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 IPR2016-_____
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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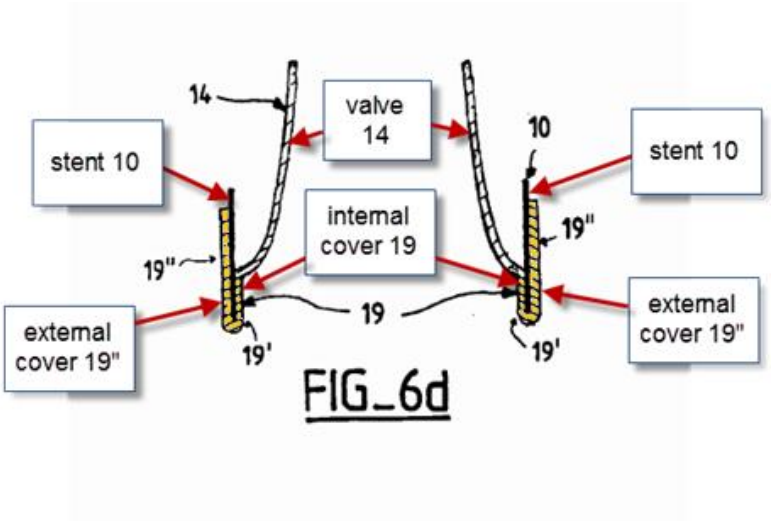
I. OVERVIEW OF PETITION

Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences AG (collectively, "Edwards") respectfully request *inter partes* review for claims 1-4 of U.S. Patent No. 8,992,608 (the "'608 patent," attached as Ex. 1001) in accordance with 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.100 *et seq.*

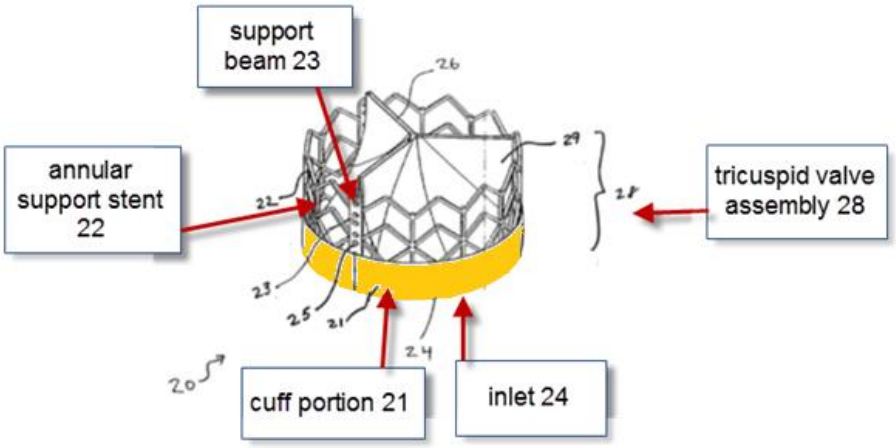
The '608 patent's purported invention is directed to a collapsible and expandable prosthetic heart valve delivered via a catheter ("transcatheter heart valve" or "THV"). Specifically, the '608 patent describes a retrievable THV that includes an anchor, commissural support elements attached to the anchor, a replacement valve with commissures attached to the commissural supports, and a fabric seal that, upon anchor foreshortening, forms a sealing structure that purportedly prevents blood from flowing between the fabric seal and heart tissue (*i.e.*, paravalvular leak). Ex. 1001 at 2:42-49, 14:21-29, Figs. 32-34. An element-by-element breakdown of Claims 1-4 of the '608 patent is provided in the Appendix attached hereto.

It is undisputed that THVs were well known before the June 16, 2004 priority date of the '608 patent. Fabric seals on THVs and similar devices were also well known before the '608 patent's priority date. Indeed, the Patent Office repeatedly rejected claims directed to a THV having a fabric seal, including a

fabric seal with "flaps" (issued Claim 1) and "pockets" (issued Claims 2-3). The claims were allowed only after the applicant added claim language requiring that "the fabric seal extends from the distal end of the replacement valve and back proximally over the expandable anchor." But the examiner's allowance was based on the mistaken belief that this added feature was novel and nonobvious. It was neither. By December 1996, Drs. Alain Cribier and Brice Letac disclosed a THV with a fabric seal ("cover") that extends from the distal end of the replacement valve and back over the expandable anchor:



See WO 98/29057 to Cribier et al. ("Cribier", Ex. 1003) at FIG. 6d (annotations and highlighting added). This feature was disclosed again in 2001 by Percutaneous Valve Technologies ("PVT"), now owned by Petitioner Edwards, in the form of a THV having a "cuff portion" that extends from the distal end of the replacement valve and back over the support stent of the THV:



See WO 03/047468 to Spenser *et al.* ("Spenser," Ex. 1004) at Fig. 1 (annotations and highlighting added).

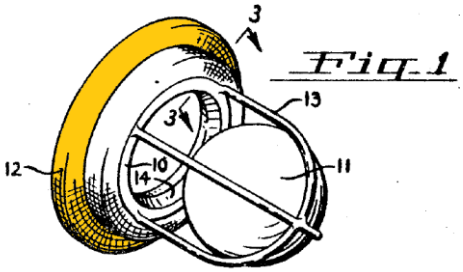
In short, by the '608 patent's priority date, THVs were well known; fabric materials used to seal both internal and external surfaces of THVs and other endovascular prostheses also were well known; and it was well known that these fabric seals, when used on the external surface of an endovascular prosthesis, could form flaps and pockets that extend into spaces in the tissue surrounding the implanted prosthesis to prevent paravalvular leaking. For these reasons, Claims 1-4 of the '608 patent are anticipated and obvious in view of known THV and other stent-based vascular prostheses and should be rendered invalid upon *inter partes* review.

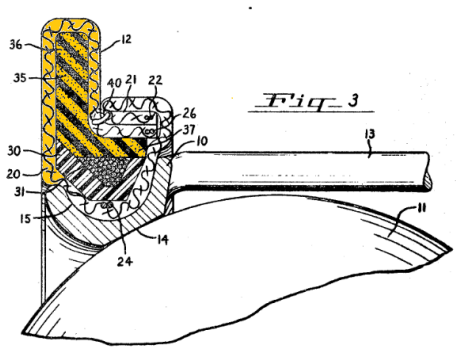
II. STATE OF THE ART AT THE TIME OF THE INVENTION

A. Surgically Implantable Prosthetic Heart Valves

Petitioner Edwards, the worldwide leader in the science of heart valves, was founded in 1958. Edwards' earliest work related to prosthetic heart valves

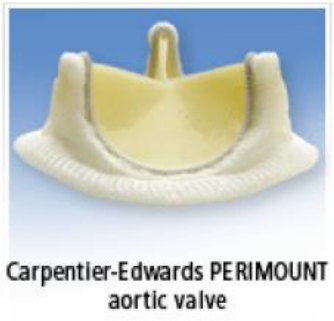
implanted surgically. Ex. 1007 at ¶ 37. One of Edwards' first commercially available prostheses was a ball-and-cage valve known as the Starr-Edwards valve, details of which are described in U.S. Patent No. 3,365,728 (Ex. 1011). Notably, even this early valve prosthesis included a circumferentially oriented sewing ring that was adapted to extend into spaces in the tissue surrounding the implanted prosthesis to prevent paravalvular leaking:





See Ex. 1011, '728 Patent at 1:38-46 and 3:12-20 ("The rubber 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); *see also* Decl. of Nigel Buller (Ex. 1007) at ¶ 38.

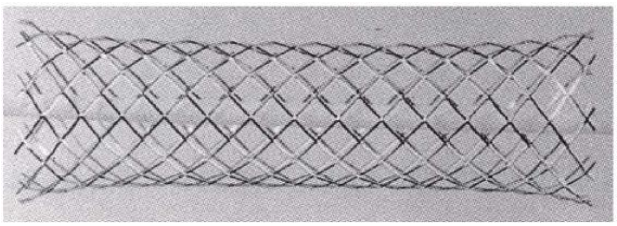
Edwards also developed surgically implantable valves with biological valve leaflets, including Edwards' Perimount valve. *See* Ex. 1007 at ¶ 39. The Perimount valve, first introduced in 1980, included a tri-leaflet bovine pericardial valve and a frame having a fabric sewing ring akin to the Starr-Edwards valve:



B. Stents

To trace the evolution of vascular prostheses implantable via a catheter, one must start with the development of vascular stents. *Id.* at ¶¶ 40-46. In 1969, Charles Dotter introduced the concept of vascular stenting through his work concerning the implantation of stainless steel coils into the peripheral arteries of dogs. *Id.* at ¶ 41. He also taught the concept of a self-expanding stent. *Id.* at ¶ 42.

It was not until the 1980s that stent technology was further developed. Among other stents designed during this time, the Wallstent was the first self-expanding stent to be implanted by a non-surgical catheterization technique in a human coronary artery. *Id.* at ¶ 45. Like the anchor structure disclosed in the '608 patent (*see* Ex. 1001 at 5:45-50, Figs. 32-33), the Wallstent is made with a collapsible and expandable braided-wire structure:

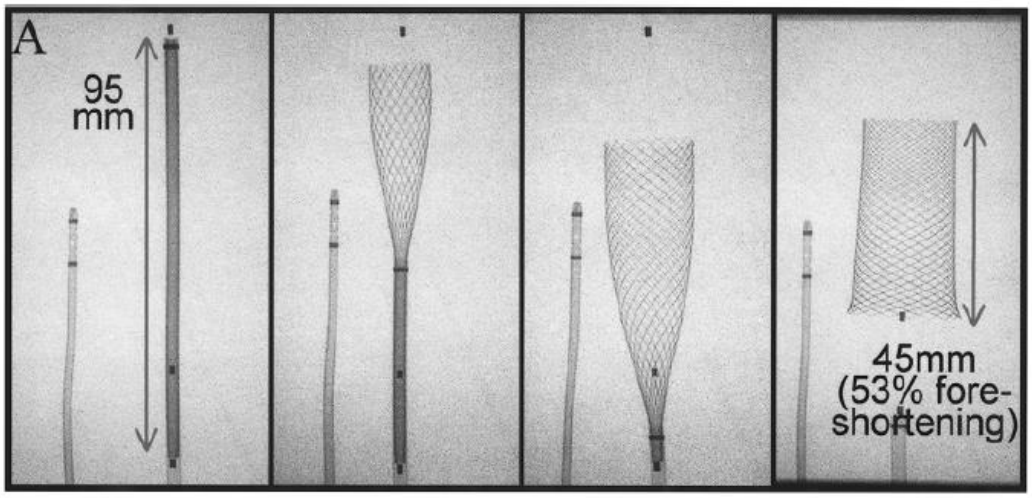


Ex. 1007 at ¶ 45. Balloon-expandable stents were also developed during this time. *See id.* at ¶ 46.

C. Stent Foreshortening

A known property for both self-expanding and balloon-expandable stents is foreshortening, the degree of which is dependent on the overall stent design. *Id.* at ¶¶ 47-51. 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,[1] not foreshorten at all, or lengthen upon radial expansion. *Id.* at ¶ 49.

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



[1] Foreshortening % = (change in length / length of collapsed stent) x 100.

Id. at ¶ 50 (citing Ex. 1013 (Ing publication)).

THVs, discussed *infra*, have also used stent designs that foreshorten. *See, e.g.*, Ex. 1003 (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)).

D. Stent Grafts and Use of Fabric Coverings to Prevent Leaking

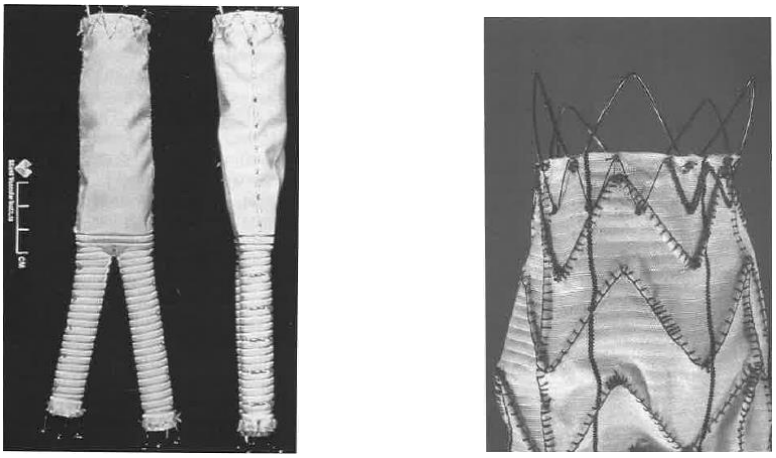
Stents were also developed with a covering (now called stent grafts). By virtue of the covering, stent grafts can be used to isolate and reinforce the wall of a blood vessel from the lumen of the vessel, prevent leakage between the stent and vessel, or to prevent exposure of a metallic stent to the surrounding tissue. Ex. 1007 at ¶ 52.

In 1973, Anatoly Kononov performed a series of animal experiments in which he implanted stent grafts in the aorta. *Id.* at ¶ 53. These stent grafts had a pleated covering as pictured below:

Id. (citing Ex. 1015 (Vossoughi textbook)). In 1985, Nicholas Volodos modified the Kononov stent graft to include a self-expanding stent covered with a Dacron

fabric and became the first to place an endovascular graft transluminally to treat a patient with iliac artery occlusive disease. Ex. 1007 at ¶ 54. Then, in 1990, Huan Parodi and Julio Palmaz implanted a plastically deformable stent graft to treat an abdominal aortic aneurysm, whereupon these devices began to attract widespread interest in the field. *Id.* at ¶ 55.

Two commercial embodiments of stent grafts that were available in the 1990s are pictured below:



Id. at ¶ 56 (citing Ex. 1016 (Dolmatch *et al.* textbook)) (EVT Endograft on left; Talent Endoprosthesis on right). As can be seen in these examples, the fabric coverings have excess material with wrinkles in the graft's expanded state.

Also shown on the lower end of the EVT Endograft (pictured above left) is the well-known use of pre-formed circumferentially oriented pleats in the graft. This pre-formed, corrugated structure permits the endograft to extend and increase its length in the longitudinal direction, akin to an accordion. Ex. 1007 at ¶ 57. As

discussed *infra*, Section V.C., these well-known pleats were recognized by the Patent Office as "flaps" and "pockets" as claimed by the '608 patent, which the patent applicants did not dispute. Specifically, during examination of the '608 patent, the examiner concluded that "[a]n implantable fabric having pleats and pockets is well known in the art, as taught by De Paulis in Figure 2":

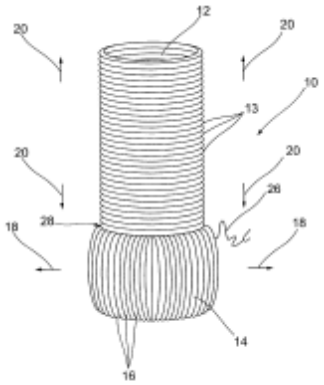


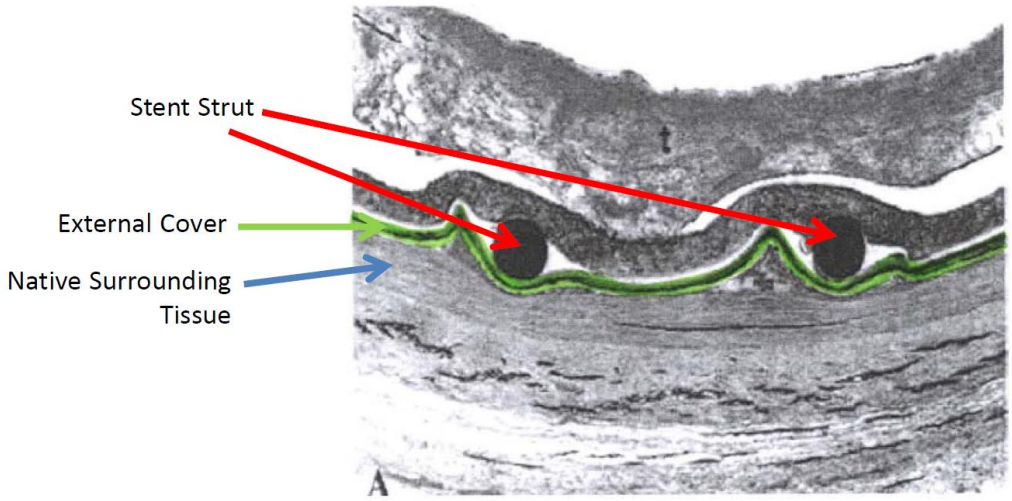
Fig. 2

Ex. 1002 ('608 patent File History), 4/10/14 Non-Final Rejection at 2-3; *see also* U.S. Patent No. 6,352,554 to De Paulis ("De Paulis," Ex. 1021) at Fig. 2.[2]

[2] The aortic grafts detailed in De Paulis are preferably made with Dacron, and comprise "circumferentially extending pleats" or "corrugations" that surround the conduit and "provide a degree of expansion in the longitudinal direction," thereby allowing the graft to "significantly increase its length." *See* Ex. 1021 at 4:52-5:8, Figs. 1-2. "The conduit … may be further provided with a prosthetic valve." *Id.* at 3:51-52.

The examiner further concluded that, in view of De Paulis, it would have been obvious to modify a sealing structure "to include pleats as an obvious alternative design choice." Ex. 1002, 4/10/14 Non-Final Rejection at 2-3.

These fabric coverings serve essentially the same purpose on stents as did the sealing rings on surgical heart valve prostheses—they reduce the risk of blood leaking between the prosthesis and the surrounding tissue (*i.e.*, "endoleaks"). Ex. 1007 at ¶ 59. Aiding in preventing such endoleaks is the selection of fabric that can conform to the surrounding tissue:



Id. (citing Ex. 1015 (Vossoughi et al. textbook)) (Hemobahn stent graft).

The graft material's ability to conform to the surrounding tissue is furthered because the target location typically is smaller in diameter than the stent graft's maximum diameter. Under these conditions, unless the covering is completely elastic, a stent graft made, for example, with Dacron fabric will have excess graft

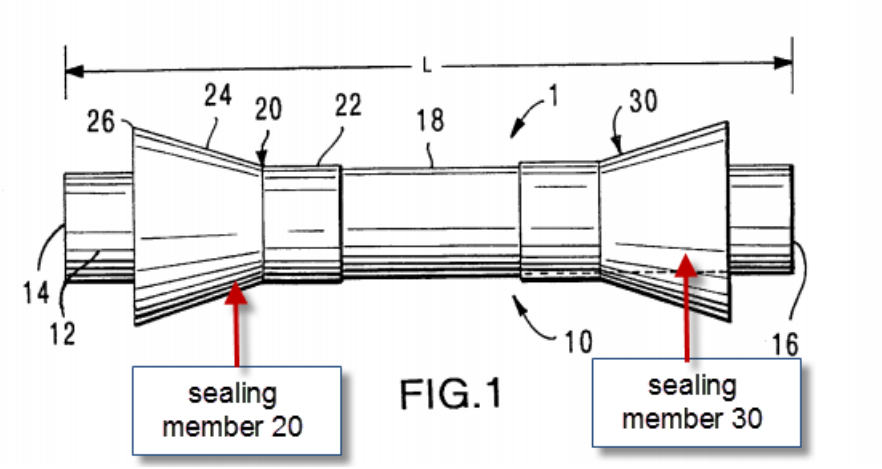
material that surrounds the stent at least when the stent is deployed short of its maximum diameter. Ex. 1007 at ¶ 60. This typically results in the formation of longitudinally oriented pleats in the graft material. *Id.* at ¶ 61 (citing Ex. 1029 (Lawrence *et al.*) at 358 ("The Dacron grafts, most of which were larger in diameter than the native lumen, were longitudinally 'pleated' inside the vessel lumen.").

Well before the June 2004 effective filing date of the '608 patent, multiple graft designs were contemplated to further enhance the external seal to prevent blood from flowing between the seal and surrounding cardiovascular tissue.

For example, U.S. Patent No. 6,015,431 to Thornton ("Thornton," Ex. 1019),[3] which was filed on December 23, 1996, discloses a "tubular member-seal member combination ... [that] has utility in the prevention of leakage flow around the outer surfaces of implantable endolumenal medical devices." Ex. 1019 at 7:5-9. "The seal member is secured to the outer surface and is adapted to occlude leakage flow externally around the tubular wall between the outer surface and the endolumenal wall when the tubular member is deployed within the endolumenal body space." *Id.* at 4:6-13. This means that the seal member will conform to the

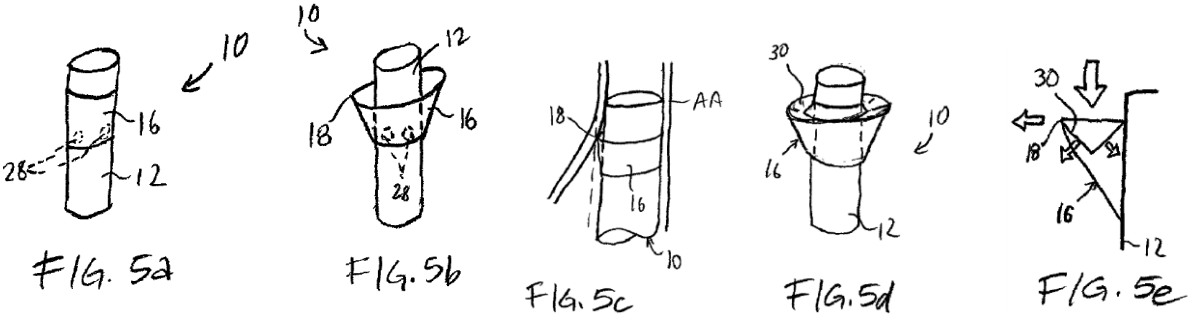
[3] The Thornton prior art reference was not disclosed to the Patent Office during prosecution of the '608 patent.

irregular surface of the surrounding tissue. Ex. 1007 at ¶ 63. Sealing members 20 and 30 are depicted, for example, in Figure 1:



Ex. 1019 at Fig. 1 (annotations added). The sealing members can be formed with Dacron fabric, among other materials, and their flared construction can be imparted by the flow of blood in a particular direction. *Id.* at 7:20-42, 8:31-54, 8:65-67. Thornton further discloses that multiple sealing members may be used, for example in series to provide a sufficient seal. *Id.* at 8:65-9:3. The Thornton prosthesis was commercialized by W.L. Gore & Associates, Inc. and sold as the Gore Excluder stent graft. *See* Ex. 1007 at ¶ 64.

U.S. Patent Application Publication 2003/0236567 to Elliot ("Elliot," Ex. 1005),[4] filed on June 25, 2002, similarly discloses a tubular prosthesis having a stent and one or more fabric "skirts" to seal against endoleaks:



Ex. 1005 at Figs. 5a-5e. The "skirt 16 terminates in a peripheral edge 18 that is spaced from a juncture between the skirt 16 and the tubular body 12. ... [P]ortion(s) of the peripheral edge 18 can be displaced to contact, and form a seal with a surrounding wall. Irregularities and/or wall displacement ... can be responded to by the skirt 16 in minimizing endoleaks about the prosthesis 10." *Id.* at ¶¶ [0024], [0036] – [0038]. Like Thorton, Elliot also discloses the use of multiple sealing members and that the flared construction of the sealing members can be imparted by the flow of blood in a particular direction. *Id.* at ¶¶ [0026], [0038], [0040].

[4] Elliot, which later issued as U.S. Patent No. 7,044,962, was owned by Boston Scientific until December 2012 but was never disclosed to the Patent Office during prosecution of the '608 patent. *See* Ex. 1028 (assignment record).

U.S. Patent Application Publication 2004/0082989 to Cook et al. ("Cook," Ex. 1006), which claims priority to an August 20, 2002 provisional application, also recognized the potential for endoleaks. Ex. 1006 at ¶ [0004].[5] To address this problem, 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":

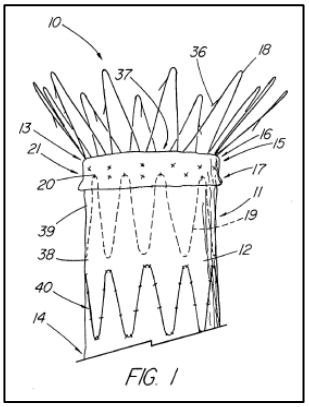


FIG. 1

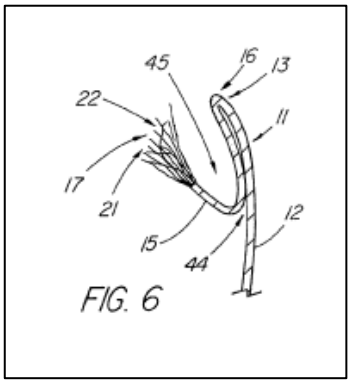


FIG. 6

Id. at Abstract, Figs. 1, 6. Cook explains that the cuff portion can by 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]. This cuff portion can be formed by either "folding [ ] excess material over upon itself," or it can be formed with a separate piece of graft material "such that the proximal edges of the main body and cuff portions 13, 16 each comprise 'cut' or free edges rather than a single folded edge."

[5] The Cook prior art reference was not disclosed to the Patent Office during prosecution of the '608 patent.

Id. 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. 1006 at [0036].

As with bare stents, foreshortening was a known property of stent grafts. *See* U.S. Patent No. 6,206,911 to Milo ("Milo", Ex. 1014) at 1:7-11, 1:33-38; U.S. Patent Application Publication No. 2004/0033364 to Spiridigliozzi *et al.* ("Spiridigliozzi", Ex. 1010) at ¶¶ [0014], [0089]; Ex. 1007 at ¶ 67. It was also known that a degree of stent graft foreshortening can form wrinkles in the graft material, and, separately, that pleats can be created in the graft material to compensate for axial elongation and longitudinal foreshortening of the stent graft. Ex. 1007 at ¶ 67. For example, Milo recognizes that when stents have external coverings, "wrinkling" of the cover may occur upon a certain degree of foreshortening. *See* Ex. 1014 at 1:33-38; 7:18-25. Spiridigliozzi further recognizes that a number of circumferentially oriented pleats can be incorporated into the expanded graft structure (shown below), whereby the pleats can unfold to compensate for axial elongation during delivery and generally return to pleated form due to foreshortening of the stent when deployed:

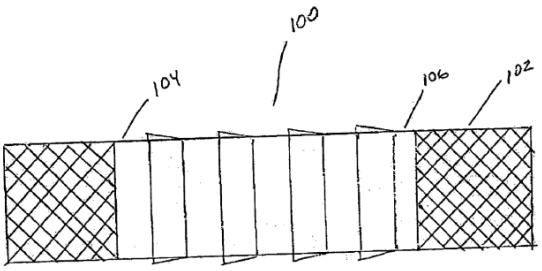


FIG. 10

Ex. 1010 at ¶¶ [0014] ("The number and length of the pleated sections can vary to control the resultant axial elongation, plastic deformation, longitudinal foreshortening and radial shrinkage of the graft material"), [0019], [0089], [0095] – [0098], and Figs. 9-10.[6]

Depending on the desired properties of the stent graft, the foreshortening could be maintained or instead minimized through stent design. *See, e.g.*, Ex. 1014 at 1:16-55; Ex. 1007 at ¶ 68. For those stent grafts designed to foreshorten, a non-uniform surface may form along the length of the graft material upon foreshortening. *Id.* The degree and dimension of any non-uniformities (if any) formed along the length of the graft are related to the degree of stent foreshortening, physical properties and dimensions of the graft material, and the attachment between the graft and stent. *Id.* For example, as discussed *infra*,

[6] The Milo and Spiridigliozzi prior art references were not disclosed to the Patent Office during prosecution of the '608 patent.

Section V.A., when a Dacron graft is secured at a series of locations along its length to a stent, extensive stent foreshortening (*e.g.*, 50% or more) will create circumferentially oriented "flaps" and "pockets" as claimed in the '608 patent. Moreover, graft structures of the type taught by Thornton, Elliot, Cook, and De Paulis detail the use of circumferentially oriented "flaps" and "pockets" regardless of whether the stent foreshortens. Ex. 1007 at ¶ 69.[7] And, under Boston Scientific's broad interpretation of "flaps" and "pockets," discussed *infra* Section V.C.1., each of these references disclose extra "excess material so that the seal can at least partially be distanced from the outer surface of the [stent]" and thus further prevent blood from flowing between the seal and surrounding tissue. *See, e.g.*, Ex. 1007 at ¶ 69 (citing Ex. 1031 (Boston Scientific's August 24, 2016 Response in Opposition Proceedings of EP 2 749 254 B1)).

E. Transcatheter Heart Valve Technology

In 1989, Dr. Henning Rud Andersen conceived of the seminal invention of a permanently implanted transcatheter bioprosthetic heart valve, the subject of the '608 patent. That year, Dr. Andersen built the first prototype by hand. *Id.* at ¶ 71.

[7] Although each of Thornton, Elliot, Cook, and Spiridigliozzi are characterized herein as exemplary stent grafts, each of these disclosures is not limited to stent grafts and broadly applies to a range of devices, including THVs. *See* Ex. 1007 at ¶¶ 63 n.1, 65 n.2, 66 n.3, 67 n.5.

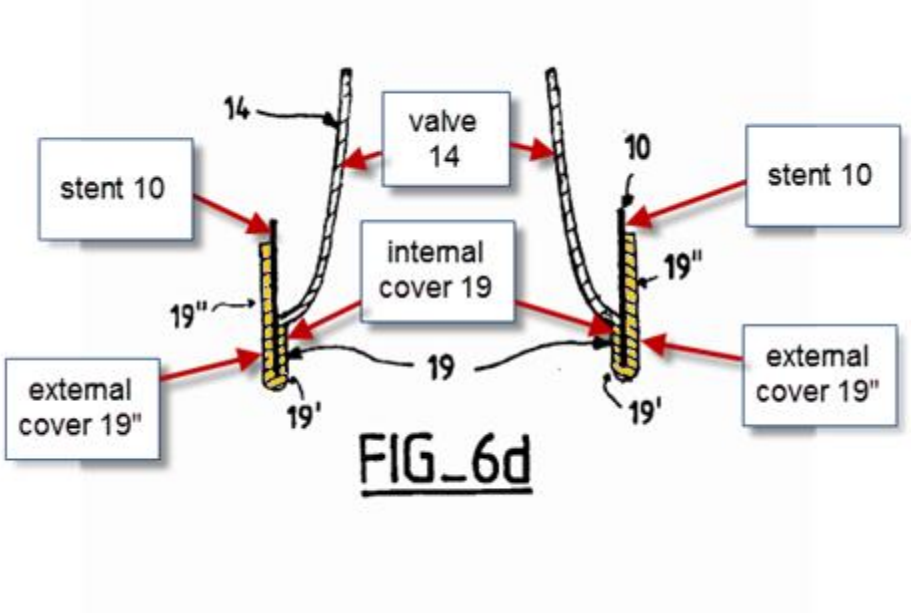
It was a balloon-expandable THV formed with a folded-wire stent and a pig valve. His Danish team successfully implanted the prototype in pigs via a catheter and published the results in a 1992 European Heart Journal article. *See id.* at ¶ 72; *see also* Ex. 1017 (Andersen European Heart Journal publication). This work also led to a series of patents, including U.S. Patent No. 5,411,552. ("Andersen," Ex. 1018). The Andersen patent expands on the early prototypes built by the Danish team, and broadly details a THV comprising a valve mounted within a collapsible and expandable stent structure. *Id.* at 5:9-28. The Andersen patent describes multiple THV embodiments, including embodiments having additional tubular graft material that can be used along the external and internal surface of the THV. *Id.* at 2:56-60, 4:3-17, 7:17-29, Figs. 11-12 ("[T]he stent may be made with a relatively great height and with a cylinder surface which is closed by a suitable material. Thus, a vascular prosthesis known per se is formed wherein the valve is mounted."); Ex. 1007 at ¶ 73.

As with stent grafts, the covers proposed to be used with THVs were designed to conform to the surface of the surrounding tissue. Ex. 1007 at ¶ 74. These covers could be made with low-porosity woven fabric materials, as described by U.S. Patent No. 5,957,949 to Leonhardt *et al.* ("Leonhardt," Ex. 1027), which issued on September 28, 1999:

> Graft material 24 is a thin-walled biocompatible, flexible and expandable, low-porosity woven fabric, such as polyester or PTFE. It is capable of substantially conforming to the surface of the living tissue to which stent 26 coerces it.

Ex. 1027 at 5:53-59 (emphasis added).

In France, Drs. Alain Cribier and Brice Letac conceived of several further THV designs in the mid-1990s that provided the basis for a family of applications claiming priority to a December 1996 filing date. *See, e.g.*, Ex. 1003 (Cribier). Cribier is aimed at providing a THV capable of withstanding the recoil forces of the native aortic valve in treating aortic stenosis. *Id.* at 5:6-10. Cribier is also aimed at providing a THV with a frame covering that "prevent[s] any passage of the body fluid through said frame." *Id.* at 5:6-10, 8:28-9:6; *see also id.* at 5:17-18, 20:26-21:3, 22:11-20. Of particular relevance to the patentability of the '608 claims, Cribier disclosed an embodiment (shown below) where an internal cover [19'] extends from the base of the valve (*i.e.*, the distal end of the valve) to the lower end of the stent [10] and is then "rolled up to be applied to the external wall of the stent" so as to form an external cover [19"]:

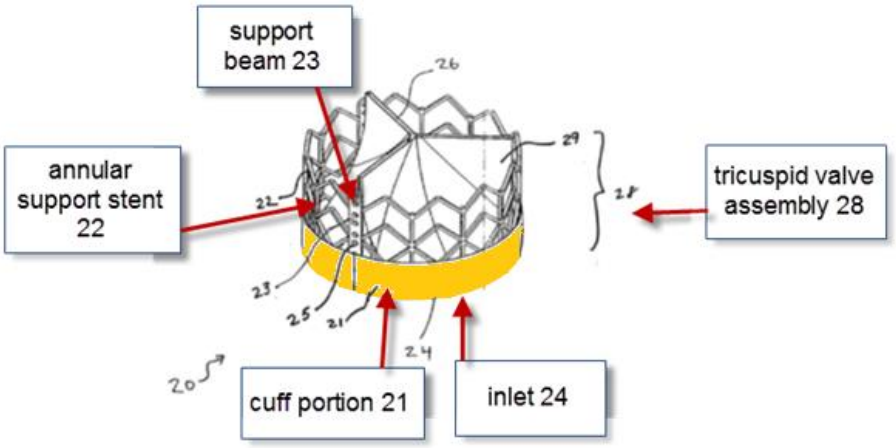


Id. at 22:23-26, Fig. 6d (annotations and highlighting added). The single-piece cover is a tubular structure that can be made with any of the materials disclosed for making the valve structure, which include fabric (*e.g.*, Dacron), biological material (*e.g.*, pericardium), or other synthetic materials (*e.g.*, polyethylene). *Id.* at 8:16-23, 22:11-20. Cribier broadly discloses various ways of securing the cover to the frame. Specifically, the cover can be secured to the frame "at various points of attachment on various parts of the internal [and external] surface" by, for example, suturing, molding, gluing, or soldering the cover to the bars of the frame and, in its expanded state, would prevent blood from flowing between the cover and heart tissue. *Id.* at 22:23-26, 23:15-16, 24:24-27, Fig. 6d; Ex. 1007 at ¶ 141; *see also* Ex. 1003 at 23:12-24:23, Figs. 7, 8a-b.

With respect to the frame and valve structures disclosed by Cribier, the frame can be either self-expanding or balloon expandable, and can foreshorten across a range of percentages, including by 50%. *Id.* at 15:19-22, 16:11-16 (disclosing a stent with an expanded length of 10 mm and a collapsed length of 20 mm); *see also* Ex. 1007 at ¶¶ 80-81. The valve structure broadly includes "any type of valvular structure," including biological valves made with "pericardium, porcine leaflets and the like." Ex. 1003 at 8:16-23, 24:7-13, and 26:13-16. This would include, for example, well known biological valve structures such as bi- and tri-leaflet valves with commissures formed between adjacent leaflets. Ex. 1007 at ¶ 82. In preferred embodiments, the valve structure of Cribier includes commissural supports secured to the surrounding frame in the form of "guiding means" that can extend "from the base to the upper extremity of the valvular structure." Ex. 1003 at 6:1-8:15. The guiding means can be made, for example, with pleats or grooves formed within the tissue, or can be made with strengthening struts incorporated in the tissue. *Id.* at 8:5-11.

In 2001, PVT, a company co-founded by Dr. Cribier, filed a patent application on another THV design that included an external cover:[8]

[8] In 2004, petitioner Edwards acquired PVT. As a result, the Edwards organization now owns the Andersen, Cribier, and Spenser patent portfolios.



See Ex. 1004 (Spenser) at Fig. 1 (annotations added). As seen above, Spenser discloses a THV having a tricuspid valve assembly 28, annular support stent 22 including support beams 23 for securing the commissures of the valve, and a cuff portion 21 wrapped around the support stent 22 at the inlet 24. *Id*. at p. 22 and Fig. 1. The support beams for the valve commissures described by Spenser are designed such that their length remains constant, thereby providing a stable attachment region for the commissures of the valve while the remaining portions of the THV undergo a degree of foreshortening. *Id.* at pp. 34-35. Spenser further discloses that the cuff portion can be rolled up over the edge of the frame so as to provide a "sleeve-like" portion at the inlet. *Id*. at p. 21. According to Spenser, rolling up the slack to form a cuff over the inlet helps prevent leakage. *Id*. ("To prevent leakage from the inlet it is optionally possible to roll up some slack wall of the inlet over the edge of the frame ... ."). The cuff portion can be formed with PET fabric (Dacron). *See id.* at pp. 25, 33.

In 2001, a different THV design was described by Dusan Pavcnik in U.S. Patent Application Publication 2001/0039450 ("Pavcnik," Ex. 1009). Pavcnik disclosed an implantable valve that is deployed "within a bodily passage, such as a blood vessel or the heart":

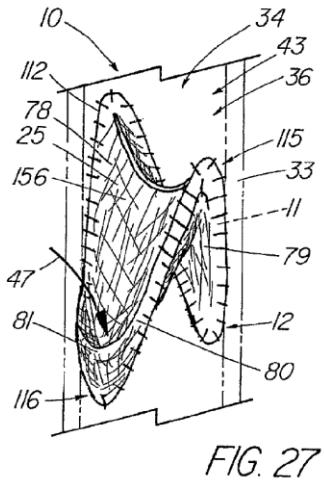


FIG. 27

Ex. 1009 at ¶¶ [0006], [0067], Fig. 27. The stent can be either self-expanding or balloon expandable, and is covered in part by a biomaterial or a synthetic material such as Dacron. *Id.* at ¶¶ [0067]-[0068]. Pavcnik also discloses the formation of an enhanced sealing structure. The enhanced sealing structure of Pavcnik is in the form of "corner flap[s] 81 or pocket[s]" secured to the stent at the edges of each "flap" or "pocket" and positioned at discrete locations around the prosthesis. *Id.* at ¶ [0074]. "This corner flap 81 can serve to catch retrograde blood flow 47 to provide a better seal between the [prosthetic valve] device 10 and the vessel wall 70 as well as providing an improved substrate for ingrowth of native intimal tissue from the vessel 33 ... ." *Id.* Boston Scientific's commonly owned European Patent

2 926 766 B1 ("EP '766") acknowledges the teachings of Pavcnik as prior art, and notes that "US 2001/0039450 describes a venous valve device having a generally serpentine shape and a corner flap." *See* Ex. 1030 at 3:44-46.

Depending on the desired end use, the device described by Pavcnik could be used as either a stent graft or a THV. *See id.* at ¶ [0012] ("The artificial valve traps retrograde blood flow and seals the lumen, while normal blood flow is permitted to travel through the device. In related embodiments, the device can be used to form a stent graft for repairing damaged or diseased vessels." (Emphasis added)). As such, Pavcnik, like De Paulis and Andersen, discloses the interchangeability of stent graft and prosthetic heart valve technology, and confirms that sealing structures with loose material used on stent grafts like those taught by Elliot, Thornton, Cook, and Spiridigliozzi, discussed *supra* Section II.D., are also

applicable to THVs like those taught by Cribier and Spenser, discussed *supra* Section II.E. Ex. 1007 at ¶ 87.[9]

III. MANDATORY NOTICES

Pursuant to 37 C.F.R. § 42.8(a)(1), Edwards provides the following mandatory disclosures.

A. Real Party-In-Interest

Pursuant to 37 C.F.R. § 42.8(b)(1), Edwards certifies that Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences AG are the real parties-in-interest.

B. Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), Edwards states that the '608 patent has been asserted in the pending litigation captioned *Boston Scientific Corp. v. Edwards Lifesciences Corp.*, C.A. No. 16-275 (SLR).

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[9] Stent graft patents and publications typically are cited in THV patents, including in the '608 Patent, which further confirms the relatedness of certain aspects of stent graft technology and THV technology. Ex. 1007 at ¶ 87 n.3. For example, the '608 Patent cites U.S. Patent No. 5,476,506 to Lunn (Ex. 1034, "Lunn"), which describes a stent graft with circumferentially oriented and longitudinally oriented pleats. *See, e.g.*, Ex. 1034 at 1:47-2:46, 3:10-18, 4:7-15, 5:59-66, Figs. 1-3 and 6b.

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

Pursuant to 37 C.F.R. § 42.8(b)(3) and 42.10(a), Edwards designates the following counsel:

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

D. Service Information

Pursuant to 37 C.F.R. § 42.8(b)(4), service information for lead and back-up counsel is provided above. Edwards consents to electronic service by email to gcordrey@jmbm.com, began@mnat.com, and cnyarady@paulweiss.com.

IV. 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

Pursuant to 37 C.F.R. § 42.104(a), Edwards hereby 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 the claims of the ’608 patent on the grounds identified herein.

B. Identification of Challenge

Pursuant to 37 C.F.R. § 42.104(b)(1)-(5), Edwards requests *inter partes* review and cancellation of claims 1-4 of the ’608 patent as set forth below in Sections V-VII.

V. SUMMARY OF THE ’608 PATENT

A. Disclosure of the ’608 Patent

Citing the work of Dr. Andersen and his colleagues, the ’608 patent acknowledges that “advancements in minimally invasive surgery and interventional cardiology have encouraged some investigators to pursue percutaneous replacement of the aortic heart valve.” ’608 patent at 1:53-56. Focusing primarily on self-expanding THV technology, the inventors of the ’608

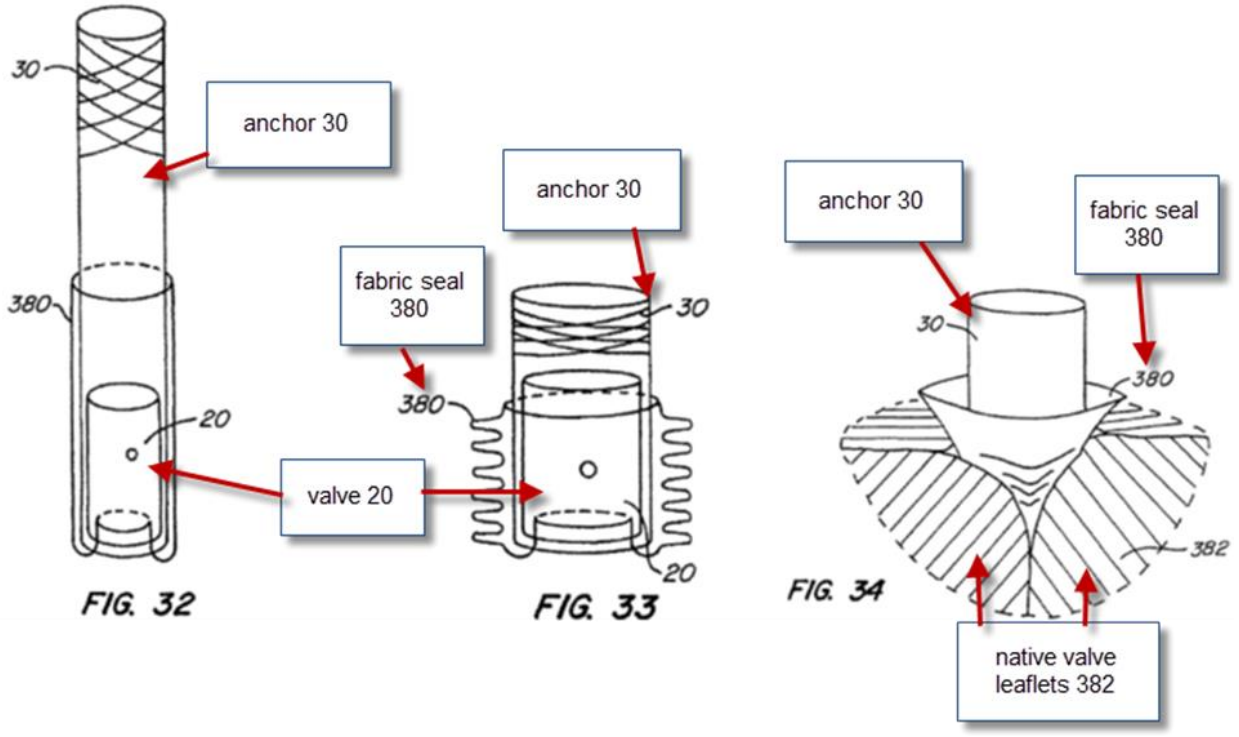
patent contend that "[s]tandard self-expanding systems have very poor accuracy in deployment" and a "lack of radial strength." *Id.* at 1:63-64, 2:10-11.

To address these problems, the '608 patent discloses a repositionable and retrievable THV with a locking mechanism actuated via stent foreshortening, wherein the "[i]mposed foreshortening will enhance radial force applied ... to surrounding tissue over at least a portion of [the] anchor ... ." *Id.* at 5:29-6:12, 6:56-66. The THV described by the '608 patent includes a collapsible and expandable anchor, commissure support elements, and a replacement valve secured to the commissure support elements. *Id.* at 3:5-12, 5:60-63, 16:63-65, 21:19-24. The commissure support elements are described as separate elements that suspend the valve within the anchor such that the valve commissures are not impacted by the foreshortening of the anchor. *Id.*; *see, e.g.*, Figs. 2A, 2B, 3B. Preferably, "at least a portion of the replacement valve is wrapped about an end of the anchor in a deployed configuration." *Id.* at 3:5-12. This can be achieved, for example, by configuring the valve to "evert about the anchor during endovascular deployment." *Id.* at 2:42-49. The '608 patent is silent as to the structure of the valve itself. Ex. 1007 at ¶ 95.

The '608 patent discloses that the anchor "preferably is fabricated by using self-expanding patterns ... , braids and materials, such as a stainless steel, nickel-titanium ('Nitinol') or cobalt chromium ... ." Ex. 1001 at 5:45-50. "In

order to avoid delivery of [the] anchor [ ] on a balloon for balloon expansion," the THV utilizes an anchor actuator that uses external non-hydraulic or non-pneumatic force via control wires and rods to actively foreshorten the anchor and expand the THV to its deployed state. *See, e.g.*, *id.* at 5:64-6:19, 7:30-54. The "[i]mposed foreshortening will enhance radial force applied ... to surrounding tissue over at least a portion of [the] anchor ... ." *Id.* at 5:29-6:12, 6:56-66. The locking mechanism locks the anchor in its fully deployed state. *See, e.g.*, *id.* at 6:13-31, 7:55-8:3. Up until the anchor is locked, the THV is both repositionable and retrievable. *See, e.g.*, *id.*

The THV described by the '608 patent also includes a structure intended to prevent blood from flowing between the THV and surrounding heart tissue. As claimed, this structure is in the form of a fabric seal having "flaps" and "pockets," which are purportedly shown (but not explicitly identified) in figures 33 and 34:

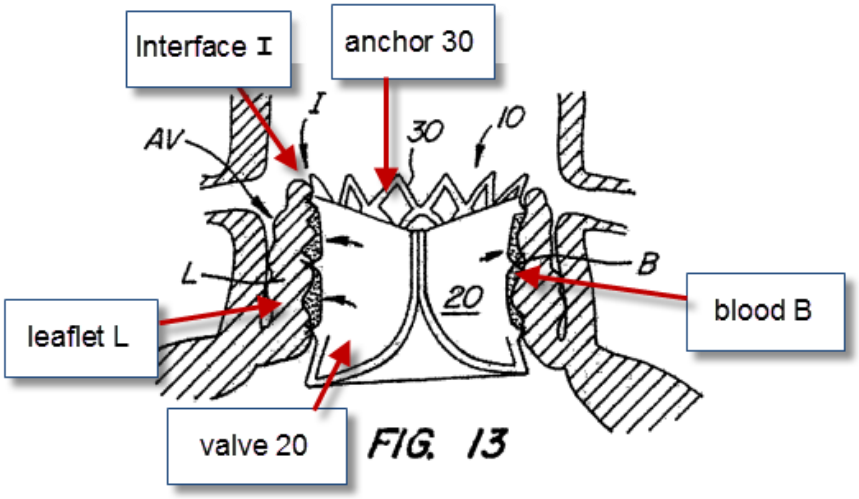


Id. at Figs. 32-34 (annotations added). Figure 33 shows, in part, an anchor 30 and a replacement valve 20 inside the anchor. A fabric seal secured to the anchor overlaps the distal, *i.e.*, lower, end of the replacement valve, extends across the bottom of the anchor, and then extends up along the outside of the anchor with circumferentially oriented corrugations. *Id.* at 14:21-29, Fig. 33.

In Figure 32, the anchor is in the collapsed state, ready for implantation. In that state, the anchor is elongated and the fabric seal lies in a smooth cylinder surrounding the anchor. In Figure 33, the anchor has been radially expanded. As it expands radially, the anchor shortens in the longitudinal direction (*i.e.*, the anchor foreshortens). As depicted, the anchor undergoes an extensive degree of foreshortening, which is expected given that the anchor is formed with a braided-

wire structure akin to a Wallstent and is also actively foreshortened. *See supra* Section II.C. (confirming that a braided-wire stent structure can foreshorten at least 53%). The result is that the fabric is no longer extended longitudinally and instead, as shown in Figure 33, "bunches up to create fabric flaps and pockets." Ex. 1001 at 14:21-29, Figs. 33-34.

The "flaps" and "pockets" purportedly "extend into spaces formed by the native valve leaflets." Ex. 1001 at 14:21-29. Some of the "spaces formed by the native valve leaflets" are illustrated in Figure 13, where "interface I between leaflets L and anchor 30 may comprise gaps where blood B may seep through":



Id. at 12:19-27, Fig. 13 (annotations added); *see also* Fig. 34.

Beyond Figures 32-34 and the limited description in the specification associated with these figures (col. 14, ll. 21-29), the '608 patent does not provide any guidance as to the scope or meaning of "flaps" and "pockets." As a result, there are a series of deficiencies in the specification of the '608 Patent as

it relates to "flaps" and "pockets," which are highlighted in the Declaration of Dr. Buller. Ex. 1007 at ¶¶ 100-102. Indeed, the specification fails to impose any parameters on "flaps" and "pockets."

That said, the skilled person would appreciate that circumferentially oriented "flaps" and "pockets" could be achieved by extensive anchor foreshortening (*e.g.*, 50% or more) when the fabric seal, made, for example, of Dacron, is secured at points along its length to the anchor. *Id.* at ¶¶ 103-105. Boston Scientific's European Patent 2 749 254 B1 ("EP '254", Ex. 1022) confirms the point. Figures identical to Figures 32-34 as well as an identical supporting description of those Figures appear in EP '254. *See* Ex. 1022 at Figs. 22-24 and ¶ [0062]. EP '254 provides additional disclosures missing from the '608 patent that concern the magnitude of foreshortening embodied by the invention, which is consistent with the known foreshortening capabilities of braided-wire stent structures. *See supra* Section II.C. (depicting the 53% foreshortening of the Wallstent). EP '254 discloses that in the collapsed configuration, the anchor preferably has a length between 5 and 170 mm, and in the expanded configuration, the anchor preferably has a length between 1 and 50 mm. *Id.* at ¶¶ [0071] – [0072]. EP '254 further discloses that "the ratio of deployed to collapsed/sheathed lengths is preferably between about 0.05 and 0.5, more preferably about 0.1 to 0.35, or more preferably about 0.15 to 0.25." *Id.* at ¶ [0073]. These correspond to a total foreshortening

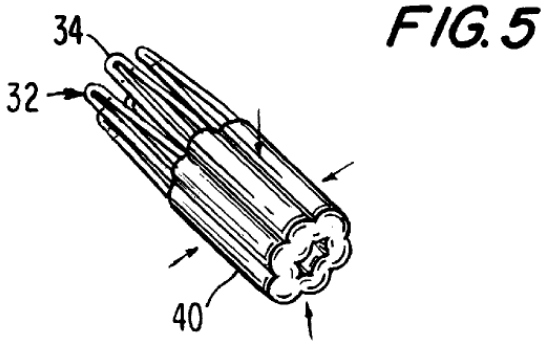
range of 50-95%. Consistent with known braided-wire stent structures, EP '254 therefore confirms that the anchor described by the '608 patent extensively foreshortens (e.g., 50% or more), which in turn forms "flaps" and "pockets" in the fabric seal. Ex. 1007 at ¶ 104.

Thus, deficiencies of the '608 patent's specification aside, a person of ordinary skill in the art would appreciate that circumferentially oriented "flaps" and "pockets" in a fabric seal could be pre-formed, or could be formed by extensive anchor foreshortening (*e.g.*, 50% or more) when the fabric seal is secured at points along its length to the anchor. *See* Ex. 1007 at ¶ 105.

Separately, Boston Scientific has taken the position that "pleats" are also present in an expanded THV where a THV is compressed to its delivery diameter by crimping, a well-known practice used to prepare a THV for delivery.[10] These longitudinally oriented pleats that Boston Scientific asserts must be present as a result of crimping would be no different to those of an expanded graft structure of the type described by Lawrence, *supra* Section II.D. Pleats of this type are also

[10] Specifically, in characterizing petitioner's own SAPIEN 3 product, Boston Scientific stated that "the outer part of the seal of the SAPIEN 3 has a pleated structure after re-expansion, because the outer part of the seal is compressed to a very small diameter on the balloon catheter. Thereby, pleats are formed by applying external pressure [via crimping]." Ex. 1032 at 46-48.

shown in U.S. Patent No. 5,855,601 to Bessler *et al.* ("Bessler", Ex. 1033), which details a compressed, self-expanding THV with a pleated seal:



Ex. 1033 at Fig. 5.

B. Prosecution History of the '608 Patent

The '608 patent issued from U.S. Patent Application No. 12/492,512 ("the '512 application," Ex. 1002), entitled "Everting Heart Valve," which was filed on June 26, 2009. The '512 application claims a priority chain back to a June 16, 2004 filing date. The '512 application names Ulrich R. Haug and six others as inventors. The application was originally assigned to Sadra Medical, Inc., then later assigned to Boston Scientific Scimed, Inc. Originally filed Claim 1 – the sole independent claim – claimed, in part, a system for replacing a heart valve comprising an expandable anchor, a commissure support element, a commissure portion of a valve leaflet attached to the commissure support element, and a seal at least partially disposed around an exterior portion of the anchor. Ex. 1002, Prosecution History, 6/26/09 Claims.

On December 17, 2010, the Patent Office issued a Non-Final Office Action rejecting all pending claims as anticipated under 35 U.S.C. § 102(b) in view of U.S. Patent Application Publication No. 2001/0021872 to Bailey *et al.* ("Bailey," Ex. 1020):

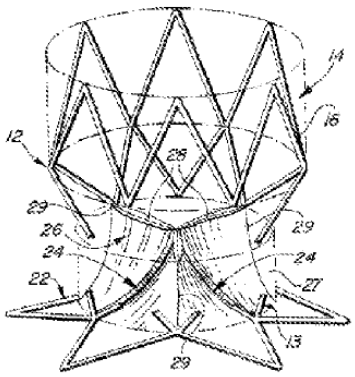


Figure 2 of Bailey

Ex. 1020, Bailey at Fig. 2. In a response dated March 7, 2011, the applicants did not dispute that Bailey discloses an expandable anchor, a replacement valve commissure support element, and a commissure portion of a replacement valve leaflet as required by pending claim 1. *Id.* at 3/7/11 Remarks at 3-4. Applicants disputed only that Bailey did not disclose a seal as claimed. *Id.* The applicants argued that "[i]t is clear from the figures and disclosure (Figures 15A-E, paragraphs [0102] and [0103]) that the recited 'seal' is a structurally distinguishable component." *Id.* at 4. The Patent Office disagreed with applicants' argument and issued a Final Rejection on the same grounds on April 8, 2011. *Id.*,

4/8/11 Final Rejection at 3-4 (finding that Bailey's "outer graft member ... disposed around an exterior portion of the anchor" is a seal as claimed).

On May 2, 2011, applicants filed an Amendment After Final Rejection and Request for Reconsideration. There, the applicants amended claim 1 and presented new independent claim 9 and 10, along with six new dependent claims. Each of independent claims 1, 9, and 10 was now aimed at claiming a different embodiment of the external seal. Specifically, claim 1 required a seal comprising "an expandable foam disposed around a circumference of a wire," claim 9 required a "fabric" seal "wherein the fabric seal has an undeployed state and a deployed state, wherein in the deployed state the fabric seal comprises flaps that extend into spaces formed by native valve leaflets," and claim 10 required a seal comprising "at least one sac disposed about the exterior of the anchor." *See id.*, 5/2/11 Amendment After Final at 2-4. But for the limitations concerning the seal structure, all other limitations in claims 1, 9, and 10 were identical. Applicants argued that support for the claim 1 embodiment could be found at paragraph [0111] of the specification and Figures 27-31, support for the claim 9 embodiment could be found at paragraph [0112] and Figures 32-34, and support for the claim 10 embodiment could be found at paragraphs [0102]-[0104] and Figures 14-16C. *Id.* at 6-7. According to the applicants, Bailey failed to disclose an external seal as claimed in claims 1, 9, and 10. *Id.*

On May 19, 2011, the Patent Office issued an Advisory Action declining to review the newly amended claims, prompting a June 10, 2011 Request for Continued Examination. In response, the Patent Office issued a Requirement for Retriction/Election on December 30, 2013, noting that the seal structures claimed in claims 1, 9, and 10 are patentably distinct species. Applicants in turn elected to pursue claim 9 directed at the "fabric" seal with "flaps," and filed new dependent claims 16-24. *Id.*, 2/28/14 Response to Election/Restriction. According to the applicants, support for claims 16-24 is found in the specification at paragraphs [0068], [0069], [00112], and [00113], and in Figures 1A, 1B, and 32-34. *Id.* at 4.

The Patent Office issued a Non-Final Rejection of all pending claims on April 10, 2014. With respect to independent claim 9 and dependent claims 16-21, the examiner rejected the claims as obvious under 35 U.S.C. § 103(a) over Leonhardt (Ex. 1027) in view of U.S. Patent No. 6,352,554 to De Paulis ("De Paulis," Ex. 1021). The examiner found that Leonhardt discloses all of the elements of these claims except for a fabric seal comprising flaps and pockets, which he found is an obvious feature in view of De Paulis:

> Leonhardt et al. does not teach the fabric seal comprising flaps and pockets. An implantable fabric having pleats and pockets is well known in the art, as taught by De Paulis in Figure 2, and would have been obvious to one of ordinary skill in the art to modify the seal of

> Leonhardt *et al.* to include pleats as an obvious alternative design choice.

Id., 4/10/14 Non-Final Rejection at 2-3 (emphasis added).

The applicants responded on July 9, 2014, and amended claim 9 to include a requirement that "a distal end of the replacement valve leaflet is attached to the fabric seal 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, the fabric seal being adapted to prevent blood from flowing between the fabric seal and heart tissue."[11] *See id.*, 7/9/14 Amendment at 2 (underlining in original to reflect added claim language). Applicants argued that support for the amendment can be found at paragraph [00112] and Figure 32 of the specification. *Id.* at 4. Applicant's further argued that:

> As shown for example in FIG. 32 of the immediate Application ... the fabric seal doubles over the distal end of the expandable anchor.

[11] The '608 patent defines the "distal" end as the end of the THV farthest along the catheter from the surgeon (i.e., the inflow end of the valve); the end of the THV closest along the catheter to the surgeon (i.e., the outflow end of the valve) is defined as the "proximal" end. *See, e.g.*, Ex. 1001 at 12:51-67; Ex. 1007 at ¶ 115 n.11.

> Further, paragraph [00112] states, in-part, "a fabric seal 380 extends from the distal end of valve 20 and back proximally over anchor 30 during delivery." ... In contrast, neither Leonhardt nor De Paulis, whether considered independently or in combination, teaches, suggests, or otherwise renders obvious a "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," as is claimed.

Id. at 4-5 (emphasis added).

Based on applicants July 9, 2014 amendments and arguments, and the examiner's mistaken belief (as evidenced by Cribier and Spenser) that a fabric seal extending from the distal end of the valve and back over the anchor is novel and nonobvious, the examiner issued a Notice of Allowance on October 6, 2014. Claims 9 and 17-24 were allowed, which became claims 1 and 2-9, respectively, in the '608 patent as issued.

C. Claim Construction

A claim subject to *inter partes* review receives the "broadest reasonable construction in light of the specification of the patent in which it appears." 42 C.F.R. § 42.100(b). Edwards submits, for the purposes of this *inter partes* review

only and pursuant to 37 C.F.R. § 42.104(b)(3), that the terms in Claims 1-4 of the ’608 patent 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.

That said, two terms used in the '608 patent – “flaps” and “pockets” – are not terms of art in the field of interventional cardiology, and would benefit from evidence concerning the ordinary and customary meaning of these terms as they would be understood by a person of ordinary skill in the art in the context of the '608 patent’s specification and prosecution history. Intrinsic and extrinsic support for “flaps” and “pockets,” along with proposed constructions for these terms, is set forth below.

1. “Flaps”(Claims 1-4)

The only disclosure of “flaps” in the ’608 patent specification identified by the applicants during prosecution appears in the description of Figures 32-34:

> FIGS. 32-34 show another way to seal the replacement valve against leakage. A fabric seal 380 extends from the distal end of valve 20 and back proximally over anchor 30 during delivery. 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, particularly when the pockets are filled with blood in response to backflow blood pressure. This arrangement creates a seal around the replacement valve.

Ex. 1001, col. 14:21-28 (emphasis added). As illustrated in Figures 32-34, *supra* Section V.A., the "flaps" are formed when the anchor shortens as it transitions from its undeployed (collapsed) state to its deployed (expanded) state, causing the fabric seal to foreshorten along with the anchor and, in turn, form circumferentially oriented "flaps." Although Figures 33 and 34 only identify "fabric seal 380" and do not separately identify the "flaps" and "pockets" purportedly illustrated in those figures, these Figures appear to depict a fabric seal 380 having circumferentially oriented folds in the fabric seal and a circumferentially oriented unattached end in the fabric seal. Ex. 1007 at ¶¶ 121-122.

During prosecution of the '608 patent, the examiner used "flaps" and "pleats" interchangeably: "Leonhardt et al. does not teach the fabric seal comprising flaps and pockets. An implantable fabric having pleats and pockets is well known in the art, as taught by De Paulis ... ." Ex. 1002, 04/24/14 Office Action at 3 (emphasis added). Moreover, the "flaps" taught by De Paulis are described as "circumferentially extending pleats" and "circumferentially extending corrugations." Ex. 1021 at 4:52-5:1.

In Boston Scientific's commonly owned EP '254, which contains figures identical to Figures 32-34 of the '608 patent and related descriptions missing from the '608 patent, "flaps" and "pleats" are also used interchangeably to describe the sealing structures purportedly shown in Figures 32-34. *See* Ex. 1022 [EP '254] at ¶ [0103] ("Figures 22-24 [identical to Figures 32-34 in the '608 Patent] illustrate the process of forming a pleated seal around a replacement valve to prevent leakage. ... The bunched up fabric or pleats occur, in particular, when the pockets are filled with blood in response to backflow blood pressure."); *see also id.* at ¶ [0017] ("The fabric seal can bunch up to create fabric flaps and pockets. The seal can bunch up and creates pleats. The seal can comprise a pleated seal.").

This is consistent with the dictionary definition of "flap," which is "something that is broad, limber, or flat and usu[ally] thin and that hangs loose or projects freely: as a: a piece on a garment that hangs free b: a part of a book jacket that folds under the book's cover c: a piece of tissue partly severed from its place of origin for use in surgical grafting d: an extended part forming the closure (as of an envelope or carton)." Ex. 1024 (Merriam-Webster's Collegiate Dictionary); *see also* Ex. 1023 (American Heritage College Dictionary) (defining "flap" as "a flat, usually thin piece attached on one side; a projection or hanging piece usually intended to double over and protect or cover."). And the dictionary definition of

"pleats" is "a fold in cloth made by doubling material over on itself." *See* Ex. 1024.

In light of the overall intrinsic and extrinsic support, a person of ordinary skill in the art would understand that, when applying the broadest reasonable interpretation standard, "flaps" are "circumferentially oriented folds or unattached ends."

It is noted, however, that patent owner Boston Scientific, in both the Opposition proceeding of the EP '254 Patent and German infringement proceeding involving EP '254, has defined "flaps" more broadly. *See* Exs. 1031 and 1032. Specifically, Boston Scientific argues "the wording 'circumferential and horizontal' is neither mentioned in the PCT application WO '980 [i.e., the parent application to EP '254] on page 34, lines 26 to 31, nor on page 86, lines 22 to 32... . Therefore, that the Proprietor cannot be forced to introduce this wording in granted claim 1." Ex. 1031 at 11; *see also* Ex. 1032 at 15-16 ("[F]rom a functional perspective, it is only necessary for the seal to rest loosely on the outer surface of the expandable anchor so that the seal can fill spaces between the anchor and the natural heart valve."). Thus, according to Boston Scientific, no directional limitations on "flaps" should be imposed. As such, under Boston Scientific's broad interpretation, longitudinally oriented "flaps" such as those formed when the graft is expanded short of its maximum diameter and those formed as Boston

alleges when a THV is compressed by crimping, would also fall within the scope of Claims 1-4. *See* Ex. 1007 at ¶ 127.

2. "Pockets" (Claims 2-3)

As with "flaps," the only discussion in the '608 patent specification regarding the term "pockets" is in the same excerpt quoted above from column 14, lines 21-28, which provides that "[w]hen 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, particularly when the **pockets** are filled with blood in response to backflow blood pressure." (Emphasis added). In Figures 33 and 34, only "fabric seal 380" is identified; no identification is made in these Figures as to exactly what portions of the fabric seal constitute "flaps" and what portions constitute "pockets."

The only additional guidance to the meaning of "pockets" is in the '608 patent's prosecution history. As noted above, the examiner rejected limitations concerning "flaps" and "pockets" as obvious in view of the teachings of De Paulis. *See supra* Section V.C. According to the examiner, Figure 2 of De Paulis (Ex. 1021) shows flaps and pockets as claimed by the '608 patent:

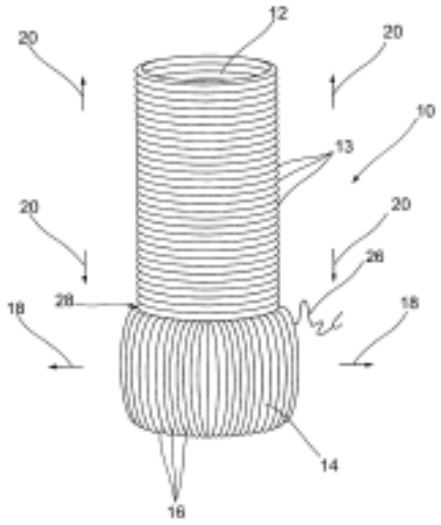


Fig. 2

In view of this limited intrinsic evidence and applying the broadest reasonable interpretation, it would be understood that "pockets," when read in light of the specification, result from the formation of "flaps," meaning that the open spaces or cavities capable of filling with blood are formed by the "flaps" of the fabric seal. Ex. 1007 at ¶ 128. As such, a person of ordinary skill in the art, applying the broadest reasonable interpretation standard, would define "pockets" as "open spaces or cavities formed by flaps of the fabric seal." *Id.*

VI. ORDINARY SKILL IN THE ART

The priority date of the '608 patent is June 16, 2004. A person of ordinary skill in the art as of the 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. 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.

VII. IDENTIFICATION OF HOW THE CHALLENGED CLAIMS ARE UNPATENTABLE

Pursuant to 37 C.F.R. § 42.104(b)(1), (2), and (4), an explanation of how claims 1-4 of the ’608 patent are unpatentable under the statutory grounds, including the identification of where each element of the claim is found in the prior art patents or printed publications, is provided below. Pursuant to 37 C.F.R. § 42.104(b)(5), the exhibit numbers of the supporting evidence relied upon to support the challenges and the relevance of the evidence to the challenges raised, including identifying specific portions of the evidence that support the challenges, are also provided below. *See also* Exhibit List.

A. Ground 1: Claims 1-4 are invalid under 35 U.S.C. § 102(b) over Cribier (Ex. 1003)

Cribier discloses each of the elements of claims 1-4 of the '608 patent.[12] Each subpart detailed below corresponds to the subpart of Claims 1-4 identified in Appendix A attached hereto.

1. Claim 1 Preamble

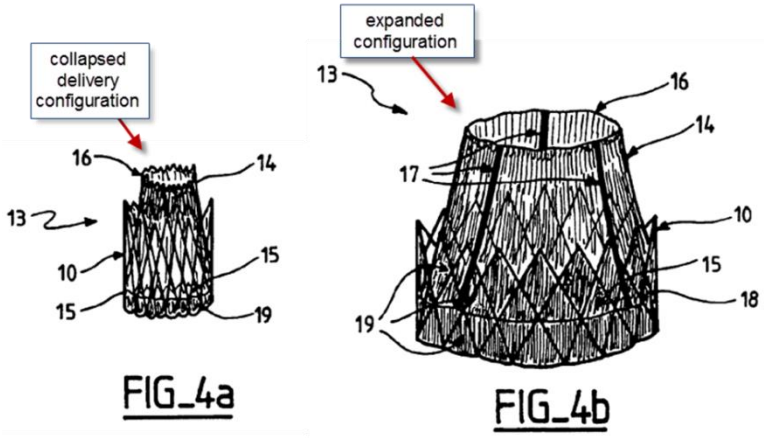
Cribier discloses a valve prosthesis for cardiac implantation or for implantation in other body ducts via a catheter. Ex. 1003 at 5:6-16; Ex. 1007 at ¶ 137.

2. Element 1.1

As seen, for example, in Figures 4a and 4b, Cribier discloses an expandable anchor (*i.e.*, an "expandable frame" on which the valve assembly is mounted) having a collapsed delivery configuration (*i.e.*, a "compressed position") and an expanded configuration (*i.e.*, an "expanded and opened position"), wherein the

[12] Boston Scientific has since admitted in the European Opposition proceedings of EP '254 that Cribier is the "closest prior art" to the subject matter of that patent, which substantially overlaps with the subject matter of the '608 patent. Ex. 1031 at p. 29. But it failed to highlight the teachings of Cribier during prosecution of the '608 patent, instead burying it in an extensive Information Disclosure Statement.

expandable anchor can be implanted transfemorally such that its inflow end is the distal end of the anchor and its outflow end is the proximal end of the anchor:



See e.g.., Ex. 1003 at Figs. 4a and 4b; 9:13-18; 11:12-14; 18:1-6; 25:4-11; Ex. 1007 at ¶ 138.

3. Element 1.2

Cribier discloses a replacement valve commissure support element attached to the expandable anchor in the form of guiding means as disclosed, for example, in Figures 4a and 4b (guiding means / struts 17). *See, e.g.*, Ex. 1003 at Figs. 4a and 4b (pictured above), 18:18-28; Ex. 1007 at ¶ 139. The commissure support elements disclosed by Cribier prevent the valve from inversion into the left ventricle and prevent the risk of regurgitation. Ex. 1003 at 7:5-8:15; 18:29-19:6.

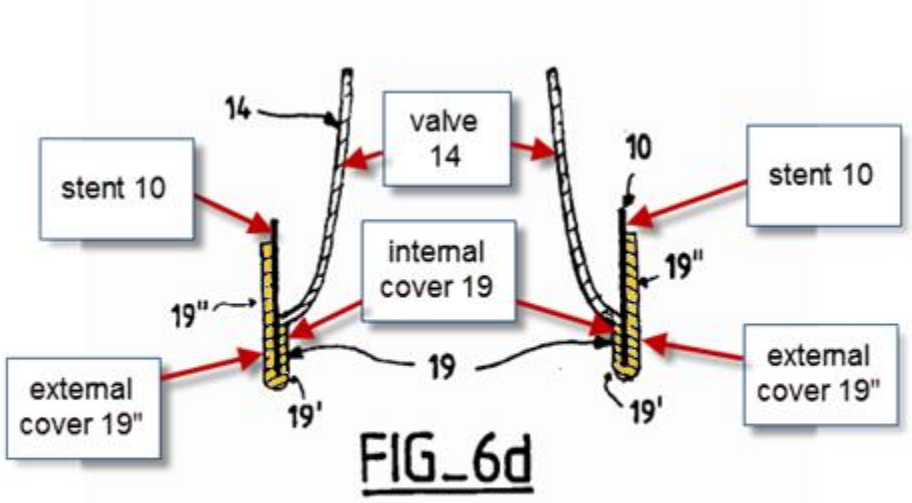
4. Element 1.3

As shown, for example, in Figure 4b above, Cribier discloses a commissure portion of a replacement valve leaflet attached to the commissure support element.

See also id. at 18:18-28. The structure of the valve commissures disclosed by Cribier can vary as Cribier discloses the use of "any type of valvular structure," including valvular structures "made with biological tissues such as the pericardium, or with porcine leaflets." *See id.* at 24:9-10, 26:13-16; Ex. 1007 at ¶ 137. Thus, Cribier contemplates various commissure and commissure support elements beyond those shown, for example, in Figure 4b. Ex. 1007 at ¶ 139.

5. Element 1.4

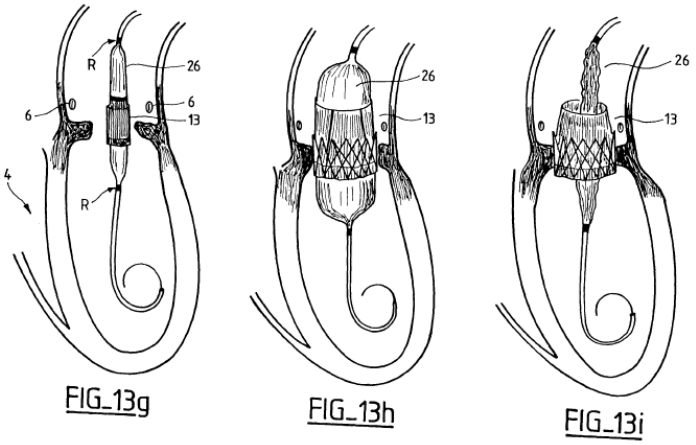
Cribier further discloses various embodiments of a cover or sleeve, which extends at least below the fastening line of the valve and covers the open cells in the frame, thereby preventing blood from leaking through and around the frame. Ex. 1003 at 8:28-9:6. As shown in Fig. 6d, Cribier discloses a fabric seal at least partially disposed around an exterior portion of the expandable frame when the frame is in the expanded configuration:



Id. at Fig. 6d (annotations and highlighting added), 20:26-21:2, 22:23-26, 24:7-13; Ex. 1007 at ¶ 140. The "fabric" disclosed by Cribier can include, for example, Dacron, Ex. 1003 at 8:16-23 and 22:11-20, a fabric known to "substantially conform[ ] to the surface of the living tissue to which stent [ ] coerces it." Ex. 1027 (Leonhardt) at 5:53-56.

6. Element 1.5

The fabric seal disclosed by Cribier, which is disposed around the frame, is able to be posed in multiple positions—for example, an undeployed state (*e.g.*, a "small size in its compressed form") and a deployed state ("When the frame is fully expanded, its intercrossing bars push against the remains of the native stenosed valve…"):



Ex. 1003 at Figs. 13g-13i, 14:23-16:2; Ex. 1007 at ¶ 140.

7. Element 1.6

During deployment, the frame disclosed by Cribier foreshortens from its collapsed state in which the frame length is about 20 mm to a length of between 10 and 15 mm when the frame is expanded. Ex. 1003 at 16:11-16. This degree of foreshortening (*i.e.*, a foreshortening up to 50%) falls within the range of foreshortening that creates flaps and pockets in a fabric seal such as Cribier's, which is secured at multiple locations along its length to the anchor. Ex. 1022 [EP '254] at [0073] (inventors of the '608 patent admitting that 50% foreshortening will create flaps and pockets); *see also supra* Section II.C. (depicting 53% foreshortening of Wallstent) . Thus, Cribier's Dacron fabric seal will form "flaps" (*i.e.*, circumferentially oriented folds or unattached ends), which in the deployed state, extend into spaces formed by native valve leaflets and further prevent the flow of blood between the frame and surrounding tissue. Ex. 1007 at ¶ 142; *see also* Ex. 1003 at 15:23-16:2.

Separately, when applying Boston Scientific's broader interpretation of "flaps" (i.e., no "circumferentially oriented" directional requirement), Cribier also discloses "flaps" that are longitudinally oriented. Ex. 1007 at ¶ 143. Cribier details that the anchor is "expandable from a size of about 4 to 5 millimeters to a size of about 20 to 25 mm in diameter ... ." Ex. 1003 at 14:12-15. Any fabric seal used would necessarily have to accommodate this range of expansion. Thus, to the

extent that the prosthesis described by Cribier is used to treat an annulus diameter smaller than the prosthesis' maximum diameter, excess fabric would surround the prosthesis, thereby forming longitudinally oriented pleats of the type described by Lawrence (in addition to the circumferential pleats described above). *See supra* Section II.D.; Ex. 1007 at ¶ 143. Moreover, Cribier is compressed or crimped as illustrated in Figure 4a, which, according to the Patent Owner, will form pleats in the cover that will remain upon expansion. Ex. 1003 at Fig. 4a; Ex. 1007 at ¶ 143; Ex. 1032 at 46-48; *see also supra* Section V.

8. Element 1.7

As shown in Figure 6d (*see* Element 1.4 above), Cribier discloses a fabric seal that is attached to and extends from the distal end of the replacement valve. Ex. 1003 at FIG. 6d, 21:16-17, 24:7-9; Ex. 1007 at ¶ 141.

9. Element 1.8

As shown in Figure 6d (*see* element 1.4 above), Cribier discloses a cover that extends along the inside surface of the frame at its lower end to form a fabric

seal that is rolled up to be applied to the external surface of the frame.[13] The sleeve is secured to the frame at various points along its length. Ex. 1003 at Fig. 6d, 22:23-26, 23:15-16, 24:24-27; Ex. 1007 at ¶ 141; *see also* Ex. 1003 at 23:12-24:23, Figs. 7, 8a-b. Thus, when the expandable anchor is in the collapsed delivery configuration, the fabric seal of Cribier extends from the distal end of the replacement valve and back proximally over the expandable anchor. Ex. 1007 at ¶ 141.

10. Element 1.9

Cribier discloses that the fabric seal is adapted to prevent blood from flowing between the fabric seal and heart tissue. *See* Element 1.6, *supra*; *see also* Ex. 1003 at Fig. 6d, 22:11-20; Ex. 1007 at ¶ 141.

11. Claims 2-3

Cribier discloses the use of a fabric seal that defines "pockets," *i.e.*, open spaces or cavities formed by flaps of the fabric seal. As explained above under

[13] Notably, during prosecution of the '608 patent, the only limitation that the examiner did not find disclosed in the prior art was a fabric seal that extends from the distal end of the valve structure and back over the outside surface of the frame. But, as is apparent from both Cribier and Spenser, this was a well-known design feature for THVs prior to the June 2004 priority date of the '608 patent. *See* Ex. 1007 at ¶¶ 132-135.

Element 1.6, upon deployment, the frame of Cribier extensively foreshortens, which forms multiple "flaps" in the fabric seal. The "flaps" create a plurality of "pockets" that fill with blood due to backflow blood pressure. *See supra*, Element 1.6; Ex. 1007 at ¶ 144. Applying Boston Scientific's broad interpretation of "flaps", "pockets" are likewise formed when longitudinally oriented "flaps" are formed as described above. *See supra*, Element 1.6.

12. Claim 4

Cribier discloses an expandable anchor formed from stainless steel or nickel-titanium alloy. Ex. 1003 at 9:13-15.

* * *

For at least these reasons there is a reasonable likelihood that claims 1-4 of the '608 patent are anticipated by Cribier. Ex. 1007 at ¶¶ 136-146.

B. Ground 2: Claims 1-4 are invalid under 35 U.S.C. § 103(a) over Cribier (Ex. 1003) in view of Spiridigliozzi (Ex. 1010)

As demonstrated above in Section VII.A. (Ground 1), incorporated herein by reference, Cribier discloses each element of claims 1-4. To the extent Cribier is interpreted as not disclosing or rendering obvious Element 1.6 of Claim 1 ("flaps") or the elements of Claims 2-3 ("pockets"), these were well-known features adopted in similar implantable prostheses, particularly in prostheses that foreshorten. *See supra*, Section II.

For example, Spiridigliozzi teaches a stent graft structure that elongates when compressed and foreshortens when radially expanded. *See* Ex. 1010 at ¶ [0014] (describing a "support structure" of a stent graft that foreshortens). To accommodate stent foreshortening, Spiridigliozzi teaches that a number of circumferentially oriented pleats can be incorporated into the graft structure, which unfold to compensate for axial elongation during delivery and generally return to form upon longitudinal foreshortening of the stent when deployed:

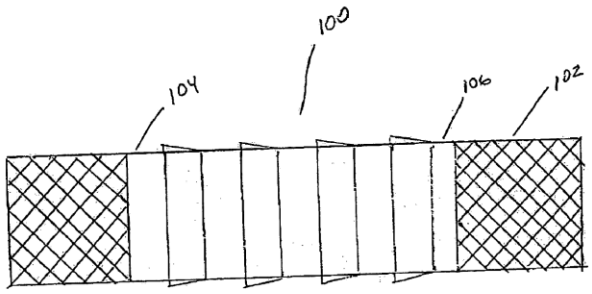


FIG. 10

Id. ("The number and length of the pleated sections can vary to control the resultant axial elongation, plastic deformation, longitudinal foreshortening and radial shrinkage of the graft material"); *see also id.* at ¶ [0019], ¶ [0088]. If the graft structure comprises more than one layer of material, the pleats can be formed in discrete layers of the multi-layered graft structure, or the entire graft structure can be pleated. *Id.* at ¶ [0019] ("The layered sheets may be pleated after being formed into a tubular structure."), [0089], [0095] – [0098], and Figs. 9-10. Once

deployed, it would be obvious to a person of ordinary skill in the art that the structure of the pleats form "flaps" that extend into spaces in the surrounding tissue, and form a plurality of "pockets" that are adapted to fill with blood in response to backflow blood pressure. *See, e.g.*, Ex. 1010 at Figs. 9-10; *see also* Ex. 1007 at ¶ 149.

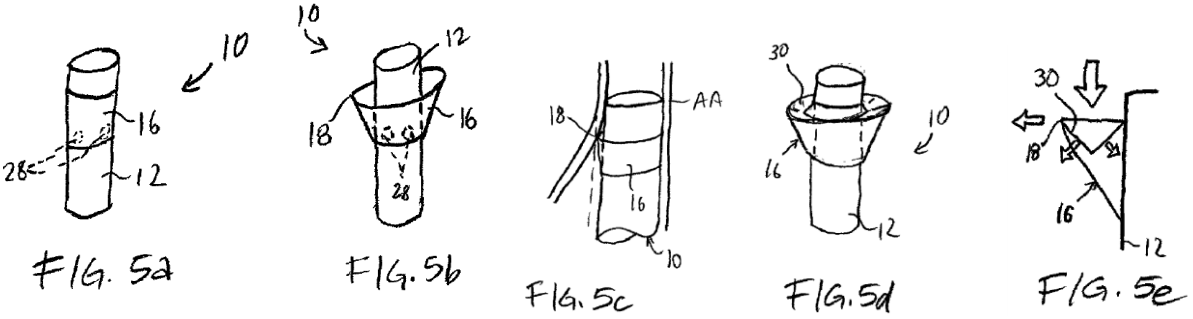
Given that the THV disclosed by Cribier foreshortens up to 50% (Ex. 1003 at 16:11-16), it would have been obvious to one of ordinary skill in the art to incorporate "flaps" and "pockets" in the fabric seal of Cribier in view of Spiridigliozzi's teaching that "pleated sections can vary to control the resultant axial elongation, plastic deformation, longitudinal foreshortening and radial shrinkage of the graft material." *See* Ex. 1007 at ¶¶ 149-150. There is clear motivation to combine the teachings of Cribier and Spiridigliozzi – the Cribier THV extensively foreshortens, and the "flaps" and "pockets" taught by Spiridigliozzi are designed to accommodate such foreshortening in a stent-based structure. *Id.*; Ex. 1010 at ¶ [0089]. "The length and number of pleats can be varied along the length of the graft in accordance with the expected stress on the graft material from the support structure." Ex. 1010 at ¶ [0089].

C. Grounds 3-4: Claims 1-4 are invalid under 35 U.S.C. § 103(a) over Cribier (Ex. 1003) in view of Elliot (Ex. 1005) (Ground 3) or, in the alternative, Thornton (Ex. 1019) (Ground 4)

As demonstrated above, Cribier discloses, expressly or inherently, every element of claims 1-4. To the extent Cribier is interpreted as not disclosing or rendering obvious Element 1.6 of Claim 1 ("flaps") or the elements of Claims 2-3 ("pockets"), other types of well-known sealing structures distinct from those described by Spiridigliozzi would have been obvious to combine with the Cribier THV to render obvious Element 1.6 and Claims 2-3. *See supra*, Section II.

1. Elliot (Ground 3)

For example, Elliot discloses the use of a fabric seal on a tubular prosthesis to prevent leakage between the prosthesis and the surrounding tissue. *See, e.g.*, Ex. 1005 at ¶ [0024]; *see also id.* at ¶¶ [0036] – [0038]. As noted, *supra* n.8, Elliot's broad teachings of a "tubular prosthesis" apply to a range of devices, including THVs. In Figs. 5a-5e, Elliot details an exemplary embodiment of a tubular prosthesis having a stent and an enhanced sealing structure in the form of one or more fabric "skirts" that seal against endoleaks:



See id. at Figs. 5a-5e. The "stent" can be formed from stainless steel or nickel-titanium alloy. *Id.* at ¶ [0022]. The "skirts" can be formed of any material used in preparing the tubular body, which includes fabric ("polyethylene terephthalate (PET)," known commercially as Dacron), polymeric material, natural tissue, or combinations thereof. Ex. 1005 at ¶¶ [0021]-[0022]. These "skirts" terminate in circumferentially oriented unattached ends that are spaced from the tubular prosthesis and conform to the surrounding tissue to seal against endoleaks. *Id.* at ¶¶ [0024], [0036]-[0038]; *see supra* Section II.D. Elliot describes and shows that pockets in the skirts are adapted to be filled with blood, particularly in response to backflow blood pressure. Ex. 1005 at ¶¶ [0010], [0037] ("[E]xpansion of the skirt 16 occurs under pressure of endoleakage. ... [A] portion or portions of the peripheral edge 18 are separated from the tubular body 12 in response to such stray blood flow."). Indeed, embodiments disclosed by Elliot closely resemble the "flaps" and "pockets" of the'608 patent:

Elliot **'608 patent**

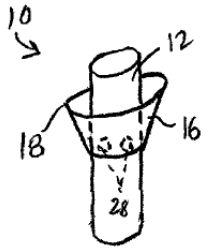


FIG. 5b

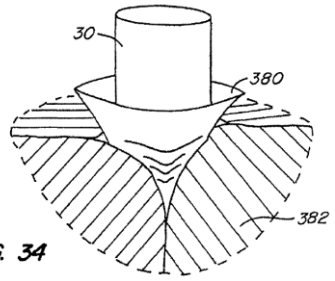


FIG. 34

Compare Elliot Fig. 5b (sealing skirt 16) *with* '608 Patent Fig. 34 (fabric seal 380).

There are a number of reasons that would have prompted a person of ordinary skill to combine the teachings of Cribier with Elliot. First, it would have been obvious to modify Cribier in view of Elliot to further improve the sealing function of the fabric seal and further minimize the risk of paravalvular leaks. *See, e.g.*, Ex. 1003 at [0107]; Ex. 1005 at [0024]; Ex. 1007 at ¶ 158. In fact, Cribier published results of his first six THV procedures and, based on these results, recognized the need for improved sealing function against paravalvular leaks. *See* Ex. 1008 (Cribier Feb. 18, 2004 Publication) at p. 5 ("[S]evere paravalvular aortic regurgitation might impair long-term clinical outcomes after [THV] [ ] implantation. Larger maximal stent diameters and other improvements in stent design might decrease the incidence and severity of paravalvular aortic regurgitation in the future."); Ex. 1007 at ¶ 158. Second, a person of skill in the art would have been prompted to modify Cribier's implantable valve prosthesis with the teachings of Elliot because doing so would merely use known techniques (*e.g.*, use of external skirts to prevent endoleaks) to improve similar devices (*e.g.*, Cribier's implantable valve prosthesis) in the same way taught by Elliot. Indeed, "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." *KSR Int'l Co. v. Teleflex*

Inc., 550 U.S. 398, 417 (2007). As such, a person of skill in the art would have recognized that combining the teachings of the THV technology in Cribier with the external skirts taught by Elliot would have led to predictable results. For at least these reasons, there is a reasonable likelihood that claims 1-4 of the '608 patent are rendered obvious by Cribier in view of Elliot. Ex. 1007 at ¶¶ 151-158.

2. Thornton (Ground 4)

Alternatively, should the patent owner attempt to swear behind the teachings of Elliot, for the same reasons set forth above, Claims 1-4 of the '608 patent are obvious over the teachings of Cribier in view of Thornton.[14] Elliot and Thornton are substantially similar disclosures, which can be seen, for example, in comparing Elliot's Figure 7 (on left) with Thornton's Figure 1 (on right):

[14] To be clear, it is Petitioner's opinion that the teachings of Elliot and Thornton are substantially similar. The teachings of Thornton are nonetheless set forth herein and relied upon as an alternative to Elliot should the patent owner attempt to swear behind the teachings of Elliot.

Elliot **Thornton**

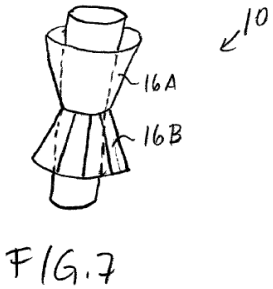


FIG.7

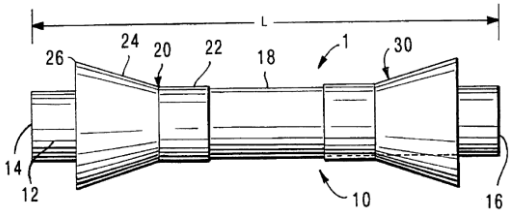


FIG.1

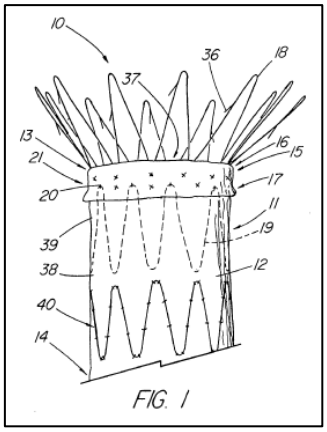
Specifically, the sealing members taught by Thornton are "adapted to occlude leakage flow externally around the tubular wall between the outer surface and the endolumenal wall when the tubular member is deployed within the endolumenal body space." Ex. 1019 at 4:6-13. The tubular member disclosed by Thornton can be formed from stainless steel or nickel-titanium alloy. *Id.* at 15:12-15. The sealing members can be formed with Dacron fabric, among other materials, and the flared construction can be imparted by the flow of blood. *Id.* at Fig. 1, 4:6-13, 6:60-65, 7:20-42, 8:31-54, 8:65-67.

As explained with respect to Elliot, it would have been obvious to one of ordinary skill in the art to combine the teachings of Cribier and Thornton to further improve the sealing function of the fabric seal in Cribier and further minimize the risk of paravalvular leaks. Ex. 1007 at ¶¶ 159-163. As with Elliot, the teachings of Thornton are not limited to stent grafts, and broadly apply to any "implantable endoluminal medical devices." *Supra* n.8. Moreover, even if Thornton were limited to stent graft technology, it was well known to those of ordinary skill in the

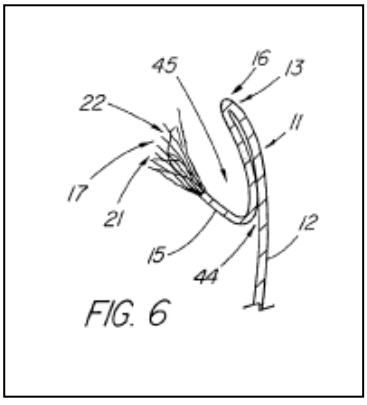
THV art to look to vascular prostheses such as stent grafts in selecting external covers for THVs. Ex. 1018 (Anderson) at 2:56-60, 4:3-17, 7:17-29, Figs. 11-12 (quoted *supra* Section II.E.); *see also* Ex. 1027 (Leonhardt) at 5:53-59 (discussing graft material for THVs); Ex. 1009 (Pavcnik) at ¶ [0012] (drawing equivalence between stent graft and THV fabric covers); Ex. 1002, 4/10/14 Non-Final Rejection at 2-3 (Examiner's reliance on De Paulis stent graft). Moreover, the fact that seals described in Thornton were successfully commercialized as the Gore Excluder stent graft further supports this conclusion, as there would have been a strong likelihood of success that the sealing structures described by Elliot and Thornton would further improve the sealing function of Cribier. *See* Exs. 1025, 1026; *see also* Ex. 1007 at ¶ 163.

D. Ground 5: Claims 1-4 are invalid under 35 U.S.C. § 103(a) over Cribier (Ex. 1003) in view of Cook (Ex. 1006)

Cook also details the features recited in Element 1.6 and Claims 2-3 beyond the disclosure of Cribier and in different configurations from Spiridigliozzi, Elliot, and Thornton, thereby confirming that Ground 5 is distinct from Grounds 1-4. As shown in Figure 1, 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. 1006 at Abstract, Fig. 1. The stent can be formed from nickel-titanium alloy. *Id*. at ¶¶ [0006], [0041]. The cuff portion is fabric and can be formed from Dacron. *Id*. at ¶ [0006]. Cook discloses that the cuff portion 15 could be formed "by folding excess material over upon itself," or as a separate piece, "to help provide a better seal [between] graft portion 11 and walls of the vessel in which the device is placed." *Id*. at ¶ [0026]. Cook also discloses, as shown in Figure 6, the use of a seal that includes both a fold and an unattached end: "[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":



Id. at ¶ [0036], Fig. 6. Thus, Cook discloses various structures of "flaps" that can be adopted to seal the device to the surrounding tissue and "pockets" that will fill with the backflow of blood to prevent endoleaks. Ex. 1007 at ¶¶ 167-168.

The same reasons that would have prompted a person of skill in the art to combine the teachings of Cribier with Elliot or Thornton also apply to the combination of Cribier with Cook. *See supra* Section VII.C. (Grounds 3-4); Ex. 1007 at ¶¶ 164-169. A person of skill in the art would have recognized that applying Cook's teachings of using an external skirt on an implantable prosthesis to prevent leakage to Cribier's implantable valve prosthesis would have led to predictable results. For at least these reasons, there is a reasonable likelihood that claims 1-4 of the '608 patent are rendered obvious by Cribier in view of Cook. Ex. 1007 at ¶¶ 164-169.

E. Ground 6: Claims 1-4 are invalid under 35 U.S.C. § 103(a) over Cribier (Ex. 1003) in view of De Paulis (Ex. 1021)

De Paulis separately details the features recited in Element 1.6 and Claims 2-3 beyond the disclosure of Cribier and in different configurations from Spiridigliozzi, Elliot, Thornton, and Cook, thereby confirming that Ground 6 is distinct from Grounds 1-5. In particular, as the Patent Office concluded and as conceded by the applicants, "[a]n implantable fabric having pleats and pockets is well known in the art, as taught by De Paulis in Figure 2" and it would have been

obvious to modify a sealing structure "to include pleats as an obvious alternative design choice." Ex. 1002 ('608 patent File History), 4/10/14 Non-Final Rejection at 2-3.[15]

The aortic graft detailed by De Paulis (which can also include a prosthetic valve (*see id.* at 3:51-52)) is preferably made with Dacron, and includes, in part, "circumferentially extending pleats" or "corrugations" that "provide a degree of expansion in the longitudinal direction," thereby allowing the graft to "significantly increase its length" when the stent graft is elongated during delivery:

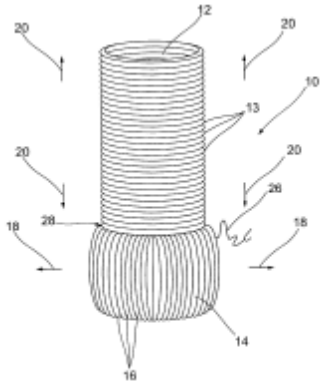


Fig. 2

Ex. 1021 at 4:52-5:8, Fig. 2.

Thus, not only would the "flaps" and "pockets" structure disclosed by De Paulis have been an obvious design choice to adopt with the THV disclosed by

[15] Further confirming the well-known use of fabric seals having flaps and pockets are the stent grafts described in Section II.D.-E., *supra*, including the transluminally deliverable Kononov, EVT, Talent, and Lunn stent grafts.

Cribier, it also would have been obvious to combine the teachings of Cribier and De Paulis as the pleated structure of De Paulis permits the seal to significantly increase in length, which would be a desirable feature in light of the extensive foreshortening of the frame and fabric seal in Cribier.

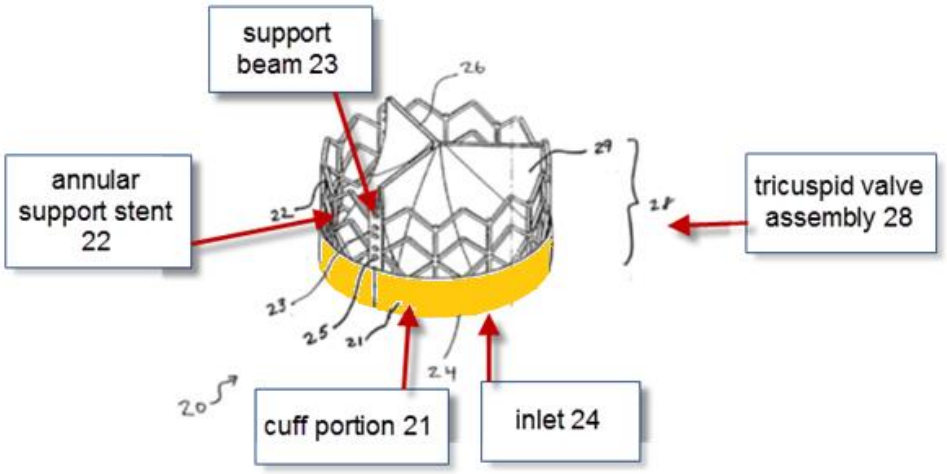
For at least these reasons, there is a reasonable likelihood that claims 1-4 of the ’608 patent are rendered obvious by Cribier in view of De Paulis. Ex. 1007 at ¶¶ 170-174.

F. Grounds 7-8: Claims 1-4 are invalid under 35 U.S.C. § 103(a) over Spenser (Ex. 1004) in view of Elliot (Ex. 1005) (Ground 7) or, in the alternative, Thornton (Ex. 1019) (Ground 8)

Spenser discloses each element of Claims 1-4 of the ’608 patent except for the “flaps” and “pockets” limitations of Element 1.6 and Claims 2-3.

1. Claim 1 Preamble

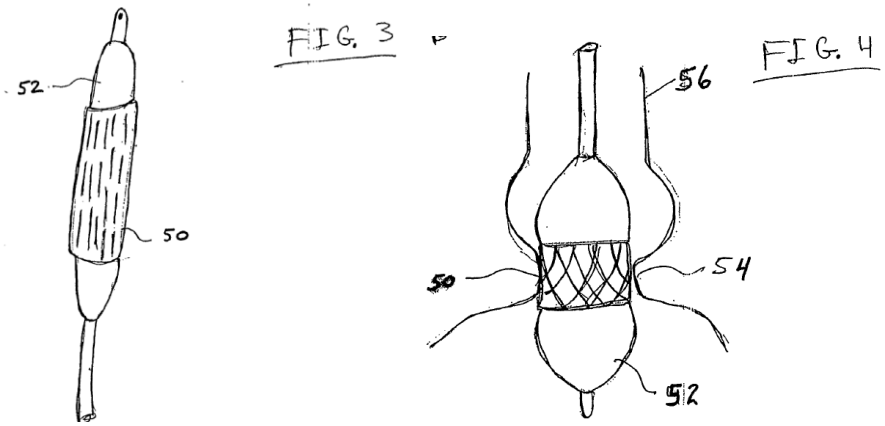
Spenser discloses a THV system for replacing a heart valve:



Ex. 1004 at 1, Fig. 1 (annotations and highlighting added); *see also* Ex. 1007 at ¶ 175.

2. Element 1.1

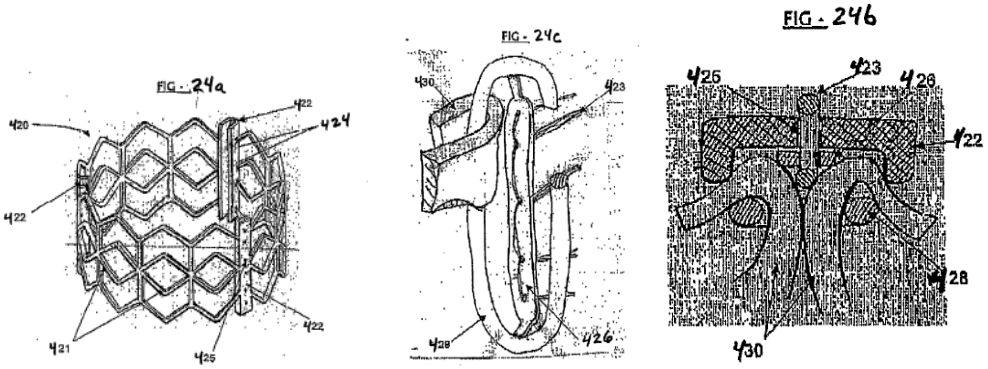
The THV disclosed by Spenser comprises an expandable anchor having a collapsed delivery configuration and an expanded configuration:



See Ex. 1004 at Figs. 3-4, pp. 14-15, 24. The anchor in Spenser is identified as "stent 50" wherein the distal end is the inflow end of the anchor when delivered transfemorally.

3. Element 1.2

Spenser's THV includes various embodiments of a commissure support element attached to the expandable anchor. *See e.g.*, *id.* at p. 34 ("Support beam 422 ... can be produced by extrusion, wire cutting, or by welding the 'U' profile to the frame's struts 421 at junction points 424."), Figs. 24a-c (shown below) and 35a-35c.



4. Element 1.3

Spenser discloses a commissure portion of a replacement valve leaflet attached to the commissure support element. *See, e.g., id.* at Figs. 24b and 24c, p. 34; *see also id.* at Figs. 35a-35c. The valve structure of Spenser is preferably a tricuspid valve structure made of biological or polymeric material. *Id.* at pp. 20-21.

5. Element 1.4

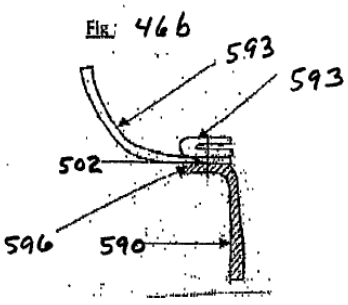
Spenser discloses a fabric seal at least partially disposed around an exterior portion of the expandable anchor (*i.e.*, support stent) when the anchor is in the expanded configuration. As shown in Figure 1, "a cuff portion 21 of the valve assembly 28 is wrapped around support stent 22 at inlet 24 to enhance the stability. Preferably cuff portion 21 of valve material 28 is attached to support beams 23." *Id.* at Fig. 1, pp. 22, 24. The cuff portion can be formed with PET fabric (Dacron). *See, e.g., id.* at pp. 25, 33.

6. Element 1.5

The Spenser THV has multiple expanded states, including undeployed and deployed states as shown in Figures 3 and 4 above. Because the fabric seal is mounted on the Spenser THV, the fabric seal has an undeployed state and a deployed state. *See, e.g., id.* at 20.

7. Element 1.7

Spenser discloses various means of attaching the valve to the frame and fabric seal, including embodiments where the distal end of the replacement valve leaflet is attached to the fabric seal with sutures:



See id. at 45-46 ("A pre-shaped PET tube 590 is cut to have substantially sinusoidal shape 596 and then bent in order to provide a suturing area. The pericardium leaflet 593 is pre-cut and assembled to PET tube 590 by means of suturing 502."), Figs. 46a-46b.

8. Element 1.8

Spenser discloses a THV 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. *See id.* at 24 (As shown in Figure 2, "[a] portion of the valve assembly 34 at an inlet zone 45 is optionally rolled over support stent 32 at the inlet, making up a rolled sleeve, which enhances the sealing of the device at the valve inlet."), Figs. 1-4.

9. Element 1.9

Spenser discloses that the THV is "deployed within the aorta thus anchoring the deployable annular stent and the coupled valve device in position." *Id.* at 10. This means that the stent is embedded into the surrounding tissue. Ex. 1007 at ¶ 180. Given that the THV would be anchored into place upon expansion, the fabric seal necessarily would conform to the surrounding tissue. *See supra* Section II.D. (discussing the Hemobahn graft). This is further evidenced by the fact that the fabric seal in Spenser can be made with Dacron, which was well known to conform to the surrounding tissue. *See* Ex. 1027 (Leonhardt) at 5:53-56 ("biocompatible, flexible and expandable, low-porosity woven fabric[s], such as polyester or PTFE," are "capable of substantially conforming to the surface of the living tissue to which stent [ ] coerces it").

In view of these features, the fabric seal in Spenser is adapted to prevent blood from flowing between the fabric seal and heart tissue. Ex. 1007 at ¶ 178.

10. Claim 4

Spenser discloses an expandable anchor that can be formed from stainless steel or nickel-titanium alloy. *See* Ex. 1004 at 21.

11. Element 1.6 and Claims 2-3

Spenser does not explicitly disclose whether the fabric seal, in the deployed state, comprises circumferential "flaps" and "pockets" as claimed by the '608 patent in Element 1.6 and Claims 2-3. That said, the limitations of Element 1.6 and Claims 2-3 would have been obvious to incorporate in Spenser as these elements were all commonly practiced in similar implantable prostheses, including stent-grafts. *See, e.g.*, *supra* Section II.D. As discussed above, Elliot, Thornton, Cook, and De Paulis disclose various embodiments of fabric seals having circumferentially oriented "flaps" and "pockets" as claimed to prevent leakage between the stent graft and the surrounding tissue. *See supra,* Section VII.C (Elliot and Thornton), D (Cook), and E (De Paulis).

The same reasons that would have prompted a person of skill in the art to combine the teachings of Cribier with Elliot or Thornton also apply to the combination of Spenser with Elliot (Ground 7) or Thornton (Ground 8). *See supra,* Section VII.C (Grounds 3-4); Ex. 1007 at ¶¶ 175-183. Moreover, a person of skill in the art would have recognized that applying Elliot's or Thornton's teachings of using an external skirt on an implantable prosthesis to prevent leakage to Spenser's

implantable valve prosthesis would have led to predictable results. This is particular evident given the commercial success of the stent grafts disclosed by Thornton. Ex. 1007 at ¶ 183. For at least these reasons, there is a reasonable likelihood that claims 1-4 of the ’608 patent are rendered obvious by Spenser in view of Elliot (Ground 7) or, in the alternative, Thornton (Ground 8). *Id.* at ¶¶ 182-183.

G. Ground 9: Claims 1-4 are invalid under 35 U.S.C. § 103(a) over Spenser (Ex. 1004) in view of Cook (Ex. 1006)

As noted, Spenser discloses each element of Claims 1-4 of the ’608 patent but for the circumferential “flaps” and “pockets” limitations of Element 1.6 and Claims 2-3. *See supra*, § VII.F (Grounds 7-8). As discussed above, *supra* § VII.D (Ground 4), Cook discloses an enhanced sealing structure that, in a deployed state, comprises “flaps” and “pockets” as claimed by the ’608 patent. Combining the teachings of Spenser with Cook renders Element 1.6 and Claims 2-3 (and Claims 1-4, collectively) obvious to one of ordinary skill in the art.

The same reasons that would have prompted a person of skill in the art to combine the teachings of Spenser with Elliot or Thornton also apply to the combination of Spenser with Cook. *See supra,* Section VII.F (Grounds 7-8). As such, a person of skill in the art would have recognized that applying Cook’s teachings of using an external skirt on an implantable prosthesis to prevent leakage

to Spenser's implantable valve prosthesis would have led to predictable results. For at least these reasons, there is a reasonable likelihood that claims 1-4 of the '608 patent are rendered obvious by Spenser in view of Cook. Ex. 1007 at ¶¶ 184-187.

H. Ground 10: Claims 1-4 are invalid under 35 U.S.C. § 103(a) over Spenser (Ex. 1004) in view of De Paulis (Ex. 1021)

As noted, Spenser explicitly discloses each element of Claims 1-4 of the '608 patent but for the circumferential "flaps" and "pockets" limitations of Element 1.6 and Claims 2-3. *See supra*, § VII.F (Grounds 7-8). As discussed above, *supra* § VII.E (Ground 6), De Paulis discloses "flaps" and "pockets" as claimed by the '608 patent.

Not only would the "flaps" and "pockets" structure disclosed by De Paulis have been an obvious design choice to adopt with the THV disclosed by Spenser, it also would have been obvious to combine the teachings of Spenser and De Paulis as the pleated structure of De Paulis permits the seal to significantly increase in length, which would be a desirable feature in light of the anchor design in Spenser. Although the support beams taught by Spenser preferably remain constant in length, the remainder of the stent structure undergoes a degree of foreshortening. *See* Ex. 1004 at 23; Ex. 1007 at ¶¶ 83, 191. It would therefore be desirable to select a seal design that can accommodate extension in the axial direction. For at

least these reasons, there is a reasonable likelihood that claims 1-4 of the '608 patent are rendered obvious by Spenser in view of De Paulis. Ex. 1007 at ¶¶ 188-191.

I. Ground 11: Claims 1-4 are invalid under 35 U.S.C. § 102(b) over Spenser (Ex. 1004)

As noted, Spenser discloses each element of Claims 1-4 of the '608 patent but for the circumferential "flaps" and "pockets" limitations of Element 1.6 and Claims 2-3. *See supra*, § VII.F (Grounds 7-8). But, when applying Boston Scientific's broader interpretation of "flaps" (i.e., no "circumferentially oriented" directional requirement), Spenser discloses "flaps" and "pockets" in the form of pleats that are longitudinally oriented.

First, Spenser details that the valve prosthesis "has the ability to change its diameter from about 4 mm to about 25 mm." Ex. 1004 at 47. Any fabric seal used would necessarily have to accommodate this range of expansion. Thus, to the extent that the prosthesis described by Spenser is expanded to treat an annulus size of a patient short of the prosthesis' maximum diameter, excess fabric would surround the prosthesis, thereby forming longitudinally oriented pleats of the type described by Lawrence. *See supra* Section II.D. Second, Spenser discloses the use of a crimping device that applies external pressure to compress the THV into its delivery state. *See* Ex. 1004 at 32 and Figs. 18a-b. As Patent Owner asserts, this will form a pleated structure that remains pleated after re-expansion. *See* Ex. 1032

at 46-48; *see also supra* Section V. Spenser's fabric seal will therefore form "flaps" (and associated "pockets"), which in the deployed state, extend into spaces formed by native valve leaflets and further prevent the flow of blood between the frame and surrounding tissue. Ex. 1007 at ¶ 195.

Thus, when applying Boston Scientific's broad interpretation of "flaps", Spenser in combination with the references detailed above not only renders obvious the "flaps" and "pockets" limitations as claimed, Spenser alone also anticipates these requirements. Ex. 1007 at ¶¶ 193-196.

VIII. CONCLUSION

Petitioner submits that the substantial evidence presented in this Petition demonstrates that there is a reasonable likelihood that Claims 1-4 of the '608 patent would have been anticipated and obvious to a person of ordinary skill in the art. Accordingly, Petitioner respectfully requests that the Board grant *inter partes* review for each of these claims pursuant to 35 U.S.C. § 314.

Dated: October 12, 2016 Respectfully Submitted,

/Gregory S. Cordrey/
Gregory S. Cordrey, Esq. (Reg. No. 44,089)
Attorney for Petitioners
Edwards Lifesciences Corporation,
Edwards Lifesciences LLC, and
Edwards Lifesciences AG

Appendix

U.S. Patent No. 8,992,608 Claims 1-4: 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.

CERTIFICATE OF SERVICE

I hereby certify that, on October 12, 2016, 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:

SEAGER, TUFTE & WICKHEM, LLP
100 South 5th Street, Suite 600
Minneapolis MN 55402

/Gregory S. Cordrey/
Gregory S. Cordrey, Esq. (Reg. No. 44,089)
Attorney for Petitioners
Edwards Lifesciences Corporation,
Edwards Lifesciences LLC, and
Edwards Lifesciences AG

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 13,993 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: October 12, 2016 By: /s/ Gregory S. Cordrey