can be in the bunched-up and not the sac, or the sac and not the bunched up.”). Boston illustrated this new claim interpretation as follows (red highlighting added by Boston):



See Ex. 1146 ((Transcript, Day 7) at 1063-65 (arguing that the above figure is the “epitome of bunching-up” in the form of flaps and pockets, but suggesting that it also includes a “sac” (in red)). If Boston’s disclosed sealing structures are not mutually exclusive (as Boston now argues), it logically follows that “sac” related prior art is now available for consideration with respect to Boston’s “flaps and pockets” claims. One such example is WO 03/003949 (“Seguin,” Ex 1150²), which describes seals that comprise sac-type “peripheral inflatable chambers,” and which now must be considered in the context of the ’608 Patent’s “flaps and pockets” claims. Seguin is the primary reference in Ground 2.

² Exhibit 1150 is a certified English translation of WO 03/003949, which was originally published in French. The original French version is separately provided at Exhibit 1153. All citations herein to WO 03/003949 are to the certified English translation.

In sum, the two new grounds of invalidity are not redundant of any grounds presented in Edwards’ first petition, they include additional claims of the ’608 Patent beyond those identified in the first petition, they are based on different prior art, and they rest on circumstances that did not exist at the time of Edwards’ first petition in October 2016. Edwards therefore respectfully submits that, notwithstanding the provisions of § 325(d), the circumstances here warrant institution of these additional grounds and, as requested in Edwards’ Motion for Joinder filed concurrently herewith, resolution of these serious new questions of validity together with the instituted grounds in Edwards first petition, IPR2017-00060.

III. STATE OF THE ART AT THE TIME OF THE INVENTION

The primary features of the THV described and claimed by the ’608 Patent—the stent (*i.e.*, “anchor”), fabric seal, commissure support elements attached to the anchor, and replacement valve with commissure portions attached to the commissure support elements—were each well-known attributes in the art as of June 2004, and regularly employed by practitioners in THV technology. Ex. 1107, ¶¶ 40-46, 52-87; Ex. 1136, ¶¶ 26-31, 33-36.

Notably, in 1994—10 years prior to the purported priority date of the ’608 Patent—Steven Bailey published a chapter in *The Textbook of Interventional Cardiology* titled *Percutaneous Expandable Prosthetic Valves*, recognizing the

early THV work of Dr. Henning Andersen as “[t]he most exciting published work in this area to date.” Ex. 1137 at 1276; *see also* Ex. 1118 (U.S. Patent No. 5,411,552 (“Andersen”)); Ex. 1117 (Andersen European Heart Journal publication). Bailey also recognized, however, that in 1994 “[c]urrent mechanical and prosthetic valves suffer from a number of problems . . . including the predisposition to thrombus formation and embolization, *perivalvular leak*, infection, difficulty sizing valve to annulus, valve degeneration, and pannus formation. The designer of any percutaneously placed valve will need to consider these issues during its design and development in order to minimize these problems.” Ex. 1137 at 1271 (emphasis added).

The Textbook design considerations in this 1994 reference are reflected in the THV claimed by the ’608 Patent, but the fifteen years between the work of Dr. Andersen and the filing of the ’608 Patent’s purported priority application had already yielded numerous THV design improvements that addressed these considerations and became state of the art well before any ’608 priority date. Ex. 1107, ¶¶ 58-69, 74-87; Ex. 1136, ¶¶ 27-31, 35-36. For example, stent designs that were better sized for the target annulus and that reduced the risk of embolization, valve designs and valve support structures that reduced the risk of valve degeneration, and external sealing structures that reduced the risk of paravalvular leak were each known prior to any claimed priority date of the ’608 Patent. *See*,

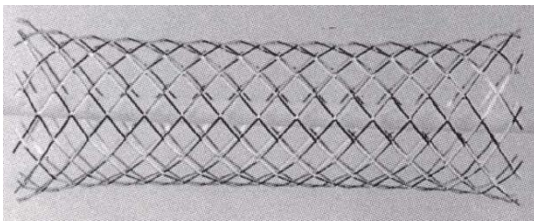
e.g., Ex. 1103 (WO 98/29057 (“Cribier”)), Ex. 1104 (WO 03/047468 (“Spenser”)), Ex. 1150 (Seguin), Ex. 1109 (U.S. Patent App. Pub. No. 2001/0039450 (“Pavcnik”)), Ex. 1120 (U.S. Patent App. Pub. No. 2001/0021872 (“Bailey”)),³ Ex. 1133 (U.S. Patent No. 5,855,601 (“Bessler”)). Because prior to June 2004 these features were among the already well-understood implementation choices for any THV and, as detailed herein, would have been known by a person of skill to be predictably, beneficially, and straightforwardly applied together in the combinations claimed by Patent Owner, the Claims are unpatentable as obvious. Ex. 1107, ¶¶ 51, 75-87, 106, 109-12; Ex. 1136, ¶¶ 23-24, 36.

A. Stent Structures Were Well Known as of June 2004

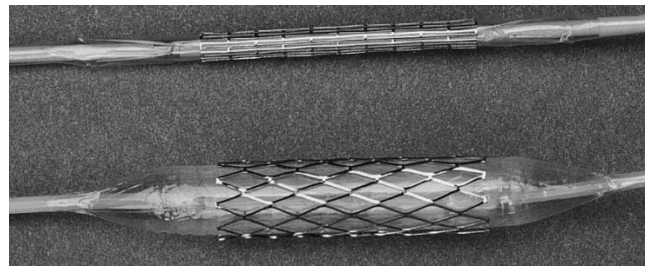
Stents trace their roots to the 1969 work of Charles Dotter, which involved implantation of stainless steel coils in an animal model. Ex. 1107, ¶¶ 41-43. A multitude of stent designs have been developed since, with millions implanted in patients. Ex. 1107, ¶¶ 44-46. By 2004, stents were commonly used in interventional procedures to provide a scaffold capable of holding open a diseased vessel. Ex. 1107, ¶¶ 40-46. Stents were implanted—and still are implanted—bare, with a covering (including stent grafts and coated stents), or as a support structure

³ The named co-inventor on U.S. Patent App. Pub. No. 2001/0021872, Steven Bailey, is the same Steven Bailey that authored the THV chapter in the Textbook of Interventional Cardiology discussed above. *See* Ex. 1137.

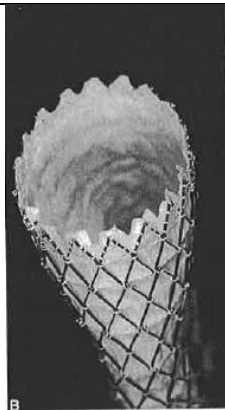
for a valve. *See, e.g.*, Ex. 1107, ¶¶ 45-46, 52-69, 71-87; Ex. 1136, ¶¶ 27-31, 36. In each case, stents are generally made of a metallic material, *e.g.*, stainless steel or nickel-titanium (Nitinol), and generally designed to be self-expanding or plastically deformable. Ex. 1107, ¶¶ 41, 43, 46. As seen below, depending on the desired end use, the same stent designs have been used for bare stents, coated stents, stent grafts, and transcatheter valves, sometimes modified to match the anatomy in which they are implanted:



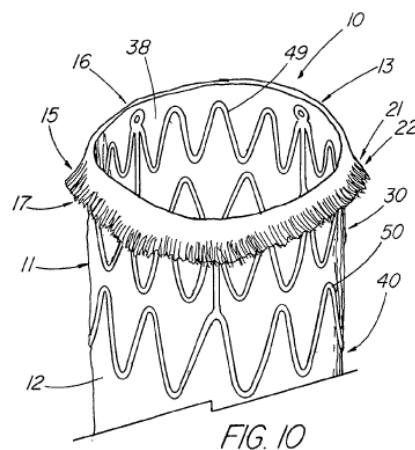
Wallstent (Ex. 1107, ¶¶ 42, 45)



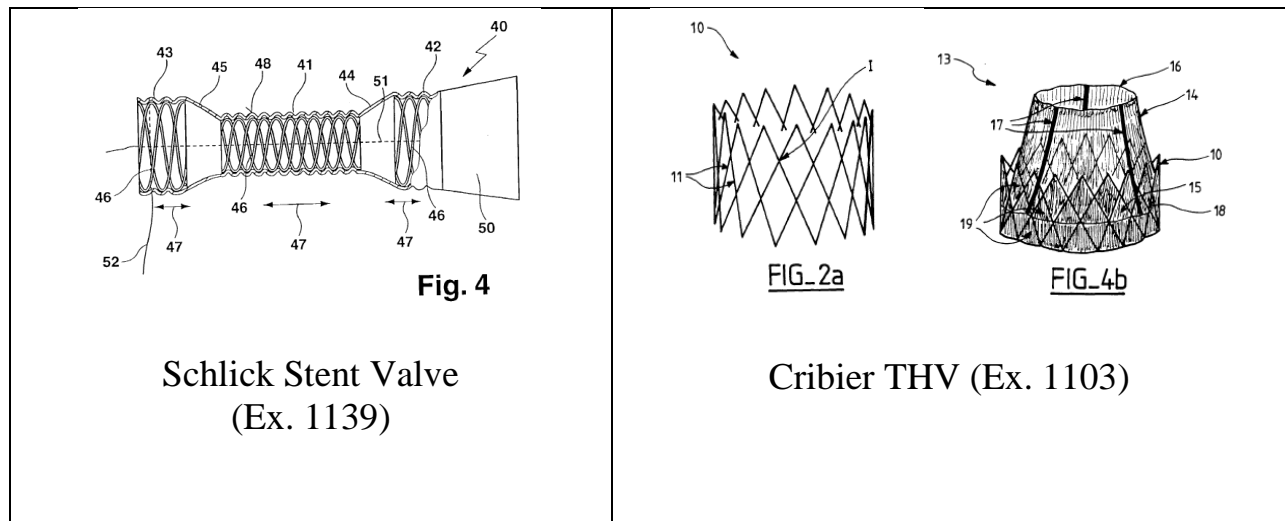
Palmaz Stent (Ex. 1107, ¶ 46)



AneuRX Stent Graft (Ex. 1116)

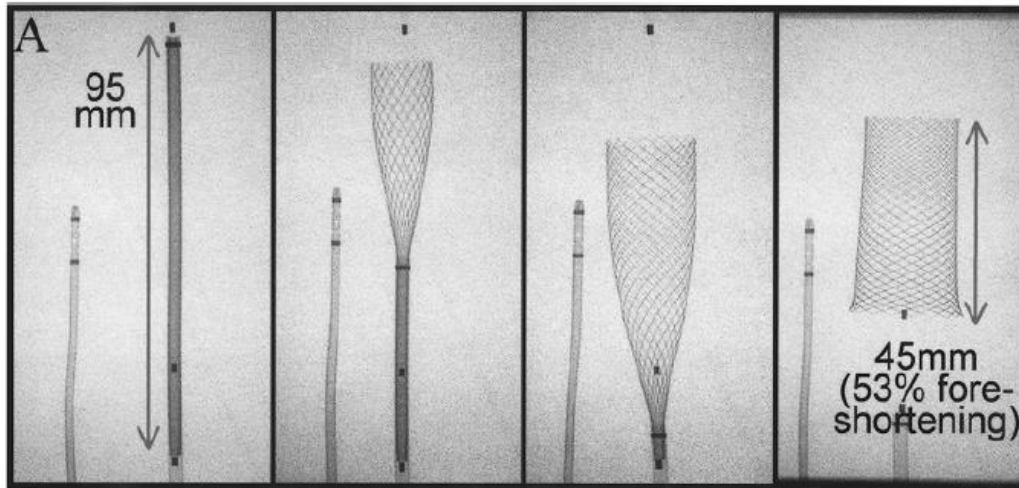


Cook Stent Graft (Ex. 1134)



A known property for both self-expanding and plastically deformable stents is foreshortening, the extent of which depends on the overall stent design. Ex. 1107, ¶¶ 47-51, 67-68; Ex. 1136, ¶¶ 21-24. A stent that foreshortens is a stent whose length decreases as the diameter of the stent increases, and vice versa. Prior to June 16, 2004, it was well known to those of ordinary skill in the art that stents could be designed to substantially foreshorten, not foreshorten at all, or actually lengthen upon radial expansion. Ex. 1107, ¶ 49.

For example, a design of a commercial braided-wire Wallstent has been shown to foreshorten by 53%:



Ex. 1107, ¶ 50 (citing Ex. 1113 (Ing publication)); *see also* Ex. 1139 (U.S. Patent No. 7,731,742 (“Schlick”)) at 4:30-51 (“the stent 40 can be lengthened in the direction of arrows 47 and subsequently be expanded in a radial direction and shortened in a longitudinal direction”); Ex. 1136, ¶¶ 21-24.

THV stent designs incorporating diamond-like stent patterns naturally exhibit a degree of foreshortening. Ex. 1136, ¶¶ 23-24. Seguin, for example, teaches that a diamond-shaped cell is elongated when compressed, and foreshortens when deployed:

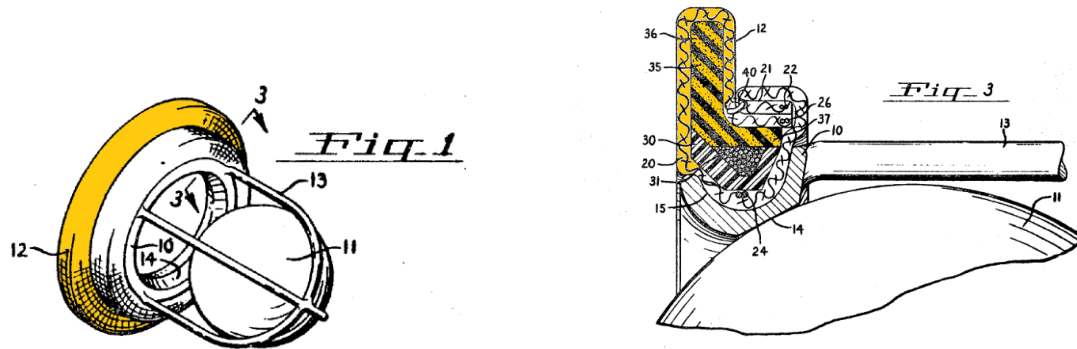


Ex. 1150, Figs. 5, 7 & at 6 (“Figure 5 is a view of another detail of the stent, on an enlarged scale, in a state of non-expansion of the stent” & “Figure 7 is a view

similar to Figure 5, in a state of expansion of the stent”); *see also* Ex. 1103 (Cribier WO ’057) at 16:11-16 (disclosing a stent with an expanded length of 10mm and a collapsed length of 20 mm (*i.e.*, 50% foreshortening)); Ex. 1120 (Bailey) at ¶ [0021] (disclosing laser-cut diamond-cell and woven-wire stent structures); Ex. 1136, ¶ 22. As explained by Seguin, “[t]he material from which the stent 2 is made is such that these meshes can pass from a contracted configuration, in which the filaments are near one another, giving the meshes an elongated shape, to an expanded configuration, shown in Figure 1 and in detail in Figure 7, in which the filaments are spaced apart from one another.” Ex. 1150 at 7.

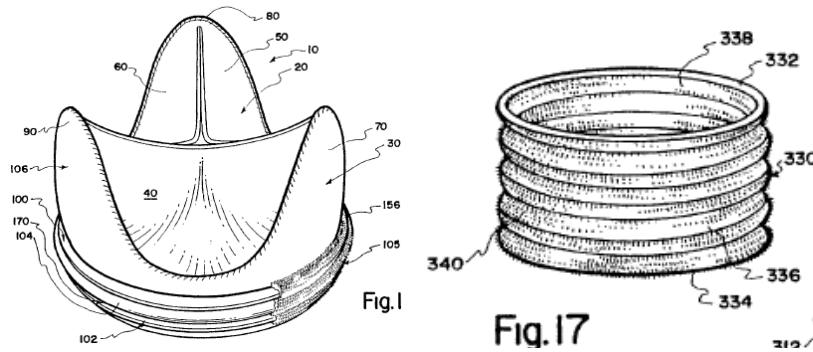
B. Fabric Seals for Use with THVs Were Well Known as of June 2004

The concept of providing an external sealing structure on a replacement heart valve to address leakage and other concerns is far from new, as it too traces its roots to the 1960s. Ex. 1107, ¶¶ 38-39. One of Petitioner Edwards’ first commercially available prostheses was a surgically implantable ball-and-cage valve known as the Starr-Edwards valve, described in U.S. Patent No. 3,365,728 (Ex. 1111, “Starr-Edwards”). This early valve prosthesis included a circumferentially oriented sewing ring that was adapted to extend into spaces in the tissue surrounding the implanted prosthesis to prevent paravalvular leaking:



See Ex. 1111, '728 Patent at 1:38-46 and 3:12-20 (“[R]ubber cushion ring 35 conforms to any irregularities of tissue contour which may exist because of disease or other causes and forms an effective seal against the tissue.”), Figs. 1, 3 (highlighting added); Ex. 1107, ¶ 38.

Surgically implantable biologic valves were similarly known to include external sealing structures. For example, U.S. Patent No. 5,469,868 (“Reger”) (Ex. 1138) details use of an external sealing structure with circumferential ridges in the form of sewing rings (100, 102) and an “interfacing portion 104,” all covered by a fabric “brim cover 105” “made from a material which is permissive to tissue in-growth so that a degree of adhesion improves adhesion of the grafted valve within the native excised valve orifice”:

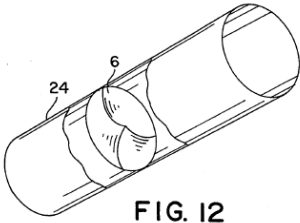
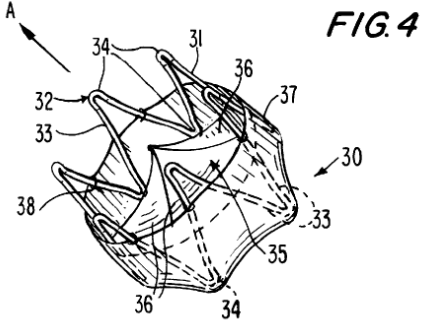
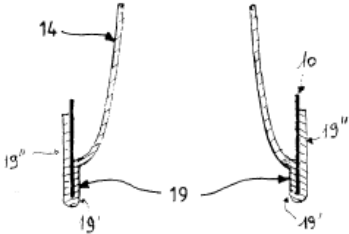
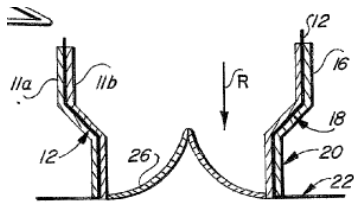


Ex. 1138 at Figs. 1, 17 (“each brim cover 105 and 286 is formed from a hollow cylinder 330”) and 10:26-58, 16:19-31; Ex. 1136, ¶ 18. The “interfacing portion 104 . . . is compressible, but . . . comprises memory which responsively expands to fill space previously vacated and unfilled by the remainder of stent 30 when compressive pressures are relieved.” *Id.* at 10:26-31.

A person of ordinary skill in the art designing a THV would have been aware of surgical prosthetic heart valves and the known sealing structures adopted to conform to and fill spaces in the surrounding tissue, and would have recognized the desirability of adopting sealing structures in THV designs that could similarly minimize the risk of paravalvular leak. Ex. 1136, ¶¶ 26, 35, 96.

Because, since the advent of prosthetic valve technology, it was well known to incorporate sealing structures to seal valve prostheses against the surrounding tissue, it is of no surprise that even the earliest THV designs included fabric seals. Ex. 1107, ¶¶ 38-39; Ex. 1136, ¶¶ 18-19. There are multiple examples of THVs with fabric seals that predate June 2004—including fabric seals extending from the

distal end of the valve portion and back proximally over the stent—some of which are pictured below. Ex. 1107, *e.g.*, ¶¶ 52-69, 80, 83, 86; Ex. 1136, ¶¶ 25-31.

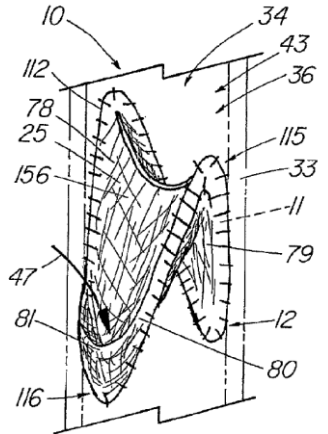
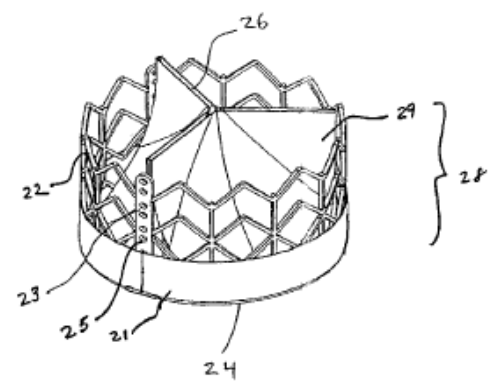
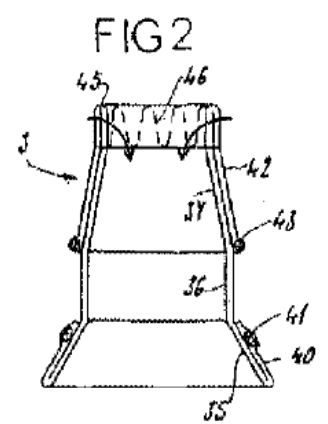
 <p>FIG. 12</p> <p>Ex. 1118 (Andersen) at Fig. 12 (“tubular means 24”)⁴</p>	 <p>FIG. 4</p> <p>Ex. 1133 (Bessler) at Fig. 4 (“cuff portion 37”)⁵</p>
 <p>FIG. 6d</p> <p>Ex. 1103 (Cribier) at Fig. 6d (“cover” 19’ and 19”)⁶</p>	 <p>Fig. 4</p> <p>Ex. 1120 (Bailey) at Fig. 4 (“graft member” 11a/11b)⁷</p>

⁴ See also Ex. 1118 at 7:17-29.

⁵ Bessler published studies related to this THV design. See Ex. 1141 (Moazami et al. Publication); see also Ex. 1133 at Fig. 1 and 5:15-51.

⁶ See also Ex. 1103 at Fig. 4b and 5:6-10, 5:17-18, 8:28-9:6, 20:26-21:3, 22:11-26.

⁷ See also Ex. 1120 at Figs. 2, 4, 20A-I and ¶¶ [0002], [0021]-[0023], [0048]-[0052], [0056].

 <p>FIG. 27</p> <p>Ex. 1109 (Pavcnik) at Fig. 27 (“corner flaps 81”)⁸</p>	 <p>Ex. 1104 (Spenser) at Fig. 1 (“cuff portion 21”)⁹</p>
 <p>FIG. 2</p> <p>Ex. 1150 (Seguin) at Fig. 2 (“flaps” 40/42, including “inflatable peripheral chambers” 41/43)¹⁰</p>	

It is also of no surprise that the importance of preventing blood from leaking between vascular prostheses and surrounding tissue led to further designs to

⁸ See also Ex. 1109 at ¶¶ [0006], [0067]-[0068], [0074].

⁹ See also Ex. 1104 at pp. 21-22, 25, 33-35.

¹⁰ See also Ex. 1150 at Figs. 3, 9 & at 1, 2, 5, 6, 8, 9, 10, & Claims 15-16.

improve the seal. These too were well known prior to June 2004. *See, e.g.*, Ex. 1106 (U.S. Patent App. Pub. No. 2004/0082989 (“Cook”)), Ex. 1147 (U.S. Patent No. 5,693,088 (“Lazarus”)), Ex. 1149 (U.S. Patent App. Pub. No. 2003/0093145 (“Lawrence-Brown”)), Ex. 1119 (U.S. Patent No. 6,015,431 (“Thornton”)), Ex. 1134 (U.S. Patent No. 5,476,506 (“Lunn”)), Ex. 1139 (Schlick). A person of skill at the time would have recognized that any of the enhanced sealing structures detailed below could readily be adopted in THV designs to further reduce the risk of paravalvular leaks. Ex. 1107, ¶¶ 19-69; Ex. 1136, ¶¶ 25-31.

a. Lazarus (1993)

Lazarus discloses a stent graft with an external seal enhanced by peripheral inflatable chambers:

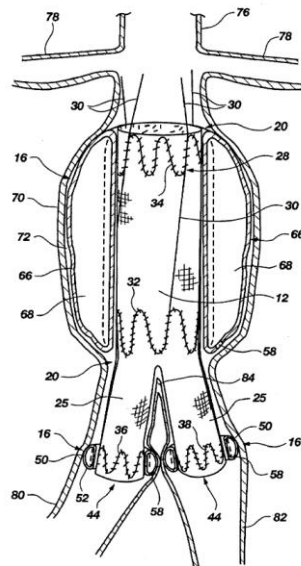
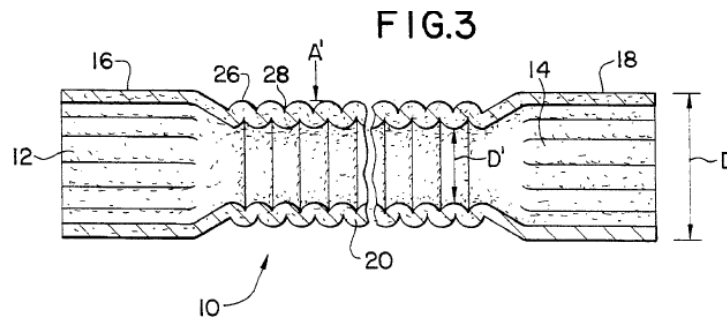


Fig. 5

Ex. 1147 at Fig. 5 (“toroidal collars 50”). These chambers can be closed such that a filling material is used to fill the chambers, or fenestrations can be formed in the walls of the inflatable chambers, which allow the flow of blood to inflate the chambers. Ex. 1147 at 15:5-14. The graft “is designed to mold and adhere to calcification within the vessel and to heal to irregular aortic surfaces,” such that the toroidal collar “adjust[s] to the unique internal dimension or shape of the vessel.” *Id.* at 6:39-58, 10:5-8; Ex. 1136, ¶¶ 27-28.

b. Lunn (1994)

Lunn discloses an external graft having flaps and pockets in the form of “ridges 26” and “troughs 28”:

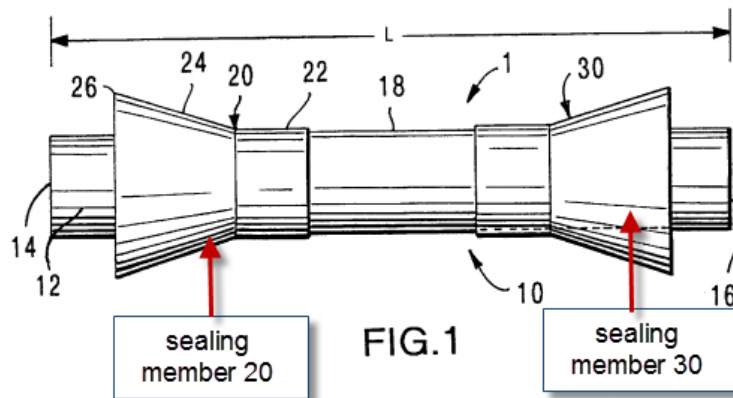


Ex. 1134 at Fig. 3 and 3:48-56. The Patent Office previously identified this graft structure as having “pleats” and concluded that the teachings of Lunn are readily combined with THV technology to arrive at a THV with a “pleated” fabric seal as was claimed by the Patent Owner in related U.S. Patent Application No.

10/972,287 (the “’287 Application”). *See* Ex. 1142 at 366-67 (3/5/09 Final Rejection at 4-5).¹¹

c. Thornton (1996)

Thornton discloses sealing structures with unattached ends that form flanges that occlude blood flow:

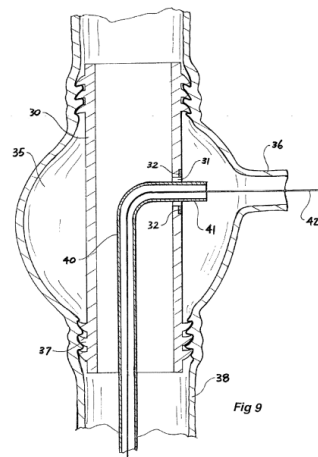
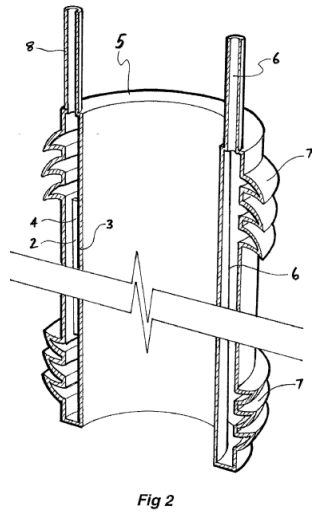


Ex. 1119 at Fig. 1 (annotations added) and 4:6-13, 7:5-9, 7:20-42, 8:31-54, 8:65-67; Ex. 1107, ¶¶ 63-64.

d. Lawrence-Brown (2001)

Lawrence-Brown discloses another sealing structure with a peripheral inflatable chamber:

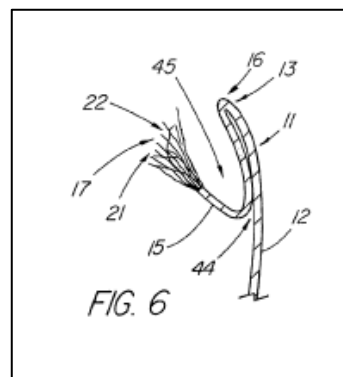
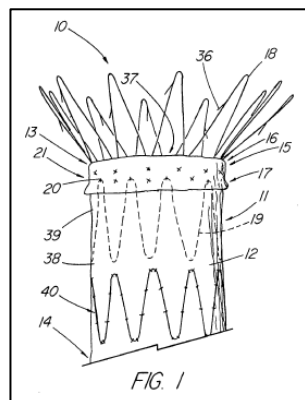
¹¹ Boston Scientific cancelled its claim in the ’287 Application directed at a “pleated” fabric seal to obviate this rejection. Ex. 1142 at 416 (5/5/09 Amendment After Final and Request for Reconsideration at 6).



Ex. 1149 at ¶ [0068], Figs. 2 (“annular flanges or ridges 7”), 9. “In use these annular flanges, when inflated, engage against the walls of the body lumen to provide a seal so that blood flow will not occur on the outside of the graft.” *Id.*; Ex. 1136, ¶ 30.

e. Cook (2002)

Cook discloses a stent graft having a “cuff portion [15] compris[ing] an external sealing zone that extends around the main body portion to help prevent leakage”:



Ex. 1106 at Figs. 1, 6 and Abstract, ¶ [0004]; Ex. 1107, ¶ 66. Cook explains that the cuff portion can be formed with at least one “free edge 17” that is “unattached to the main body 12 so that it is allowed to extend or flair outward to comprise a lip that serves as an external sealing zone 21.” *Id.* at ¶ [0026]. Cook also discloses that the cuff portion could be folded over “to produce a fold 44 that creates gutter-like pocket 45 that is able to collect any blood passing around the leading edge 16 of the graft 11 to prevent an endoleak and promote thrombus formation.” Ex. 1106 at [0036].

f. Schlick (2003)

Finally, Schlick details a stent graft that is capable of supporting a valve structure. Ex. 1139 at 4:30-51 (detailing an embodiment in which a “foil valve” can be incorporated in the stent graft structure).¹² Regardless of its ultimate application, the stent graft described by Schlick includes an external seal (*i.e.*, “elastic tubular section”) that, upon foreshortening (*i.e.*, “the stent 40 can be lengthened in the direction of arrows 47 and subsequently be expanded in a radial

¹² Like Schlick, the Pavcnik Patent also details the interchangeability of THV and stent graft technology. *See, e.g.*, Ex. 1109 (Pavcnik), ¶ [0012] (detailing that, depending on the desired end use, the disclosed device could be used as either a stent graft or a THV).

direction and shortened in a longitudinal direction”), has a “surface contour” in the form of flaps and pockets:

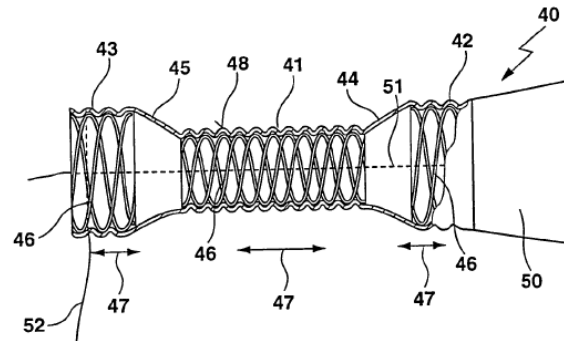


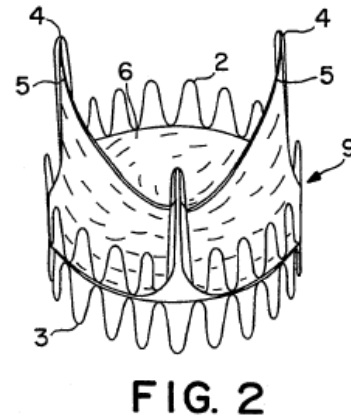
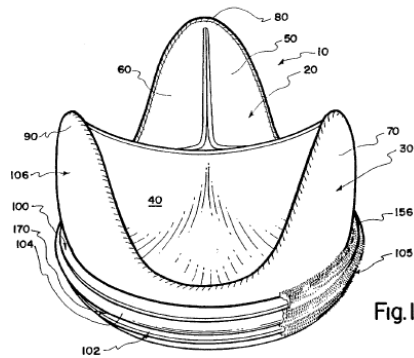
Fig. 4

See id. and Fig. 4; Ex. 1136, ¶ 31. The external seal “can adjust to the surface contour in a hollow organ without forming gaps.” *Id.* at 3:58-4:3.

C. Commissure Supports and Valves Attached Thereto Were Well Known in THV Designs as of June 2004

The remaining two features of the THV claimed in the ’608 Patent—commissure support elements attached to the stent and a replacement valve with commissure portions attached to the commissure support elements—were also well known as of June 2004.

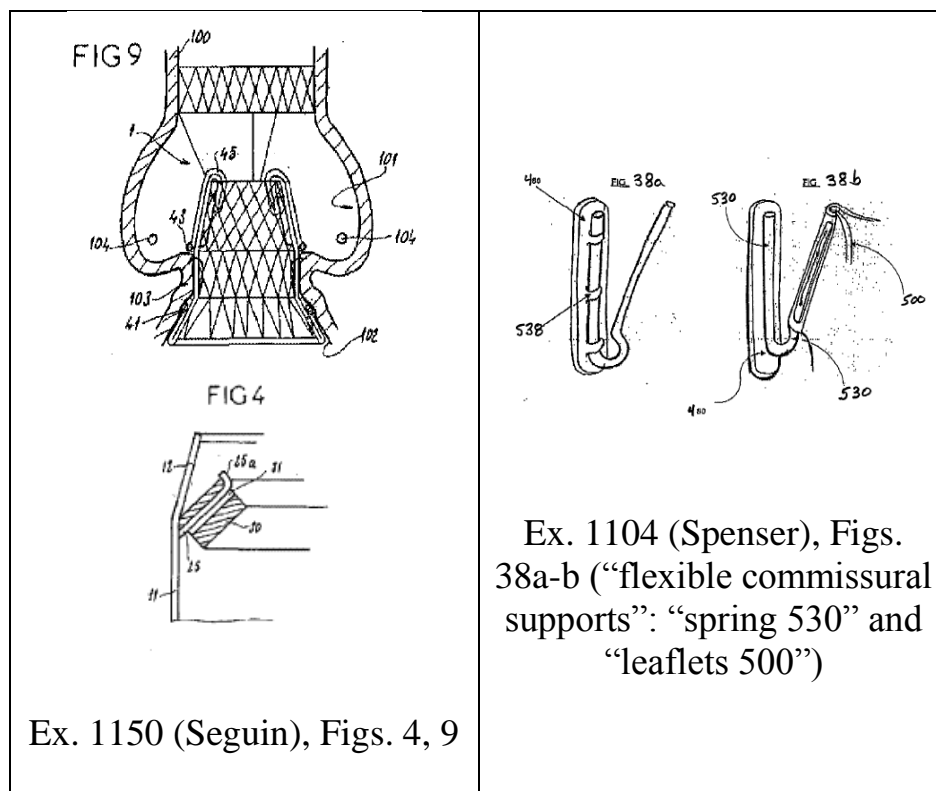
As with fabric seals, surgical valve prostheses also provided the initial designs of the commissure support structures in THVs:



Compare Ex. 1138 (Reger) at Fig. 1 *with* Ex. 1118 (Andersen) at Fig. 2. As explained, *e.g.*, by Reger, the purpose of this design is to secure the commissures of a trileaflet valve to a structure that “substitutes for natural supporting structure in the native orifice” and to “provide reliable structure where flexing and wear is the greatest in [the] heart valve leaflet apparatus” Ex. 1138 at 11:53-12:8; *see also* Ex. 1118 at 5:9-28 (“Three loops 4 are 14 mm in height and are intended to secure the commissural points 5 . . . from a biological cardiac valve 6 which is mounted in the stent 1.”); Ex. 1107, ¶ 71-73; Ex. 1136, ¶ 18-19. As detailed by Andersen, the “commissural supports project[] from one side of the cylindrical support means” and are depicted as integral portions of the stent structure. Ex. 1118 at 8:9-19 & Fig. 2.

Several THV designs that followed the early work of Andersen modified the commissure support structure such that commissure supports became separate elements that were attached to the surrounding stent while providing a structure for

attaching commissure portions of a valve thereto. Examples of these commissure support elements and associated valves are provided below.



Spenser notes, for example, that “[i]f a spring is added to the structure, the spring will bear the highest portion of the impact, thus reducing the stress applied to the leaflets during the time the valve is closed.” Ex. 1104 at p. 41. The “arms” of Seguin allow the valve to be suspended within the stent such that the commissures of the valve are supported by the arms rather than by way of direct attachment to the stent. Ex. 1150 at 1, 3. This allows the valve and frame to expand to different degrees, which ensures proper coaption of the valve leaflets and improved compliance of the THV with the surrounding anatomy. *See, e.g.*, Ex. 1150 at 5, 8-9 (“The portion 12 additionally comprises a series of internal arms 25 These

arms 25 are inclined toward the inside of the portion 12 before placement of the valve 4 on the stent 2, and Figure 4 shows that in this position they can receive the valve 4.”), 11 & Figs. 2, 3, 9, 14; Ex. 1136, ¶ 82.

IV. MANDATORY NOTICES PURSUANT TO 37 C.F.R. § 42.8(A)(1)

A. Real Party-In-Interest—37 C.F.R. § 42.8(b)(1)

Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences AG are the real parties-in-interest.

B. Related Matters—37 C.F.R. § 42.8(b)(2)

As discussed above, Edwards filed a first IPR, IPR2017-00060, which was instituted as to Grounds 7-9 on March 29, 2017.

The '608 Patent has also been asserted in the pending litigation captioned *Boston Scientific Corp. v. Edwards Lifesciences Corp.*, C.A. No. 16-275 (SLR).

Further, there is at least one pending U.S. patent application, serial number 14/873,462, that claims priority to the '608 Patent.

C. Lead and Back-Up Counsel—37 C.F.R. § 42.8(b)(3) and 42.10(a)

Edwards designates the following:

Lead Counsel	Back-Up Counsel
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Telephone: 949-623-7200 Facsimile: 949-623-7201	Email: began@MNAT.com Telephone: 302-351-9454 Facsimile: 302-498-6216 Catherine Nyarady (Reg. No. 42,042) Paul, Weiss, Rifkind, Wharton & Garrison LLP 1285 Avenue of the Americas New York, NY 10019 Email: cnyarady@paulweiss.com Telephone: 212-373-3532 Facsimile: 212-492-0532
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D. Service Information—37 C.F.R. § 42.8(b)(4)

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

V. REQUIREMENTS FOR *INTER PARTES* REVIEW

As set forth below and pursuant to 37 C.F.R. § 42.104, each requirement for *inter partes* review of the '608 Patent is satisfied.

A. Grounds for Standing—37 C.F.R. § 42.104(a)

Edwards certifies that the '608 Patent is available for *inter partes* review and that Edwards is not barred or estopped from requesting *inter partes* review challenging Claims 1-9 of the '608 Patent on the grounds identified herein.

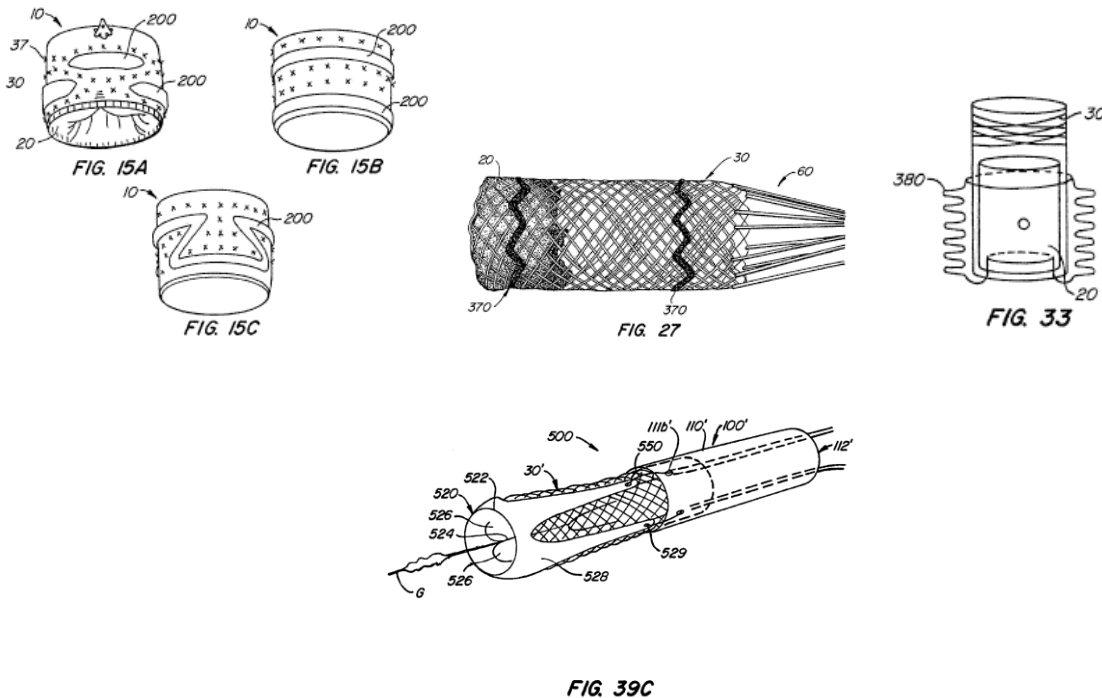
B. Identification of Challenge—37 C.F.R. § 42.104(b)(1)-(5)

Edwards requests IPR and cancellation of claims 1-9 of the '608 Patent as set forth below in Section VIII.

VI. SUMMARY OF THE '608 PATENT

A. The '608 Patent's Claimed Invention

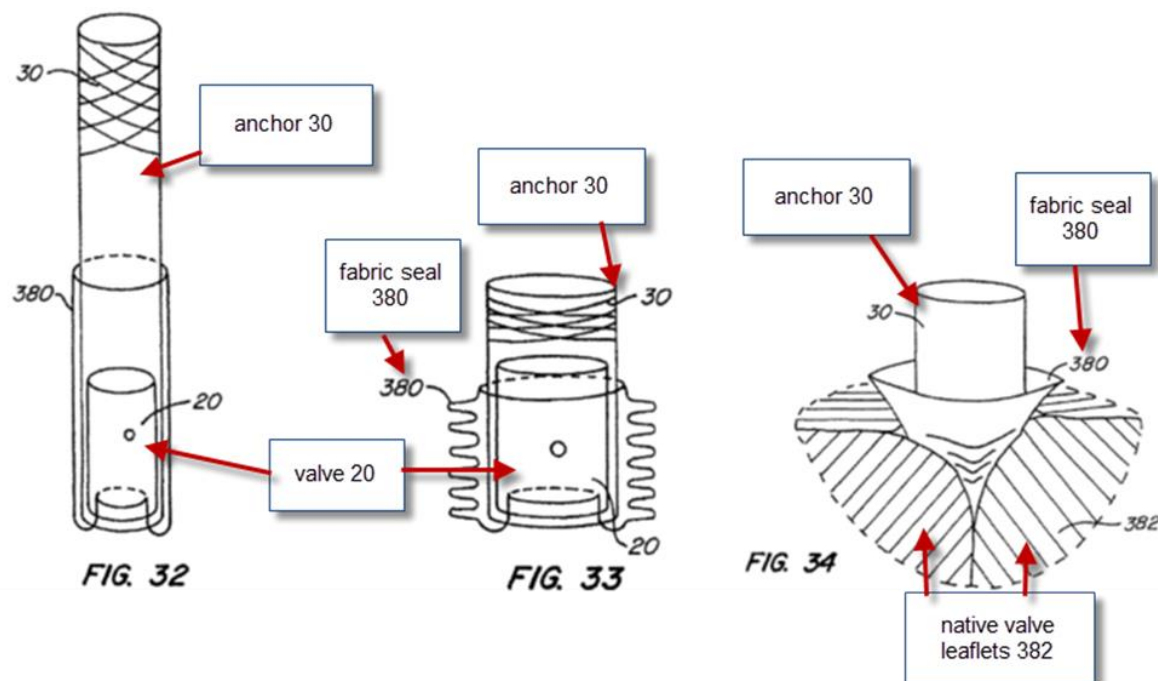
The '608 Patent describes a series of distinct THV embodiments throughout the specification, including several mutually exclusive sealing mechanisms, pictured below:



For example, Figures 14-16 illustrate seals in the form of inflatable peripheral chambers referred to as “sacs” (element 200, top left); Figures 27-31 detail a “Nitinol wire surrounded by an expandable foam” (element 370, top middle), Figures 32-34 detail a fabric seal that bunches up to form circumferential “flaps and pockets” (fabric seal 380, top right), and Figures 39-44 detail a replacement

valve with an everting segment (valve 520 and everting segment 528, bottom middle).

It is the “flaps and pockets” embodiment shown in Figures 32-34 that the ’608 Patent ultimately claimed as its invention. As claimed, the THV includes a collapsible and expandable anchor, a commissure support element, and a commissure portion of a replacement valve leaflet attached to the commissure support element. Ex. 1101 at Claim 1; *see also id.* at 3:5-12, 5:60-63, 16:63-65, 21:19-24. The THV also includes a fabric seal that “extends from the distal end of the replacement valve and back proximally over the expandable anchor.” *Id.* at Claim 1. And the fabric seal has “flaps” and “pockets” that “extend into spaces formed by the native valve leaflets.” *Id.* The “flaps” and “pockets” are purportedly shown (but not explicitly identified) in Figures 33 and 34:



Id. at Figs. 32-34 (annotations added).

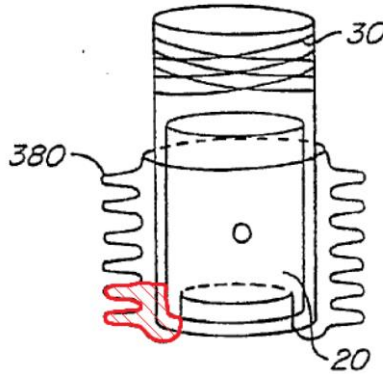
Of note, during prosecution of the '608 Patent, the Patent Office issued a restriction requirement when the “flaps” and “pockets” claims were first added by way of amendment. Ex. 1102 at 229-30, 331-32. At the time, other claim amendments were directed at a THV seal having “sacs,” and a THV seal having “expandable foam.” *Id.* at 229-30. In its restriction requirement, the Patent Office provided that a seal having “flaps” and “pockets” is mutually exclusive from a seal having “sacs” or “expandable foam.” *See* Ex. 1102 at 331-32 (10/30/13 Restriction Requirement) (sealing structures with “expandable foam,” “sacs,” and “flaps” are “species [that] are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current records.”). In response, the Patent Owner elected *without traverse* the “flaps” and “pockets” claims that ultimately led to the '608 Patent. *Id.* at 337, 352.

B. Boston Scientific Has Recently Taken the Position that Seals with “Sacs” Are Not Mutually Exclusive from Seals with “Flaps” and “Pockets”

Despite the '608 Patent's acknowledgement that the claimed “flaps” and “pockets” embodiment is “another way to seal the replacement valve against leakage,” and the Patent Office's recognition that the “flaps” and “pockets” embodiment is mutually exclusive from other disclosed sealing structures,

including “sacs,” Boston Scientific has taken a contrary position since the filing of Edwards’ first IPR petition.

In January 2017, Boston Scientific and Edwards were involved in a trial in the UK regarding the validity and infringement of EP 2 749 254 (“EP 254,” Ex. 1122) and EP 2 926 766 (“EP 766,” Ex. 1130), which are European counterparts of the ’608 Patent, and include identical disclosures related to both the “flaps” and “pockets” embodiment and the “sacs” embodiment in the ’608 Patent. In fact, EP 254 has claims directed at “flaps” and “pockets,” *see, e.g.*, Ex. 1122 at Claim 2, and EP 766 has claims directed at “sacs,” *see, e.g.*, Ex. 1130 at Claim 1. During trial, Boston Scientific took the position that its disclosed embodiments of a seal that bunches up to create flaps and pockets and a seal comprised of a sac are not mutually exclusive, and that bunched-up fabric that forms flaps and pockets can read on a sac (and vice versa). *See* Ex. 1145 (Boston’s Closing Arguments) at ¶¶ 137-38 (*e.g.*, “[I]t is difficult to draw any clear-water between a ‘pocket’ and a ‘sac.’”); Ex. 1146 (Transcript, Day 7) at 1063-65 (explaining that the “bunched up” fabric could also be read as “sacs”). Boston Scientific created the below drawing, which it used in its closing arguments, to argue that a “sac,” drawn onto the figure in red by Boston, is not mutually exclusive from “flaps” and “pockets”:



See Ex. 1146 ((Transcript, Day 7) at 1063-64 (arguing that the above figure is the “epitome of bunching-up,” but suggesting that it also includes a “sac”).

Merits of Boston Scientific’s argument aside, Boston’s new argument about the meaning of these claim limitations means, *inter alia*, that Boston cannot now argue that seals comprising “sacs” are outside the broadest reasonable interpretation of “flaps” and “pockets” in the challenged claims, notwithstanding the Patent Office’s prior conclusion that “sacs” are mutually exclusive from “flaps” and “pockets,” and thus for purposes of proceedings before the Board prior art that is directed at seals comprising sacs in the form of peripheral inflatable chambers now must be considered to determine whether such structures read on claims directed at “flaps” and “pockets.” One example of such a structure is provided in the Seguin patent (Ex. 1150), which includes a folded-over fabric seal with peripheral inflatable chambers that now must be considered in the context of the

'608 Patent's "flaps" and "pockets" claims.¹³ Thus, as a result of the statements made by Boston Scientific in January 2017, Edwards now presents as Ground 2 in this petition an argument that Claims 1-4 of the '608 Patent are invalid in view of

¹³ Edwards has separately instituted oppositions of EP 254 and EP 766 in the European Patent Office. *See* Exs. 1148 & 1152. There, Seguin has been identified by Edwards as invalidating prior art only with respect to the "sacs" embodiment claimed in EP 766, which further confirms Edwards' previous understanding of the "sacs" embodiment as mutually exclusive from the "flaps" and "pockets" embodiment. Ex. 1152 at 32-38; *see* Ex. 1148. In fact, when a third party raised Seguin in the EP 254 opposition proceedings, Boston Scientific argued that the Seguin patent "proposes structure and a teaching which is not comparable to the inventive solution of the opposed patent. . . . [Seguin] does not have a bunched-up fabric seal, i.e. a fabric seal with excess material which can extend into spaces formed between the anchor/stent and the surrounding native tissue." Ex. 1131 at 19-20; *see also* Ex. 1151 (Third Party Opposition to the 254 Patent) at 4-5. This can no longer be reconciled with the positions taken by Boston Scientific in the 2017 UK proceedings, since, in accordance with Boston Scientific's new argument, the sac-type "inflatable peripheral chambers" of Seguin *are* comparable to the allegedly inventive solution of the '608 Patent.

the teachings of Seguin in combination with Lazarus and Lawrence-Brown. *See infra*, Section VIII.B.

C. Issuance of the '608 Patent

The '608 Patent issued from U.S. Patent Application No. 12/492,512 (“the '512 Application,” Ex. 1102), entitled “Everting Heart Valve,” filed June 26, 2009, and attempting to claim priority back to June 16, 2004.

During prosecution, the Examiner concluded that each element of what ultimately issued as independent Claim 1 was known up until the Claim was amended to further require that:

when the expandable anchor is in the collapsed delivery configuration, the fabric seal extends from the distal end of the replacement valve and back proximally over the expandable anchor, the fabric seal being adapted to prevent blood from flowing between the fabric seal and heart tissue.

See Ex. 1102, 7/9/14 Amendment at 2 (underlining in original to reflect added claim language); *see also id.* at 4/10/14 Non-Final Rejection at 2-3 (a fabric seal “having pleats and pockets is well known in the art” and it would have been obvious “to include pleats as an obvious alternative design choice”). Based on this amendment, and Boston Scientific’s unfounded argument that a fabric seal

extending from the distal end of the valve and back over the anchor was novel and not obvious, the Examiner issued a Notice of Allowance.

D. Claim Construction

In response to Edwards’ first petition, the Patent Owner chose not to offer claim constructions of its own, despite suggesting that the claims should be defined more broadly than proposed by Edwards. As a result, the Board’s Institution Decision there concluded that “no terms require express construction for purposes of this Decision.” *See* IPR2017-00060, Paper No. 7 at 7. Here, it is Edwards’ position that the new Grounds presented in this petition apply under both of Edwards’ proposed constructions set forth below, which are the same proposed constructions presented in Edwards’ first petition, and any broader constructions thereof. Thus, should Boston again suggest that the claims are broader than proposed by Edwards, no express construction of terms is necessary at least for purposes of an institution decision.

That said, two terms used in the ’608 Patent—“flaps” and “pockets”—are not terms of art in the field of interventional cardiology, and thus may ultimately benefit from construction, particularly in light of Boston Scientific’s new argument that “flaps” and “pockets” are not mutually exclusive from “sacs.” Intrinsic and extrinsic evidence supports that a person of ordinary skill in the art would define

“flaps” as “circumferentially oriented folds or unattached ends,”¹⁴ and define “pockets” as “open spaces or cavities formed by flaps of the fabric seal.” *See* Ex. 1101, Figs. 32-34 and col. 14:21-28 (“When deployed, as shown in FIGS. 33 and 34, fabric seal 380 bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets 382 ...”); Ex. 1102, 04/24/14 Office Action at 3 (Examiner using “flaps” and “pleats” interchangeably, and also relying on U.S. Patent No. 6,352,554 to De Paulis’s teaching of “circumferentially extending pleats” (Ex. 1121 at 4:52-5:1) as a teaching of “flaps” and “pockets”); Ex. 1122 [EP 2 749 254 (“EP ’254”)] at ¶¶ [0103], [0017] (Patent Owner using “flaps” and “pleats” interchangeably in related application); Exs. 1123-1124 (dictionary definitions of “flaps” and “pleats”); *see also* Ex. 1107 at ¶¶ 118-29.

Moreover, in view of Boston Scientific’s new arguments from the UK proceedings, if the “sacs” and “flaps and pockets” embodiments are not mutually exclusive as the Patent Office previously concluded, under the broadest reasonable

¹⁴ Edwards disagrees with an overbroad interpretation of “flaps” that would allow flaps to extend in the longitudinal direction. This is because, for example, longitudinally oriented “flaps” and “pockets” could create paths for blood to leak past the device, rather than “prevent blood from flowing between the fabric seal and heart tissue” as required by the Claims. *See, e.g.*, Ex. 1119 (Thornton) at 10:13-30 (detailing formation of longitudinally oriented “leakage path”).

interpretation standard applied here, “flaps” and “pockets” as claimed can include circumferentially oriented folds or unattached ends in the form of “sacs” as described by the ’608 Patent, *e.g.*, “sacs 200 are provided as discrete sacs at different positions along the height of anchor 30,” including “continuous cylinders at various heights.” *See* Ex. 1101 at 12:28-50; *see also* Ex. 1136, ¶¶ 49-52.

For the remaining terms in Claims 1-9 of the ’608 Patent, Edwards submits, for purposes of this *inter partes* review only and pursuant to 37 C.F.R.

§ 42.104(b)(3), that they take on the ordinary and customary meaning that the terms would have to one of ordinary skill in the art in view of the ’608 Patent’s specification and file history. Edwards’ position regarding the scope of the claims should not be taken as an assertion regarding the appropriate claim scope in other adjudicative forums where a different claim interpretation standard may apply.

E. The ’608 Patent Should Be Afforded a Priority Date No Earlier than November 24, 2008, Because the Grandparent of the ’608 Patent Does Not Adequately Describe the Claims of the ’608 Patent

Via the only independent claim of the ’608 Patent (Claim 1), every claim of the ’608 Patent uses the open-ended “comprising” transition and requires “*a replacement valve commissure support element* attached to the expandable anchor” and “*a commissure portion* of a replacement valve leaflet attached to the commissure support element.” Ex. 1101, Claim 1. Thus, all claims of the ’608 Patent cover both THVs with a plurality of commissure support elements and valve

commissure portions **and** THVs with only a single commissure support element or a single valve commissure portion. *See Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1023 (Fed.Cir.1997) (“[T]he article ‘a’ suggests a single chamber. However, patent claim parlance also recognizes that an article can carry the meaning of ‘one or more,’ for example in a claim using the transitional phrase ‘comprising.’”); Ex. 1136, ¶ 38. Dependent Claims 5, 6, and 8 further highlight this point, claiming “the commissure support element” in reference back to the “a commissure support element” recited in Claim 1. *See Free Motion Fitness, Inc. v. Cybex Int’l, Inc.*, 423 F.3d 1343, 1350-51 (Fed. Cir. 2005) (“Like the words ‘a’ and ‘an,’ the word ‘the’ is afforded the same presumptive meaning of ‘one or more’ when used with the transitional phrase ‘comprising.’”); Ex. 1136, ¶ 39. As such, claims 5, 6, and 8 amplify the priority date issue.

The grandparent application of the ’608 Patent, U.S. Patent Application No. 10/870,340 (the “’340 Application” or the “grandparent application” (Ex. 1143)), however, describes only THVs with a plurality of commissure support elements and valve commissure portions, and thus does not provide written description support for the full scope of the claims of the ’608 Patent. Ex. 1136, ¶¶ 40-46. As explained at the outset of this Petition, there is a real distinction between THVs with a plurality of commissure support elements and valve commissure portions compared to a THV with only one of each of these claimed features. *Supra* pp.4-6

(comparing, *e.g.*, Figs. 3B and 12B of the grandparent application with Figures 11c-e of Cribier); Ex. 1136, ¶¶ 41, 45. A valve with only a single commissure support and a single valve commissure portion would require a completely different and unique design, which is not described or contemplated in any way by the grandparent application. Ex. 1136, ¶ 45. The '608 claims thus include a broader scope of invention than the grandparent application supports. *See Liberty Mutual Insurance Co. v. Progressive Casualty Insurance Co.*, CBM2012-00003, Paper 78 (Final Written Decision) at 41 (P.T.A.B. 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.” (citing *Studiengesellschaft Kohle, m.b.H. v. Shell Oil Co.*, 112 F.3d 1561, 1564 (Fed. Cir. 1997) & *Transco Prod. Inc. v. Performance Contracting Inc.*, 38 F.3d 551, 556 (Fed. Cir. 1994))).

The word “commissure” appears only four times in the specification of the '340 Application, and each reference is clearly made to multiple commissures and commissure support elements, plural. Ex. 1143 at ¶ [0065] (“Annular base 22 of replacement valve 20 preferably is coupled to skirt region 34 of anchor 30, while *commissures* 24 of replacement valve leaflets 26 *are coupled to and supported by posts* 38.”); ¶ [00104] (“Valve *commissures* 24 are connected to male interlocking

elements 302 along their length.”); ¶ [00127] (“Everting valve 520 is similar to previously described valve 20, in that *commissures* 524 of replacement valve leaflets 526 *are coupled to and supported by posts* 38 of anchor 30’.”); and ¶ [00145] (“Everting valve 720 further comprises *posts 722 to which valve leaflets 726 are attached to provide commissure support.*”) (all emphases added); Ex. 1136, ¶ 42. Further, every reference to the “post” element that the specification of the ’340 Application describes as providing support for the commissures clearly describes a plurality of posts. *See* Ex. 1143 at ¶¶ [0064], [0065], [0067], [0074], [0077], [0093], [0096], [0097], [00106], [00126], [00127], [00129], [00139], [00140], [00145], [00147], [00149], [00150], [00152], [00153], [00154]; Ex. 1136, ¶ 42.

Similarly, in the original claims of the grandparent application, although they included “a replacement valve support” limitation that supported the valve as a whole (as opposed to specifically supporting commissures of the valve), the only reference to “a replacement valve support” in the specification describes “[a] replacement valve 354 [that] is disposed within anchor 350 and supported by *a replacement valve support, such as the posts described in earlier embodiments.*” Ex. 1143 at ¶ [00106] (emphasis added); Ex. 1136, ¶¶ 43-44. Further, with respect to the commissures, the original claims of the grandparent application were limited to multiple commissures. *See id.* at Claims 18, 64 (“18. The apparatus of claim

17, wherein the supporting connection is adapted to support replacement valve *commissures*.”; “64. The apparatus of claim 63, wherein the supporting connection is adapted to support replacement valve *commissures*.” (emphases added)). Because the grandparent application provides written description support only for a plurality of valve commissure portions and commissure support elements, it does not describe the full scope of the claims of the ’608 Patent, creating a defect in the priority chain. *See* Ex. 1136, ¶ 46. As a result of this break in priority, the ’608 Patent is not entitled to the June 16, 2004 priority date of the ’340 Application.

The first reference to a singular commissure and support element in the family of the ’608 Patent did not appear until claims were added via preliminary amendment to the ’213 Application on November 24, 2008. Ex. 1144 at 117 (Nov. 24, 2008 Preliminary Amendment at 3); Ex. 1136, ¶ 47. (The ’608 Patent is a divisional of the ’213 Application.) Like the claims of the ’608 Patent, these claims included “a replacement valve commissure support element attached to the expandable anchor” and “a commissure portion of a replacement valve leaflet attached to the commissure support element.” *Id.* Thus, the earliest description in the ’608 Patent family of a singular commissure and singular commissure support, and the earliest date to which the full scope of the claims of the ’608 Patent can claim priority, is November 24, 2008. Ex. 1136, ¶¶ 40, 45-47.

VII. ORDINARY SKILL IN THE ART

A person of ordinary skill in the art as of the purported June 16, 2004 priority date of the '608 Patent would have been an interventional cardiologist with a working knowledge of heart valve designs and expandable stents, including stent-grafts. Ex. 1107, ¶¶ 34-36; Ex. 1136, ¶ 13-14. This person of ordinary skill in the art would, where necessary, work as a team in combination with a medical device engineer to experiment with or manufacture a device as claimed in the '608 Patent. Ex. 1107, ¶ 36; Ex. 1136, ¶¶ 13-14.

VIII. IDENTIFICATION OF HOW THE CHALLENGED CLAIMS ARE UNPATENTABLE

Pursuant to 37 C.F.R. § 42.104(b)(1), (2), (4), and (5), an explanation of how Claims 1-9 of the '608 Patent are unpatentable, along with the exhibit numbers of supporting evidence, are provided below. Each subpart detailed below corresponds to the subpart of Claims 1-9 identified in the attached Appendix.

A. Ground 1: Claims 1-9 are invalid under 35 U.S.C. § 102(b) over Haug (Ex. 1135)

As discussed above, *supra* Section VI.E., because the grandparent application of the '608 Patent fails to provide written description support for a THV that includes only one “commissure support element,” and only one valve “commissure portion,” as claimed in each of the Claims, there is a break in the priority chain, and the '608 Patent can at most only claim priority to November 24,

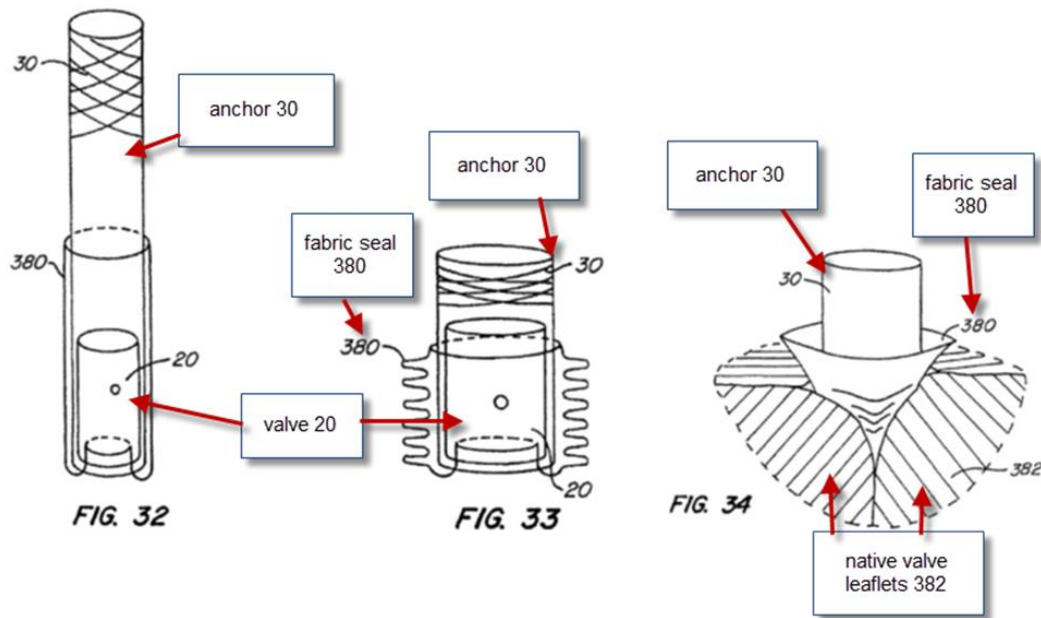
2008.¹⁵ As a result, the '608 Patent's grandparent application, which published as US 2005/0283231 on December 22, 2005 (the "Haug publication" (Ex. 1135)), is prior art under 35 U.S.C. § 102(b). Because the specification of the Haug publication is identical to the '608 Patent's, it anticipates each and every limitation of Claims 1-9. *See, e.g.*, Ex. 1135 at Figs. 1-4, 32-34, and ¶¶ [0064]-[0067], [0111]; Ex. 1136, ¶¶ 55-75.

To be clear, because Claim 1 is a "comprising" claim, although it broadly includes THVs with only a single "commissure support element" and single "commissure portion" (which is the basis for the break in priority), a THV with a plurality of commissure support elements and commissure portions also falls within the scope of the claims. As such, Haug, which only discloses THVs with a plurality of commissure support elements and commissure portions, reads on each of Claims 1-9. Although the specification of Haug is identical to the '608 Patent's specification, an element-by-element analysis is provided below for completeness.

1. Claim 1 (Preamble)

Haug discloses a system for replacing a heart valve in the form of a THV:

¹⁵ Edwards reserves the right to address § 112 issues, as appropriate, in other fora where those arguments may be presented. *See* 35 U.S.C. § 311(b).



See Ex. 1135 at Figs. 32-34 and ¶ [0111]; Ex. 1136, ¶ 58.

2. Element 1.1

Haug discloses an expandable anchor having a collapsed delivery configuration and an expanded configuration, the expandable anchor comprising a distal end. Ex. 1135 at Figs. 32 (collapsed configuration) and 34 (expanded configuration); Ex. 1136, ¶ 59.

3. Elements 1.2-1.3

Haug discloses a THV with commissure support elements attached to the expandable anchor, and a commissure portion of a replacement valve leaflet attached to each commissure support element. Ex. 1135 at ¶¶ [0064]-[0065] (“First, second and third posts 38a, 38b and 38c, respectively, are coupled to skirt region 34 and extend within lumen 31 of anchor 30. . . . [C]ommissures 24 of

replacement valve leaflets 26 are coupled to and supported by posts 38”), Figs. 1-4; Ex. 1136, ¶ 60.

4. Element 1.4

Haug discloses a fabric seal at least partially disposed around an exterior portion of the expandable anchor when the anchor is in the expanded configuration. *See* Ex. 1135 at Figs. 32-34 (“fabric seal 380”) and ¶ [0111]; Ex. 1136, ¶ 61.

5. Element 1.5

Haug discloses that the fabric seal has an undeployed state and a deployed state. *See* Ex. 1135 at Fig. 32 (undeployed state) and 34 (deployed state); Ex. 1136, ¶ 62.

6. Element 1.6

Haug discloses that in the deployed state, the fabric seal comprises flaps that extend into spaces formed by native valve leaflets. *See* Ex. 1135 at Figs. 32-34 (“fabric seal 380” extending into spaces formed by native valve leaflets (Fig. 34)) and ¶ [0111] (“fabric seal 380 bunches up to create fabric flaps and pockets”); Ex. 1136, ¶ 63.

7. Element 1.7

Haug discloses that a distal end of the replacement valve is attached to the fabric seal, and thus its leaflets are attached to the fabric seal. Ex. 1135 at Fig. 33 and ¶ [0111]; Ex. 1136, ¶ 64.

8. Element 1.8

Haug discloses that in the collapsed delivery configuration, the fabric seal extends from the distal end of the replacement valve and back proximally over the expandable anchor. Ex. 1135 at Fig. 33 and ¶ [0111]; Ex. 1136, ¶ 65.

9. Element 1.9

Haug discloses that the fabric seal is adapted to prevent blood from flowing between the fabric seal and heart tissue. Ex. 1135 at Fig. 32-34 and ¶ [0111] (“FIGS. 32-34 show another way to seal the replacement valve against leakage.”); Ex. 1136, ¶ 66.

10. Claims 2-3

Haug discloses that the fabric seal, in the deployed state, defines a plurality of pockets that are adapted to fill with blood in response to backflow blood pressure. Ex. 1135 at Fig. 32-34 and ¶ [0111] (“the pockets are filled with blood in response to backflow blood pressure”); Ex. 1136, ¶ 67.

11. Claim 4

Haug discloses an anchor formed from stainless steel or nickel-titanium alloy. Ex. 1135 at ¶ [0065]; Ex. 1136, ¶ 68.

12. Claims 5-6

Haug discloses that the commissure support element is configured to interface with an anchor actuator, wherein the anchor actuator is adapted to apply a proximally directed force on the commissure support element to foreshorten the expandable anchor. Ex. 1135 at ¶¶ [0066]-[0067] (“In order to avoid delivery of anchor 30 on a balloon for balloon expansion, a non-hydraulic or non-pneumatic anchor actuator is used.”; “Anchor 30 may be actuated using external non-hydraulic or non-pneumatic force to actively foreshorten in order to increase its radial strength.”); Ex. 1136, ¶ 71.

13. Claims 7-9

Haug discloses that the THV has a lock having a first lock element and a second lock element, the first and second lock elements being attached to the expandable anchor and configured to interlockingly engage one another to lock the expandable anchor in the expanded configuration. *See, e.g.*, Ex. 1135 at Exs. 1-4 & ¶ [0067] (“Locks 40 include posts or arms 38 preferably with male interlocking elements 44 extending from skirt region 34 and mating female interlocking elements 42 in lip region 32”); Ex. 1136, ¶ 75. The commissure support element

includes the first lock element, and the second lock element is attached to the expandable anchor and is disposed proximal to the first lock element when the expandable anchor is in the collapsed delivery configuration. Ex. 1135 at Exs. 1-4 and ¶ [0067]; Ex. 1136, ¶ 75.

B. Ground 2: Claims 1-4 are invalid under 35 U.S.C. § 103(a) over Seguin (Ex. 1150; 1153) in view of Lazarus (Ex. 1147) and Lawrence-Brown (Ex. 1149)

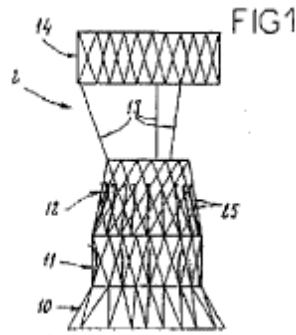
The teachings of Seguin in view of Lazarus render obvious each of the elements of claims 1-4 of the '608 Patent.

1. Claim 1 Preamble

Seguin discloses a system for replacing a heart valve: “a kit for placing a prosthetic valve in a duct in the body, especially a heart valve, and in particular an aortic valve.” Ex. 1150 at 1; Ex. 1136, ¶ 77.

2. Element 1.1

The prosthetic valve of Seguin is a THV comprising an expandable anchor (*i.e.*, “stent”) with collapsed and expanded delivery configurations. Ex. 1150 at 1-2 (“The kit according to the invention comprises . . . a radially expandable framework, called a stent”); Ex. 1136, ¶ 78. As detailed in the exemplary embodiment of Figure 1, the anchor in Seguin has distal and proximal ends:



Referring to Figure 1, it will be seen that the stent 2 comprises ... proximal [] portion 10, a proximal ... portion 11, a distal ... portion 12, several connection rods 13, and a distal ... portion 14.

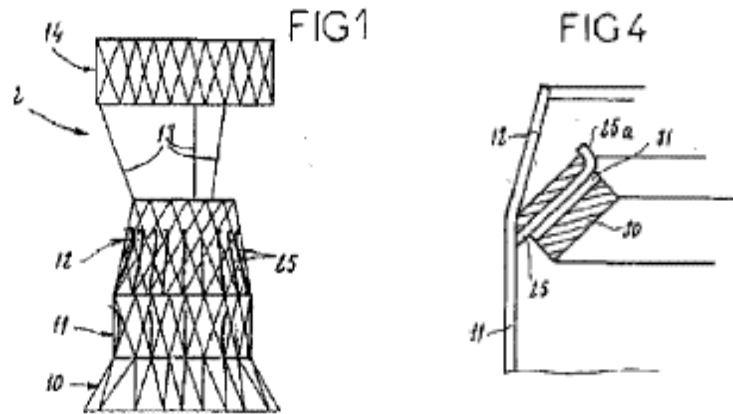
Ex. 1150 at 7; Ex. 1136, ¶ 78.

To avoid confusion, it is noted that for a transfemoral delivery of the prosthesis (*i.e.*, delivery via a catheter against the flow of blood), the “distal” end of the prosthesis in the ’608 Patent is the end furthest along the catheter from the control handle of the delivery system, whereas in Seguin, that end is the “proximal” end of the prosthesis. Ex. 1136, ¶ 79. Thus, in this context, when Seguin refers to the “proximal” end of the device, that is the “distal” end of the device according to the ’608 Patent, and vice versa.

3. Elements 1.2-1.3

Seguin discloses a replacement valve commissure support element attached to the expandable anchor, and a commissure portion of a replacement valve leaflet attached to the commissure support element.

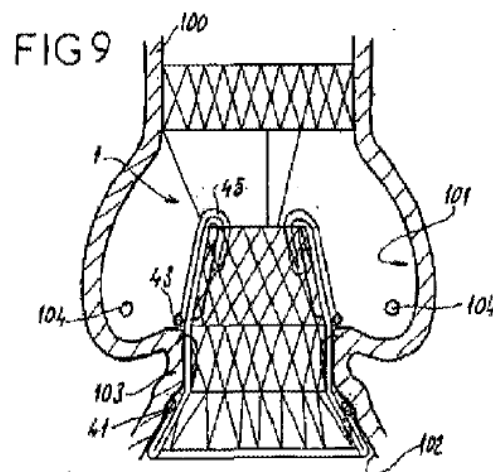
Seguin discloses commissure support elements in the form of “arms 25,” shown, for example, in Figures 1 and 4:



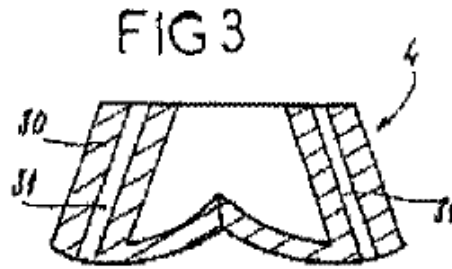
The portion 12 additionally comprises a series of internal arms 25

These arms 25 are inclined toward the inside of the portion 12 before placement of the valve 4 on the stent 2, and Figure 4 shows that in this position they can receive the valve 4.

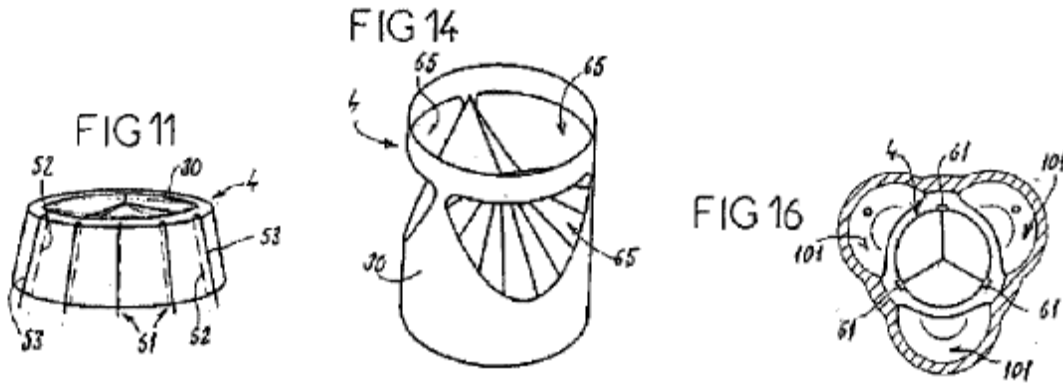
Ex. 1150 at 8-9; Ex. 1136, ¶ 81. The “arms 25” of Seguin’s prosthesis “allow the valve 4 to be mounted in the portion 12, as is shown in Figure 9”:



Ex. 1150 at 9 & Fig. 9. The valve can “comprise[] a peripheral wall 30 in which there are longitudinal tunnels 31 for receiving the arms 25,” which results in the attachment of the valve, including its commissure portions, to the commissure support elements:



Id. at 9 and Fig. 3; Ex. 1136, ¶ 82. As shown in Figure 1, there are a multitude of “arms 25” secured to the valve, a subset of which will be longitudinally aligned with and engage the commissure portions of the trileaflet valve. *See* Ex. 1150 at Fig. 1 and at 1 (recognizing need to attach commissures to element separate from anchor), 4 (“elements limiting the maximum diameter of expansion of the valve . . . in the area of the commissure points of this valve”); Ex. 1136, ¶ 83. This alignment is apparent throughout the various embodiments of Seguin in addition to the Figure 1 embodiment:

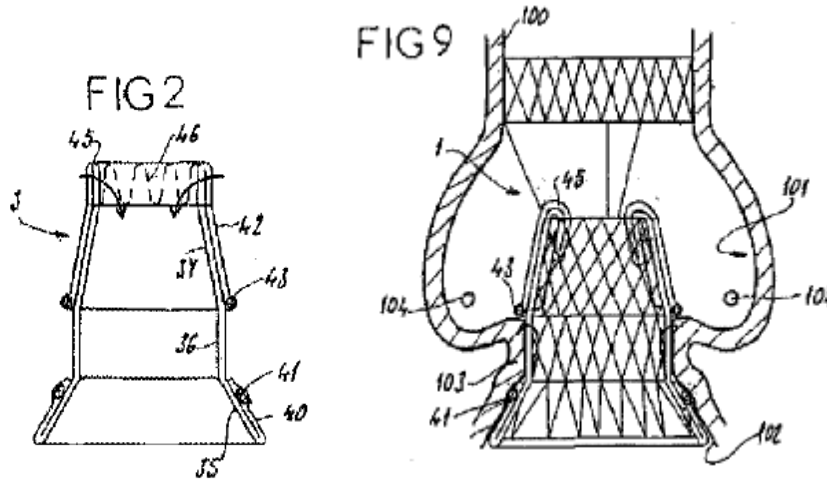


See Ex. 1150 at Fig. 11 (subset of “inner arms 52” engaging commissure portion of valve), Fig. 14 (wall 30 engaging commissure portions of valve), Fig. 16 (longitudinal wires 61 engaging commissure portions of valve); Ex. 1136, ¶ 83.

To the extent it is argued that Seguin does not disclose a replacement valve commissure support element attached to the expandable anchor or a commissure portion of a replacement valve leaflet attached to the commissure support element, a person of ordinary skill in the art would at minimum have found it obvious to include these features in light of the same disclosures of Seguin detailed above with respect to these claim elements. Ex. 1136, ¶ 84.

4. Element 1.4

Seguin discloses various THV embodiments with a fabric seal in the form of a “sheath” with “flaps” having “peripheral inflatable chambers” that is at least partially disposed around an exterior portion of the expandable anchor when the anchor is in the expanded configuration:



Ex. 1150 at Figs. 2 & 9 (“sheath 3” with “flaps” 40 and 42 comprising “peripheral inflatable chambers” 41 and 43); Ex. 1136, ¶ 85. “The sheath 3 is made of an impermeable biocompatible material, such as . . . ‘DACRON’.” Ex. 1150 at 9.

Because the “inflatable peripheral chamber[s]” and “flap[s]” are components of the “sheath,” the disclosure that the “sheath” is made with fabric such as Dacron means that both the “inflatable peripheral chamber[s]” and “flap[s]” are made with this fabric. *Id.* at 9-10; Ex. 1136, ¶ 85.

5. Element 1.5

The fabric seal disclosed by Seguin can assume various states—for example, an undeployed state (*i.e.*, “contracted configuration”) and a deployed state (*i.e.*, “expanded configuration”). *See* Ex. 1150 at 8; Ex. 1136, ¶ 86.

6. Element 1.6

As detailed above, the fabric seal of Seguin includes a “sheath” with “flaps” that “extend[] on the outer face” of the anchor and circumferentially oriented

“inflatable peripheral chambers” at the “free edge” of the “flaps.” Ex. 1150 at 9-10 & Figs. 2, 9. The “inflatable peripheral chambers” of the sheath ensure “leaktightness between the sheath 3 and the ring 103 [i.e., the aortic annulus].” *Id.* It is the “inflatable peripheral chambers” of the sheath that have otherwise been characterized by Edwards as “sacs,” but given the positions taken by Boston Scientific in the UK proceedings, discussed *supra* Section VI.B., these “sacs” also render obvious the ’608 Patent’s “flaps” and “pockets” limitations as more fully set forth below.

a. “wherein in the deployed state the fabric seal comprises flaps”

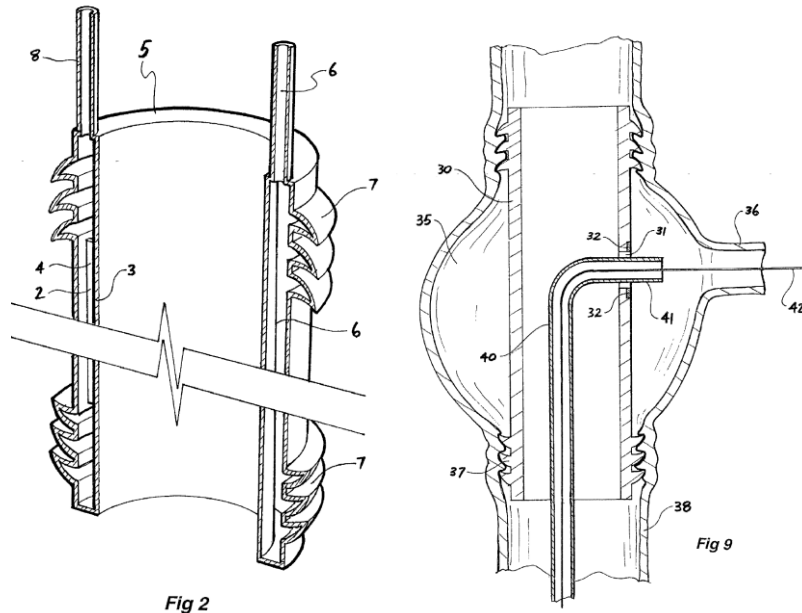
Seguin provides that “[t]he kit [] is assembled by placing the sheath 3 on the stent 2 and placing the valve 4 on the arms 25, the stent 2 being in the contracted state.” Ex. 1150 at 10. The kit is then placed in a catheter and introduced into a patient, wherein the inflatable peripheral chambers are not yet inflated. *Id.* The THV is positioned in the aorta, and balloons are used to deploy the prosthesis, expanding into place portions 10, 11, and 14 in the preferred embodiment shown in Figures 1 and 9. *Id.* Upon deployment, the inflatable peripheral chambers remain unfilled. *Id.* It is only at this stage that “[t]he chambers 41, 43 are then inflated to ensure leaktightness of the sheath 3 with respect to the ring 103” *Id.* Seguin does not explicitly detail the contour of the outer surface of the inflatable peripheral chamber in its deployed state prior to inflation, or detail its contour after

inflation. Ex. 1136, ¶ 90. Given Seguin’s recognition, however, that “[the] leaktightness is . . . guaranteed notwithstanding the possible presence of calcified portions which give a cardiac ring an irregular shape,” Ex. 1150 at 5, a person of ordinary skill in the art would recognize it is implicit in Seguin that the fabric seal adapts to the irregular shape of calcified tissue, and the inflatable peripheral chamber would have an outer surface with an irregular shape that forms “flaps” and “pockets” that extend into spaces formed by the native valve leaflets ensuring a leaktight seal. Ex. 1136, ¶ 90.

To the extent it is argued that Seguin does not disclose “flaps” and “pockets” that “extend into spaces formed by native valve leaflets” as claimed, it would have been obvious to a person of ordinary skill in the art to modify the structure of the fabric seal of Seguin to include these features in view of the teachings of Lazarus and Lawrence-Brown. Ex. 1136, ¶¶ 91-94.

Lazarus teaches a stent graft structure with peripheral inflatable chambers “designed to mold and adhere to calcification within the vessel and to heal to irregular aortic surfaces,” such that the inflatable chamber (*i.e.*, “toroidal collar”) “adjust[s] to the unique internal dimension or shape of the vessel.” Ex. 1147 at 6:39-58, 10:5-8; *see also id.* at Fig. 5. Depending on the desired end use, toroidal collars are positioned at the distal, proximal, and/or middle portion of the prosthesis. *See id.* at Figs. 3, 5, 7B.

Separately, Lawrence-Brown discloses a graft structure with inflatable portions in the form of “annular flanges or ridges 7”:



Ex. 1149 at ¶ [0068], Figs. 2, 9. “At each end of the graft are a series of annular flanges or ridges 7 which are in effect continuations of the outer wall 2 and when the body is inflated with the settable or filler material, the annular flanges or ridges 7 are also inflated. In use these annular flanges, when inflated, engage against the walls of the body lumen to provide a seal so that blood flow will not occur on the outside of the graft.” *Id.* Lawrence-Brown further notes that “[a] clear advantage of the graft and deployment system of the present invention over the prior art is that the graft can mould itself to the walls of the artery and/or the laminated thrombus” and thereby “deform to fit the small irregularities” in the surrounding tissue, thereby preventing “endoleaks.” *Id.* at ¶ [0102].

It would have been obvious to a person of skill in the art to modify the inflatable peripheral chamber of Seguin in view of the “toroidal collar” teachings of Lazarus and “annular flanges” teachings of Lawrence-Brown. Ex. 1136, ¶ 95-97.

First, since the advent of surgical valve technology, persons of ordinary skill in the art have been motivated to design sealing structures that conform to the surrounding tissue to reduce the risk of paravalvular leak. *See* Ex. 1111 (Starr-Edwards) and Ex. 1138 (Reger), *supra* Section III.B. A person of ordinary skill in the art would approach Seguin with the very same motivation, and would readily combine Seguin with other teachings, including those of Lazarus and Lawrence-Brown, to provide a sealing structure with “flaps” and “pockets” that “extend into spaces formed by the native valve leaflets” in order to reduce the risk of paravalvular leak. Ex. 1136, ¶ 96.

Second, a person skilled in the art would have known of and employed structures similar to both Lazarus and Lawrence-Brown with Seguin, adapting Seguin to “adhere to calcification within the vessel and to heal to irregular aortic surfaces,” while providing a structure that provides “[a] clear advantage . . . over the prior art” by providing a seal that “deform[s] to fit the small irregularities” in the surrounding tissue, thereby preventing “endoleaks.” Ex. 1147 at 6:39-58, 10:5-8; Ex. 1149, ¶ [0102]; Ex. 1136, ¶ 97. That is, it would have been obvious to a

person of ordinary skill in the art to modify the fabric seal of Seguin in view of the teachings of Lazarus to ensure that the inflatable peripheral chamber of Seguin molds to the surrounding calcified tissue, while adopting the inflatable “annular flange” structure taught by Lawrence-Brown in order to provide a seal with discrete flaps that deform to fit the spaces formed by the surrounding calcified tissue and prevent leaks. Ex. 1136, ¶ 97.¹⁶

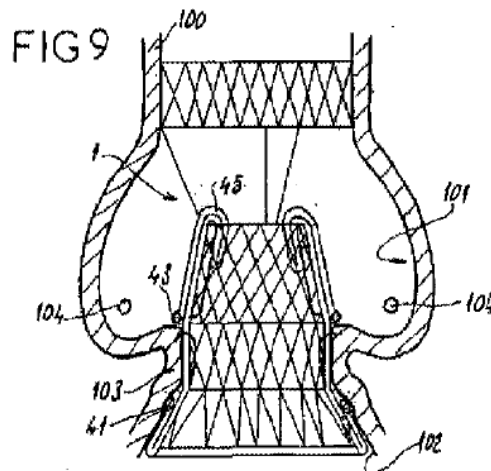
b. “[the flaps] extend into spaces formed by native valve leaflets”

With respect to the native valve leaflets, Seguin explicitly recognizes the need to provide a leaktight seal “in the area of the valvular ring which is particularly affected when calcified zones give the valvular ring an irregular form and/or a certain rigidity.” Ex. 1150 at 1. Seguin provides that “[i]n the expanded state, the portion 11 has a diameter such that it is able to bear against the natural valvular ring 103 and a radial force such that it can push the natural valve (or its

¹⁶ It is also noted that despite Seguin’s teaching that the anchor will foreshorten, Seguin does not explicitly identify the degree to which it foreshortens. Ex. 1150 at Figs. 5, 7 & at 4. To the extent a stent design is selected in Seguin that exhibits extensive foreshortening, additional “flaps” and “pockets” will form along the length of the fabric seal, as confirmed by Schlick. Ex. 1139 at Fig. 4 and 3:58-4:3, 4:30-51; *see also* Ex. 1136, ¶ 97, n.3.

remnants after partial exeresis) against the ring 103 in order to ensure leaktightness at this site.” *Id.* at 8; *see also id.* at 6, 8, Claims 15-16. Thus, Seguin includes procedures in which the native valve leaflets are left in place or partially excised. Ex. 1136, ¶ 98. Seguin also notes that the natural valve leaflets are removed prior to THV implantation only “if necessary.” Ex. 1150 at 10; Ex. 1136, ¶ 98.

In Seguin’s Figure 9 embodiment, “the stent has two inflatable peripheral chambers placed on each side of that portion of the stent intended to bear against a cardiac valvular ring”:



Ex. 1150 at Fig. 9 and at 5. In this and other schematic Figures, Seguin does not illustrate the native valve leaflets or their particular location, as the native leaflets may be partially or wholly removed in addition to being left in place. Ex. 1136, ¶ 99. It is clear, however, that the inflatable peripheral chambers in the Figure 9 embodiment are intended to contact portions of the native valve leaflets if they are

present; otherwise, no seal in the “area of the valvular ring” will form. Ex. 1136, ¶ 99.

Nonetheless, Seguin’s disclosure is broader than just this particular Figure 9 embodiment. Seguin provides that:

The stent preferably has, fixed on said sheath, at least one inflatable peripheral chamber which can be inflated in order to form a seal ensuring leaktightness between the stent and the wall of the body duct to be fitted with the valve. This leaktightness is thus guaranteed notwithstanding the possible presence of calcified portions which give a cardiac ring an irregular shape.

Ex. 1150 at 5. Thus, Seguin contemplates placement of the one or more inflatable peripheral chambers at any point along the length of the sheath “between the stent and the wall of the body duct to be fitted with the valve.” *Id.*; Ex. 1136, ¶ 100.

Seguin’s Claims 15-16 confirm the point. Claim 16, which depends from Claim 15, requires that “the stent has two inflatable peripheral chambers placed on each side of that portion of the stent intended to bear against a cardiac valvular ring.” Ex. 1150 at Claim 16. The reference to “each side” would be understood by a person of ordinary skill in the art to mean that the peripheral chambers of Seguin abut distal and proximal portions of the native valve leaflets (if not removed prior to implanting the THV). Ex. 1136, ¶ 101. And Claim 15 is broader in that it is not

limited to placement of the peripheral chambers on each side of the cardiac valvular ring. Ex. 1136, ¶ 101. Claim 15 requires only “that the stent has, fixed on said sheath, at least one inflatable peripheral chamber which can be inflated in order to form a seal ensuring leaktightness between the stent and the wall of the body duct to be fitted with the valve.” Thus, Claim 15 again confirms that Seguin contemplates placement of the one or more inflatable peripheral chambers at any point along the sheath “between the stent and the wall of the body duct to be fitted with the valve.” Ex. 1150 at Claim 15; Ex. 1136, ¶ 101. Seguin is therefore not limited by Figure 9. The peripheral inflatable chambers may be positioned at any point along the length of the sheath. Ex. 1136, ¶ 102.

Moreover, combining the teachings of Seguin with those of Lazarus and Lawrence-Brown as detailed above, it likewise would have been obvious to a person of ordinary skill in the art to position the inflatable peripheral chambers of Seguin as modified so as to contact and extend into spaces formed by the native valve leaflets. Ex. 1136, ¶ 103. Seguin recognizes “the possible presence of calcified portions which give a cardiac ring an irregular shape.” Ex. 1150 at 5. As a result, Seguin would be motivated to ensure that its sheath comprising the inflatable peripheral chambers conforms to and seals the THV to the calcified portions of the native valve leaflets to prevent leaks. Ex. 1136, ¶ 103. Lazarus, in turn, teaches that an inflatable peripheral chamber akin to that disclosed by Seguin

is “designed to mold and adhere to calcification within the vessel and to heal to irregular aortic surfaces,” Ex. 1147 at 6:39-58, 10:5-8, and Lawrence-Brown confirms that the use of “annular flanges” “mould . . . to the walls of the artery and/or the laminated thrombus” and thereby “deform to fit the small irregularities” in the surrounding tissue and prevent “endoleaks.” Ex. 1149 at ¶ [0102]. It therefore would have been obvious to a person of ordinary skill in the art to modify Seguin in view of Lazarus and Lawrence-Brown to include a fabric seal that molds and adheres to the surrounding calcification of the native valve leaflets and fits into the small irregularities of the calcifications to prevent leaks. Ex. 1136, ¶ 103.

Furthermore, the calcified native valve leaflets are rigid whereas the surrounding tissue distal and proximal to the native valve leaflets is elastic. Ex. 1136, ¶ 104. There is a greater likelihood of success in forming a leaktight seal if the inflatable peripheral chambers of Seguin as modified by the teachings of Lazarus and Lawrence-Brown are expanded at least in part in the area of the native calcified leaflets as opposed to areas in which the elasticity of the vessel walls risks interfering with formation of a proper seal. *Id.* Thus, it would have been obvious to a person of ordinary skill in the art to deploy Seguin, as modified in view of the teachings of Lazarus and Lawrence-Brown, in a location where the inflatable peripheral chambers contact, at least in part, the calcified native valve leaflets to

ensure that the THV is stably positioned so as to form a seal between the THV and surrounding tissue.

* * *

In sum, a person of ordinary skill in the art implementing Seguin would have found it obvious and straightforward to combine the teachings of Seguin with the teachings of Lazarus and Lawrence-Brown to include a fabric seal with “flaps” (and “pockets”) that “extend into spaces formed by the native valve leaflets.” Ex. 1136, ¶ 105. This modification of Seguin requires adapting only a single element, the inflatable peripheral chamber, in view of teachings specifically directed at inflatable peripheral chambers in the same field and for the same end result of sealing the prosthesis to the surrounding tissue. *Id.* Moreover, a person of ordinary skill in the art would have recognized that the combination of Seguin with Lazarus and Lawrence-Brown would work as expected to produce a fabric seal with “flaps” (and “pockets”) that extend into spaces formed by the native valve leaflets. *Id.* The combination is nothing more than an arrangement of old elements, each performing the same function it’s known to perform, and would yield the expected result of a THV with a fabric seal having “flaps” (and “pockets”) that reduce the risk of paravalvular leak. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (“When a patent ‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more

than one would expect from such an arrangement, the combination is obvious.”); Ex. 1136, ¶ 105. As such, a person of skill in the art would have recognized that combining the teachings of the THV technology in Seguin with the sealing structures taught by Lazarus and Lawrence-Brown would work as expected to yield, as a predictable result, the claimed structure. *Id.*

7. Element 1.7

Seguin discloses that a distal end of the replacement valve leaflet is attached to the fabric seal. Ex. 1136, ¶ 106. Seguin provides that the “sheath forms a fixation base for the valve and at the same time a means of sealing between the stent and the wall of the body duct.” Ex. 1150 at 5. Moreover, as detailed in Figure 4, the base of the valve (*i.e.*, the distal end of the valve) including its leaflets, are attached to the fabric seal, which are lined along stent portions 10-12. *Id.*, Fig. 4 and at 9; Ex. 1136, ¶ 108. This forms a beneficial attachment between the leaflets and the fabric seal—spaces between the valve leaflets and sheath would otherwise form gaps along the inside surface of the prosthesis where leakage would occur. Ex. 1136, ¶ 108; *see also* Ex. 1150, Fig. 12 and at 11 (detailing an analogous leaflet attachment mechanism: “The inner arms 52 can comprise (see Figure 12) proximal hooks which complete the deployment of the valve 4 by being fastened to the wall of the sheath 3 . . .”).

To the extent it is argued that Seguin does not disclose a distal end of the replacement valve leaflet attached to the fabric seal, a person of ordinary skill in the art would at minimum have found this feature obvious based on the same disclosures and analysis detailed above with respect to this claim element. Ex. 1136, ¶ 109.

8. Element 1.8

In those embodiments of Seguin where the valve is secured within the anchor prior to delivery, the fabric seal of Seguin extends from the distal end of the replacement valve and back proximally over the expandable anchor in the anchor's collapsed delivery configuration. *See* Ex. 1150 at Figs. 2, 9 (“sheath 3” with “flaps” 40 and 42 comprising “peripheral inflatable chambers” 41 and 43), 13 and at 9 (“At the proximal end, the sheath 3 has a flap 40 extending on the outer face of the portion 35.”); Ex. 1136, ¶ 110. Seguin provides that “[t]he kit 1 is assembled by placing the sheath 3 on the stent 2 and placing the valve 4 on the arms 25, the stent 2 being in the contracted state. The kit 1 is then placed in a catheter permitting its introduction into the patient's body” Ex. 1150 at 10.

To the extent it is argued that Seguin does not disclose that the fabric seal extends from the distal end of the replacement valve and back proximally over the expandable anchor when the expandable anchor is in the collapsed delivery configuration, a person of ordinary skill in the art would at minimum have found

this feature obvious based on the same disclosures and analysis detailed above with respect to this claim element. Ex. 1136, ¶ 111.

9. Element 1.9

Seguin discloses that the flaps of the fabric seal, including the inflatable chambers, prevent blood from flowing between the fabric seal and heart tissue:

“The chambers 41, 43 are then inflated to ensure leaktightness of the sheath 3 with respect to the ring 103” Ex. 1150 at 10; *see also id.* at 9-10; Ex. 1136, ¶ 112.

“[T]he portion 11 has a diameter such that it is able to bear against the natural valvular ring 103 and a radial force such that it can push the natural valve (or its remnants after partial exeresis) against the ring 103 in order to ensure leaktightness at this site.” Ex. 1150 at 8.

To the extent it is argued that the fabric seal of Seguin does not prevent blood from flowing between the fabric seal and heart tissue, it would have been obvious to modify Seguin in view of Lazarus and Lawrence-Brown for the reasons set forth above, *supra* Element 1.6, which would result in a fabric seal that prevents blood from flowing between the fabric seal and heart tissue. Ex. 1136, ¶ 113-16.

First, Lazarus confirms that “the toroidal collars . . . contact the inner vessel wall to assure a comprehensive seal between the graft 10 and the vessel wall.” Ex. 1147 at 14:20-30.

Second, Lawrence-Brown confirms that its “annular flanges” provide “[a] clear advantage ... over the prior art” because “the graft can mould itself to the walls of the artery and/or the laminated thrombus” and thereby “deform to fit the small irregularities” in the surrounding tissue, thereby preventing “endoleaks.” Ex. 1149 at ¶ [0102].

Thus, for the same reasons set forth under Element 1.6, *supra*, it would have been obvious to combine Seguin with the teachings of Lazarus and Lawrence-Brown in order to provide a “comprehensive seal” between the THV and native valve leaflets, and to provide a sealing structure that can mold itself to the walls of the surrounding tissue and deform to fit the small irregularities in that tissue, thereby preventing blood from flowing between the fabric seal and heart tissue. Ex. 1136, ¶ 113-16.

10. Claims 2-3

Seguin discloses pockets, for example, in the form of “chambers” that, in the deployed state, are “inflated to ensure leaktightness of the sheath 3 with respect to the ring 103” Ex. 1150 at 10 Ex. 1136, ¶ 117. Lazarus likewise teaches pockets, for example, in the form of “toroidal collars” that “contact the inner vessel wall to assure a comprehensive seal between the graft 10 and the vessel wall.” Ex. 1147 at 14:20-30; Ex. 1136, ¶ 117. And Lawrence-Brown teaches pockets, for example, in the form of “a hollow space 6 into which can be inserted a settable or

filler material under slight pressure to inflate the graft,” wherein “the annular flanges or ridges 7 are also inflated.” Ex. 1149 at ¶¶ [0066]-[0068]; Ex. 1136, ¶ 117.

Seguin and Lawrence-Brown are silent as to whether the pockets are adapted to fill with blood in response to backflow blood pressure. Ex. 1136, ¶ 118.

Lazarus, however, discloses that fenestrations can be formed in the walls of the inflatable chambers to allow the flow of blood to inflate the chamber:

Following deployment of the graft 10 within the vessel . . . the toroidal collars 50 may be enlarged or inflated by the introduction of, for example, a fluid into the internal space 52 of each toroidal collar 50. The toroidal collars 50 may be inflated in any number of suitable ways. For example, fenestrations (not shown) may be formed through the wall of the tubular body 12, in alignment with a toroidal collar 50, thereby providing means for flow of blood into the internal space 52 of the toroidal collar 50 to fill or inflate the toroidal collar 50 with blood.

Ex. 1147 at 15:5-14.

It would have been obvious to a person of ordinary skill implementing Seguin to modify Seguin using the teachings of Lazarus and Lawrence-Brown by providing fenestrations in the walls of the inflatable peripheral chambers to allow

the flow of blood, which includes the backflow of blood, to inflate the chambers. *See* Ex. 1136, ¶ 119. By adopting a structure that allows the chambers to inflate with blood, any additional process steps that would be required to fill a closed chamber with a filling agent could beneficially be avoided, streamlining the implantation process and avoiding any concerns related to the biocompatibility of the filling agent. *Id.*

A person of ordinary skill in the art implementing Seguin with the teachings of Lazarus and Lawrence-Brown, as discussed under Element 1.6, *supra*, would have found it obvious and straightforward to combine the teachings of Seguin with the teachings of Lazarus and Lawrence-Brown, particularly given that the modification of Seguin requires adapting only a single element, the inflatable peripheral chamber, in view of teachings specifically directed at inflatable peripheral chambers in the same field and for the same end result of sealing the prosthesis to the surrounding tissue. Ex. 1136, ¶ 120. Moreover, a person of ordinary skill in the art would have recognized that the combination of Seguin with Lazarus and Lawrence-Brown would work as expected to produce a fabric seal with fenestrations that allow the “pockets” to fill with the backflow of blood. Ex. 1136, ¶ 120. The combination is nothing more than an arrangement of old elements, each performing the same function it’s known to perform, and would yield the expected result of a THV with an inflatable peripheral chamber that is

filled by the flow of blood. *KSR*, 550 U.S. at 417; Ex. 1136, ¶ 120. As such, a person of skill in the art would have recognized that combining the teachings of the THV technology in Seguin with the sealing structures taught by Lazarus and Lawrence-Brown, including in particular the fenestrations taught by Lazarus, would work as expected to yield, as a predictable result, the claimed structure. Ex. 1136, ¶ 120.

11. Claim 4

Seguin discloses an expandable anchor formed from stainless steel or nickel-titanium alloy. Ex. 1150 at 5.

* * *

For at least these reasons, there is a reasonable likelihood that claims 1-4 of the '608 Patent are obvious over Seguin in view of Lazarus and Lawrence-Brown. Ex. 1136, ¶¶ 76-121. To the extent the Patent Owner argues that any further disclosure is required for a claimed limitation, a person of ordinary skill in the art would have found that limitation obvious to include based on the same disclosures and analysis identified herein.

IX. CONCLUSION

Petitioner submits that the substantial evidence presented in this Petition demonstrates that there is a reasonable likelihood that Claims 1-9 of the '608 Patent would have been invalid in view of the prior art described herein.

Petition for *Inter Partes* Review of U.S. Patent No. 8,992,608

Accordingly, Petitioner respectfully requests that the Board grant *inter partes* review for each of these claims pursuant to 35 U.S.C. § 314.

Dated: April 18, 2017

Respectfully Submitted,

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Appendix

U.S. Patent No. 8,992,608 Claims 1-9: Element-by-Element Breakdown

Claim No./ Subpart	Claim Element
1 (Preamble)	A system for replacing a heart valve, comprising:
1.1	an expandable anchor having a collapsed delivery configuration and an expanded configuration, the expandable anchor comprising a distal end;
1.2	a replacement valve commissure support element attached to the expandable anchor;
1.3	a commissure portion of a replacement valve leaflet attached to the commissure support element; and
1.4	a fabric seal at least partially disposed around an exterior portion of the expandable anchor when the anchor is in the expanded configuration,
1.5	the fabric seal having an undeployed state and a deployed state,
1.6	wherein in the deployed state the fabric seal comprises flaps that extend into spaces formed by native valve leaflets;
1.7	wherein a distal end of the replacement valve leaflet is attached to the fabric seal
1.8	and when the expandable anchor is in the collapsed delivery configuration, the fabric seal extends from the distal end of the replacement valve and back proximally over the expandable anchor,
1.9	the fabric seal being adapted to prevent blood from flowing between the fabric seal and heart tissue.
2	The system of claim 1, wherein, in the deployed state, the fabric seal defines a plurality of pockets.
3	The system of claim 2, wherein the pockets are adapted to fill with blood in response to backflow blood pressure.
4	The system of claim 1, wherein the expandable anchor is formed from stainless steel or nickel-titanium alloy.
5	The system of claim 1, wherein the commissure support element is configured to interface with an anchor actuator.
6	The system of claim 5, wherein the anchor actuator is adapted to apply a proximally directed force on the

	commissure support element to foreshorten the expandable the expandable anchor.
7	The system of claim 1 further comprising a lock having a first lock element and a second lock element, the first and second lock elements being attached to the expandable anchor and configured to interlockingly engage one another to lock the expandable anchor in the expanded configuration.
8	The system of claim 7, wherein the commissure support element includes the first lock element.
9	The system of claim 8, wherein the second lock element is attached to the expandable anchor and is disposed proximal to the first lock element when the expandable anchor is in the collapsed delivery configuration.

CERTIFICATE OF SERVICE

I hereby certify that, on April 18, 2017, I caused a true and correct copy of the foregoing Petition for inter partes review of U.S. Patent No. 8,992,608 (“the ’608 Patent”) and all associated supporting materials to be served via Express Mail delivery at the correspondence address of record for the ’608 Patent:

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COURTESY COPY TO PATENT OWNER’S COUNSEL OF RECORD IN IPR2017-00060:

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CERTIFICATE OF WORD COUNT UNDER 37 C.F.R. § 42.24(a)

I, the undersigned, do hereby certify that the attached Petition, including footnotes, contains 13,608 words, as measured by the Word Count function of Word 2007. This is less than the limit of 14,000 words specified by 37 C.F.R. § 42.24(a)(i).

Date: April 18, 2017

/s/ Gregory S. Cordrey
Gregory S. Cordrey