IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES, L.L.C and EDWARDS LIFESCIENCES PVT, INC.,	)	
Counterclaimants,	)	
v.	)	
MEDTRONIC COREVALVE, L.L.C., MEDTRONIC CV LUXEMBOURG SARL, MEDTRONIC, INC., MEDTRONIC VASCULAR GALWAY, LTD. and MEDTRONIC VASCULAR, INC.,	)	C.A. No. 12-cv-23 (GMS)
Counter-Defendants.	)	

ORDER CONSTRUING THE TERMS OF U.S. PATENT NO. 8,002,825

After having considered the submissions of the parties and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent No. 8,002,825 (the "'825 Patent"):

1. The term "a prosthetic valve for implantation in a stenosed aortic valve" is construed to mean "an artificial valve with a frame, flexible valvular structure, and internal cover, capable of placement in a narrowed aortic valve."[1]

[1] The court largely agrees with the plaintiffs' proposed construction of this term, which both sides concur is not amenable to plain and ordinary meaning. The parties' primary dispute centers on whether the '825 Patent requires the valve to be "within" the aortic valve. Specifically, the defendants contend that, according to the plain language of the claims, all three components must be designed so that "when the valve is implanted each component sits within (i.e., is "in") the stenosed aortic valve." (D.I. 56 at 4.) The defendants argue that this position is supported by the Summary of the Invention, which expressly states that "[a] particular aim of the present invention is to provide an IV [implantable valve] . . . which structure is capable of resisting the powerful recoil force and to stand the forceful balloon inflation performed to develop the IV and *embed it into the aortic valve*." (*Id.* (emphasis in defendants' Opening Brief) (citing '825 Patent at col. 3, ll. 35-39).) In addition, the defendants cite to other examples where the specification explains that the frame, valvular structure, and internal cover must also be "in" the stenosed aortic valve. (*Id.* at 4-5 (citing '825 Patent at col. 7, 11. 49-51; col. 4, ll. 50-52; col. 12, ll. 27-46; col. 13, ll. 46-57).) Moreover, the defendants assert that this position is further supported by the fact that, during prosecution of a priority application, Application No. 10/139,741, the inventors argued that this invention was different than the prior art patent to Andersen because Andersen disclosed placing a prosthetic valve "within the aorta" and not within the "native aortic valve." (*Id.*

2. The terms "metallic frame having intersecting bars" and "frame made with intersecting metallic bars" is construed to have its plain and ordinary meaning.[2]

3. The term "frame" is construed to mean "a circumferential stent structure."[3]

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at 5 (citing A0372, App. 10/139,741, Jan. 27, 2005 Remarks at 8).) Thus, the defendants argue that the '825 Patent requires that the frame, valvular structure, and internal cover must each be designed "for implantation in a stenosed aortic valve." (D.I. 65 at 2 (citing '825 Patent at col. 21, ll. 34-67).) The defendants further clarified at the *Markman* hearing that their proposed construction does not require each of the three valve components to be entirely in the aortic valve, but, instead, would require that a portion of each be in that valve.

The court disagrees with the position the defendants assert. As the plaintiffs explained in their claim construction briefing and during the *Markman* hearing, the claimed invention would have the artificial valve ideally "sitting squarely within the remains of [the aortic valve]." *See* Transcript of Hearing ("Tr.") (D.I. 86) at 15:7-14. Importantly, the '825 Patent does not require the frame, valvular structure, and internal cover to each be entirely or partially in the stenosed aortic valve. First, and with respect to the defendants' initial argument that each of the three components must rest entirely within the aortic valve, figures in the Patent, such as Figure 131, make clear that the frame, valvular structure, and internal cover of the prosthetic valve can extend above and below the native aortic annulus, which is the portion of the wall of the passageway where the native leaflets attach. (D.I. 70 at 2 (citing '825 Patent at Fig. 131).) It is well-established that excluding this preferred embodiment would be improper. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). Second, and supporting the plaintiffs' contention that the frame, valvular structure, and internal cover do not have to be even partially in the stenosed aortic valve, the internal cover, as claimed in the '825 Patent, "prevent[s] the passage of blood through spaces between the bars of the frame," which provides leeway in the positioning of the flexible valvular structure at, above, or below the level of the native valve. (D.I. 70 at 3 (citing '825 Patent at Claims 1 and 4).) For instance, the flexible valvular structure can be positioned above the native valve, and the internal cover will maintain a seal between the prosthesis and the native valve to avoid regurgitation of blood back into the left ventricle. (*Id.* at 4 (citing '825 Patent at col. 11, ll. 53-57 ("This internal cover prevents any passage of blood through the spaces between the bars 11 of the frame and the implantable valve would be positioned with the fastening line of the valvular structure on the frame not exactly on the remains of the dilated aortic valve, i.e., either above or below")).) Thus, there is no requirement that the flexible valvular structure and internal cover be positioned only "within" the native valve. Third, and as the plaintiffs' detailed at the *Markman* hearing, the Patent expressly recognizes that the positioning of the device "when the interventional cardiologist is putting it in" is "not always easy." Tr. at 17:19:24. Specifically, the plaintiffs detailed that the "skirt" exists because "what the patent teaches is [a] regurgitation phenomenon," such that "if you can get it positioned perfectly so that the valve structure is exactly coextensive with the remains of the native annulus, you won't have a regurgitation problem because nothing can pass through." *Id.* at 18:1-11. Thus, regurgitation "arises precisely because you have miss positioned [sic] it slightly." *Id.* at 18:12-14. To this end, the device is "designed so that it will function, if it is miss positioned [sic]," as is expressly disclosed in the Patent. In view of the foregoing, the court concludes that the frame, valvular structure, and internal cover do not need to positioned entirely or partially in the stenosed aortic valve.

[2] The parties' Joint Claim Construction Chart included "metallic frame having intersecting bars" and "frame made with intersecting metallic bars" as disputed terms. During the *Markman* hearing, however, the parties agreed that the disputed language from these claims is "intersecting bars" and that both terms should be construed to have their plain and ordinary meaning. *See* Tr. at 66:5-68:3.

[3] The court adopts the plaintiffs' proposed construction of this term. The defendants assert that the dimensional upper limit and positioning of the frame should be included in the construction of this term because this construction "reflects what [the inventor,] Dr. Cribier[,] believed was a key aspect of his invention, which is that the 'positioning of the implantable value is an important point' and that the 'upper limit of the frame should be placed below the opening of the coronary arteries.'" (D.I. 56 at 6.) The defendants contend that the "specification sets forth specific dimensions for accomplishing the inventor's stated goal" and that, by design, the frame would "not impede free blood flow in the coronary arteries." (*Id.*) Moreover, the height restrictions, the defendants argue, have the additional advantage of not creating a "drawback" during the transcutaneous introduction of the prosthetic valve and its positioning within the aortic annulus. (*Id.* at 7.) The defendants note that, in Dr. Cribier's view, a prosthetic valve

4. The term "18 French arterial introducer" is construed to mean "a sheath with a diameter of 5.7 mm or less that facilitates delivery of a catheter to an artery."[4]

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that is higher than about 20 mm when compressed would be difficult to maneuver over the aortic arch and into position within the native aortic valve. (*Id.*) Therefore, the specification's definition of an appropriate height for the frame is important, in the defendants' view, "both for the final placement of the device (i.e., in a position that avoids the coronary ostia) and for the process of implanting the device." (*Id.*)

The court disagrees with both assertions. The specification states that the frame height of 10 to 15 millimeters when fully expanded is a preferred embodiment, not a maximum height. Specifically, the specification states "[t]he height of the fully expanded frame of the illustrated frame 10 is preferably between 10 and 15 mm." (D.I. 70 at 5 (citing A-24, '825 Patent at 9:27-28).) Indeed, the '825 Patent discloses a longer 20 millimeter frame, when fully expanded, when it states that "FIGS. 2a and 2b show respectively an example of a cylindrical frame or stent 10 . . . with for instance a 20 mm height . . ." (*Id.* (citing A-24, '825 Patent at 8:22-26).) Moreover, in addition to the absence of a frame height limitation in the asserted claims, there is also no "upper limit" that restricts the frame to placement "at or below the opening of the coronary ostia" as the defendants propose. Rather, the '825 Patent states that "[t]he upper limit of the frame should be placed below the opening of the coronary arteries, i.e., the coronary ostia 6, or at their level so that the frame does not impede blood flow in the coronary arteries." (*Id.* at 6 (citing A-24, '825 Patent at 7:61-64).) To this end, the upper limit of the frame is preferably at or below the coronary ostia, but there is no requirement that the upper limit must be positioned at or below the coronary ostia. (*Id.*) In fact, the specification explains that the natural anatomy of a patient helps avoid blocking the arteries even when the upper limit of the frame is at the level of or above the coronary ostia. (*Id.* (citing A-24, '825 Patent at 7:67-8:3).) Again, the defendants seek to import a preferred embodiment into the construction of the term, which is inappropriate. *See On-Line Techs., Inc. v. Bodenseewerk Perkin-Elmer GmbH*, 386 F.3d 1133, 1138 (Fed. Cir. 2004) ("A claim interpretation that excludes a preferred embodiment form the scope of the claim is rarely, if ever, correct."); *see also Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998) ("[w]hile . . . claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims."); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

[4] The plaintiffs contend that the disputed term should be construed to mean "[a] sheath with an internal diameter of about 18 French that facilitates delivery of a catheter to an artery." (D.I. 56 at 9; D.I. 70 at 8.) The defendants propose that the term should mean "a sheath with a diameter of 5.7 mm for transcutaneous introduction of the prosthetic valve." (D.I. 53 at 10; D.I. 65 at 5; *see also* Tr. at 31:10-16.) The court disagrees with both proposed constructions.

As an initial matter, the court rejects the plaintiffs' assertion that "18 French" should be construed to have its plain and ordinary meaning, as that term would be defined in the cardiology field and by a person of ordinary skill in the art. Specifically, the '825 Patent defines "18 French" as "5.7 mm." *See* '825 Patent at Abstract (explaining that the "frame is compressed for delivery into a patient's vasculature through an 18F (5.7 mm) arterial introducer using a catheterization technique"); *id.* at col. 14, ll. 4-13 (explaining that because delivery through a percutaneous route is intended, the prosthetic valve should have the "smallest possible external diameter" and that it would be "acceptable" if it could be introduced into the femoral artery through "even a 18F (5.7 mm) introducer"). The plaintiffs assert that the 5.7 mm references included in the Patent represent a mere "typographical" error, because the Patent also details, in connection with the statement, that "F means French, a unit usually used in cardiology field)," that each "French" unit would be "roughly [] equivalent to 0.33 mm in diameter, i.e., 18 French (18F) indicates a diameter of 6 mm." (D.I. 53 at 10-11 (citing '825 Patent at col. 8, ll. 62-66; Egan Decl., Ex. C., *Dorland's Illustrated Medical Dictionary* (28th ed. 1994)).) The plaintiffs argue that, rather than applying a 3:1 conversion ratio from French to millimeters, the inventors divided the French value by pi (3.14). Thus, the plaintiffs argue that, because the '825 Patent specification includes a typographical error, 18 French should be construed to mean 6 millimeters, rather than 5.7 millimeters.

For the reasons the defendants advance, however, the court disagrees and concludes that the inventors did, in fact, define 18 French to mean 5.7 mm and, therefore, acted as their own lexicographer. *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1051 (Fed. Cir. 2010) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005)).) When an inventor sets forth a clear definition in the specification, it should be adopted. *See Simorgchem Co. v. ITC*, 511 F.3d 1132, 1136 (Fed. Cir. 2007). Here, the inventors clearly defined "18 French" as "5.7 mm" and

5. The term "the frame being expandable" is construed to mean "the frame is capable of increasing or being increased in diameter."[5]

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this definition informs the construction. *See Edwards Lifesciences, LLC v. Cook, Inc.*, 582 F.3d 1322, 1329 (Fed. Cir. 2009) (construing "graft" and "intraluminal graft" where the terms were used interchangeably in the specification). The court further notes, in support of this conclusion, that the plaintiffs reiterated this definition during the '825 Patent's prosecution. Specifically, Edwards amended the pending claims that recited that the frame could be compressed to a "compressed external diameter capable of being introduced through an 18 F (5.7 mm) arterial introducer" to instead recite "the size of the arterial introducer only in French (i.e., 18 F, 16F, and 14F)," because the "additional recitation of arterial introducer in millimeters . . . was duplicative and had been removed to improve readability." (D.I. 56 at 9-10 (citing A0042-46, App. 12/915,538, Remarks *May 26, 2011), at 2-3 (amending claim 1), 4-5 (amending claim 14), 6. Similarly, when the inventors distinguished over a prior art reference in a priority application to the '825 Patent, it told the PTO that Dr. Cribier's invention was different than the prior art because there was "no teaching or suggestion in the cited references" regarding a prosthetic valve assembly that included a stent, a valvular structure[,] and an internal cover, where the entire assembly was collapsible to a diameter of "5.7 mm or less for advancement through an introducer and into a patient's vasculature via a catheterization technique." (*Id.* at 10 (citing A0123, App. 11/942,690, Remarks (May 26, 2010) at 13.) In view of the foregoing, the court concludes that the inventors did, in fact, define 18 F and, therefore, that the plaintiffs' construction of plain and ordinary meaning is inconsistent with that definition.

In addition, the court further concludes that the plaintiffs' inclusion of "about" in their proposed construction is likewise improper here. (D.I. 53 at 10; D.I. 70 at 11-12.) The plaintiffs contend that, because an arterial introducer is a sheath through which an interventional cardiologist gains access to a patient's artery and then facilitates delivery of a catheter, the size 18 French would be understood by skilled artisans to refer to the "internal diameter." (D.I. 53 at 12.) Moreover, the plaintiffs note that, because persons of skill in the art would know the diameter to mean the internal diameter of the introducer, that artisan would also know that the introducer may be "slightly larger than 18 French to permit delivery of an 18 French device." (*Id.*) The court disagrees, however, that "about" should be included in this term's construction. Specifically, the Patent specification explains:

> . . . the IV should preferably have the smallest possible external diameter. Ideally, it should be able to be introduced in the femoral artery through a 14 F (4.5 mm) size arterial introducer which is the size of the arterial introducer commonly used to perform an aortic dilatation. However, a 16 F (5.1 mm) or even a 18 F (5.7 mm) introducer would also be acceptable. Above this size, the introduction of the IV in the femoral artery should probably be done by a surgical technique.

'825 Patent, col. 14, ll. 6-17. In light of this and other instruction in the specification and in consideration of the patentee's representation to the PTO that the claimed invention is collapsible to a diameter of 5. 7 mm or less, the court concludes that "about" should not be included in this term's construction.

[5] The court rejects the defendants' proposed construction "the frame being balloon expandable from a fully compressed state" in favor of the plaintiffs' construction. The defendants assert that "balloon explainable" and "from a fully compressed state" should be included in the construction of this term because the Summary of the Invention in the '825 Patent states that "a particular aim of the present invention" is a prosthetic valve with a "structure . . . capable of resisting the powerful recoil force and to stand the forceful balloon inflation performed to deploy the valve." (D.I. 56 at 10 (citing '825 Patent at col. 3, ll. 35-39, ll. 50-52).) The defendants maintain that, based on this statement in the Summary of the Invention, as well Patent's description of a balloon-expandable valve in two different processes wherein each is referenced as the "present invention," it is evident that Dr. Cribier described his invention as a balloon-expandable prosthetic valve. (*Id.*) The defendants note that when the specification describes an embodiment "as the invention itself, the claims are not necessarily entitled to a scope broader than that embodiment" and, further, that describing the invention as an embodiment will trump arguments of claim differentiation. (*Id.* at 10-11 (citing *Edwards Lifesciences, L.L.C. v. Cook, Inc.*, 582 F.3d 1322, 1330 (Fed. Cir. 2009)); *see also* (D.I. 65 at 6 (citing *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380, 1381 (Fed. Cir. 2006)).) In fact, as the defendants note, the claimed invention is only described as a balloon-expandable prosthetic valve. (D.I. 65 at 7.) To this end, the defendants assert that the '825 Patent should not cover self-expanding valves.

In addition, the defendants contend that the plaintiffs represented as much to the PTO when they stated during the prosecution of the priority application that the invention was unique because "it must be capable of resisting the

powerful recoil force and of standing (sic) the forceful balloon inflation necessary to deploy the implantable valve and to embed it in the aortic annulus." (D.I. 56 at 12 (citing A0363, App 10/139,741 (July 6, 2004) Remarks at 12).) The plaintiffs, however, were unable to get claims issued with the broad scope including self-expanding and balloon-expanding frames as it argues here. Moreover, the defendants argue that "from a fully compressed state" is a necessary element of the construction because the specification instructs that balloon inflation of the prosthetic valve is critical to ensure that the frame expands from its compressed state to its maximum diameter. (*Id.* at 11 (citing '825 Patent at col. 8, l. 61-col. 9, l. 2, col. 9, ll. 38-42).) Specifically, the defendants maintain that the balloon expansion step is critically important because it is the force of the balloon that embeds the prosthetic valve in the stenotic aortic annulus. (*Id.* at 11-12 (citing. '825 Patent at col. 3, ll. 35-39, col. 15, ll. 45-52).)

In consideration of the '825 Patent specification and the relevant law, the court adopts the plaintiffs' proposed construction for the reasons that follow. First, the plaintiffs note that independent Claims 1 and 14 recite that the "frame" of the prosthetic valve is expandable. (D.I. 53 at 13 (citing '825 Patent at Claim 1 (21:41), Claim 14 (22:42, 50).) Indeed, only dependent Claims 7 and 18 limit the claimed invention to a specific means of expansion (i.e., by balloon). (*Id.*) Therefore, the plaintiffs argue, and the court agrees, that "the frame being expandable," as used in the independent claims should not be limited to a particular means of expansion. (*Id.* (citing Joint Chart, Edwards' Intrinsic Support, pp. 36-53; *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 632 F.3d 1254-56 (Fed. Cir. 2011)).) The defendants' proposed construction would improperly import limitations from two dependent claims into the independent claims and, in so doing, violate the doctrine of claim differentiation and render Claims 7 and 18 superfluous. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-15 (Fed. Cir. 2005) (differences among claims, such as a dependent claim with a limitation not present in the independent claim, helps differentiate the claim definitions); *see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004) (concluding that, where independent claims lack reference to a limitation in dependent claims, this absence provides strong support that all claims are not intended to include the limitation).

Second, and reinforcing this conclusion, the plaintiffs refer to the '825 Patent's broad disclosure that the "frame is preferably a metallic frame." (D.I. 53 at 10 (citing '825 Patent, 9:3-4, 5:50).) The plaintiffs also note that the well-known understanding in the art as of December 1996, which is supported by the intrinsic record, was that an "expandable" frame, for a THV could be either self-expanding or balloon-expanding. (*Id.* at 13 (citing '552 Patent at col. 2, ll. 38-55 (disclosing both balloon- and self-expanding THV embodiments); A-2 (confirming that the '552 Patent is part of the '825 Patent's intrinsic record).) It was also known that metallic frames included both balloon- and self-expandable frames. (D.I. 70 at 10.) Indeed, the '825 Patent encompasses various types of metallic frames, including, for instance, frames made of balloon-expandable material, such as steel, and frames made of self-expanding material, such as Nitinol. (*Id.* at 13-14.) It was also known at that time that stainless steel was not only used in forming balloon-expandable frames, but was also used in self-expanding frames and self-expanding Nitinol was also known as of the priority date. (*Id.* at 14 n.5).) In addition, while the defendants are correct that the Summary of the Invention does state in part that "[a] particular aim of the present invention is to provide an IV . . . capable . . . to stand [sic] the forceful balloon inflation performed to deploy the IV and to embed it in the aortic annulus," this is only one aim of the invention. '825 Patent at col. 3, ll. 35-39. The Summary of the Invention also states that:

> Another aim of the present invention is to provide an efficient prosthesis valve which can be implanted by a catheterization technique, in particular in a stenosed aortic valve, taking advantage of the strong structure made of the distorted valve and of the large opening area produced by preliminary balloon inflation, performed as an initial step of the procedure. . . . A further aim of the present invention is to provide an implantable valve which would not produce any risk of fluid regurgitation.

Id. at col. 3, ll. 40-49. Importantly, neither of these additional "aims" is limited by the specification to balloon-expandable frames. *See generally* '825 Patent. The '825 Patent also describes the invention as an "improvement" over the Andersen patent, which claimed self-expansion, such that the Patent at issue here does not preclude a self-expandable mode. *See* Tr. at 34:24-35:18.

Third, the plaintiffs maintain that the defendants' reference to statements made during the prosecution of related Dr. Cribier applications is a mischaracterization of the evidence. Specifically, the plaintiffs note that the cited statements that the claimed device was "unique in that it must be capable of resisting the powerful recoil force and of standing [sic] the forceful balloon inflation necessary to deploy the implantable valve" and that the invention was different because the prior art "concerns self-expanding structure, not balloon-expandable ones," refer not to the claimed invention, but to an invention limited to balloon-expandable frames. (D.I. 70 at 11 (citing A363, App. No. 10/139,741 (July 6, 2004) Remarks at 12); A177, App. No. 1-/202,458 (Aug. 23, 2004) Remarks at 13); *see also* A355-359 at A358 (pending independent claim 16: "inflating said second dilation balloon to cause said valve prosthesis to adhere to said aortic valve and annulus"); A169-172 at A169 (pending independent claim 1: "inflating

6. The term "zig-zag shape" is construed to mean "one of a series of short sharp turns, angles, or alternations in course."[6]

7. The term "a flexible valvular structure" is construed to mean "a pliable structure that facilitates unidirectional flow of blood, with a geometry appropriate for fastening to the frame."[7]

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said second dilation balloon to cause said valve prostehsis to adhere to said stenotic valve and annulus")).) Conversely, only Claims 7 and 18 of the asserted Patent are limited to balloon-expandable frames. In view of the foregoing, the court agrees that the defendants' citation to statements made during prosecution do not guide this construction.

Further, the court finds the defendants' inclusion of "from a fully compressed state" to be improper, as this language is not included in any of the asserted claims and would inject ambiguity into the term. *See Phillips*, 415 F.3d at 1315 ("[T]he specification 'is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term." (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F3.d 1576, 1582 (Fed. Cir. 1996)).)

[6] During the *Markman* hearing, the parties agreed on this construction of term. *See* Tr. at 40:16-41:9.

[7] For substantially the same reasons discussed above in reference to "the frame being expandable" term, the court adopts the plaintiffs' proposed construction. The defendants propose that this term should be construed to mean "valvular tissue that forms a continuous surface and is provided with guiding means creating stiffened zones which induce the valvular structure to follow the patterned movement; unicuspid or excluding separable leaflets" because Dr. Cribier referenced these features in the Summary of the Invention. (D.I. 56 at 14.) Specifically, the defendants note that the Summary of the Invention: (1) expressly teaches that this term is one which, "according to the present invention . . . comprises a collapsible continuous structure with guiding means providing stiffness" ('825 Patent at col. 3, ll. 53-57); and (2) states that the "guiding means" of the invention are important because they "induce the valvular structure to follow a patterned movement from its opened position to its closed state and vice-versa" (*id.* at col. 4, ll. 2-6).

The court disagrees and concludes that adopting the defendants' construction requiring the inclusion of a "valvular tissue that forms a continuous surface and is provided with guiding means creating stiffened zones which induce he valvular structure to follow a patterned movement" would violate the doctrine of claim differentiation. *See supra* note 2. In particular, beyond the preferred embodiments described in the '825 Patent specification—none of which can be imported into independent Claims 1 and 14 to limit the scope of those Claims—the specification makes clear that the valvular structure encompasses "any type of valve structure" that can be sewed, molded or glued to the surface of the internal cover. (D.I. 53 at 15-16 (citing '825 Patent at col. 13, ll. 39-41).) In addition, the '825 Patent specification itself notes that:

> A valvular structure according to the invention is made of a supple and reinforced tissue which has a thickness to be thin enough to occupy as less as possible space in the compressed form of the valve, is pliable, and also strong enough to stand the unceasing movements under the blood pressure changes during heart beats. The valvular structure is capable of moving from its closed position to its open position under the action of the force exerted by the movements of the blood during systole and diastole, without having any significant resistance to blood displacements.

'825 Patent at col. 14, ll. 31-40. Moreover, the specification details that, with respect to geometry, "[t]he valvular structure of the invention can have several types of designs and shapes. *Id.* at col. 14, ll. 65-66. Thus, the court concludes that importing limitations from the preferred embodiments in this case would be improper and would violate the doctrine of claim differentiation. *See supra* note 1; *see also Comark Communications, Inc.*, 156 F.3d at 1186 ("While . . . claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims.").

Moreover, the defendants argue that Dr. Cribier explicitly disclaimed leaflet designs in the prior art, because these designs were simply too fragile to withstand the forceful balloon inflation that is required to position his prosthetic valve. (*Id.* at 15 (citing '825 Patent at col. 3, ll. 2-9).) To remedy this failure, the inventive valvular structure's "continuous" shape is "stronger and has less risk of being distorted or destroyed by the forceful balloon

8. The term "internal cover" is construed to mean "a circumferential lining around the inside of the frame."[8]

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inflation." (*Id.* (citing '825 Patent at col. 11, ll. 39-42).) Thus, the defendants contend, because the '825 Patent specification describes a particular embodiment as "the present invention," the plaintiffs are not entitled to claims with a broader scope, which would be allowed by their construction. (D.I. 56 at 14 (citing *Edwards Lifesciences LLC*, 582 F.3d at 1330).)

The court, however, disagrees that "unicuspid or excluding separable leaflets" should be included in this term's construction. Specifically, the court finds, as noted, that the specification makes clear that the valvular structure encompasses "any type of valve structure." (D.I. 53 at 15 (citing '825 Patent at col. 13, ll. 39-41).) Such valve structures would include unicuspid valves, the preferred valve design set forth in the '825 Patent specification, as well as multi-leaflet pericardial valves, which are also described in the specification. (*Id.* at 16 (citing '825 Patent at col. 4, ll. 18-28 (a "truncated hyperboloidal shape"), col. 5, 11. 18-26 ("made of biological material such as pericardium, procine leaflets and the like"), col. 14, ll. 52-55 ("the valvular structure can . . . be made with biological tissue such as the pericardium, or with porcine leaflets, which are commonly used in bioprosthetic surgically implanted valves").) Moreover, the valvular structure may include "guiding means formed or incorporated within, . . . which induce the valvular structure to follow a patterned movement from its open position to its closed state and vice versa." (*Id.* (citing '825 Patent at col. 4, 11. 2-10, col. 4, ll. 56-57 ("The guiding means can comprise pleats, struts or thickened zones.")).) Thus, the court concludes that the defendants' proposed construction is inconsistent with the '825 Patent specification and improperly imports limitations from the preferred embodiments and dependent Claims 4 and 5. Tr. at 42:18-43:3; *see also supra* note 1; *see also Comark Communications, Inc.*, 156 F.3d at 1186 ("While . . . claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims.").

[8] The court adopts the plaintiffs' construction and rejects the defendants' proposed construction requiring that the "internal cover" be a "cover that is fastened solely to the internal surface of the frame and does not extend below a zig-zag line along the lower extremity of the frame." (D.I. 56 at 16; D.I. 65 at 9.) The court also disagrees with the defendants' argument that limitations from a related application—rather than from the asserted claims—should be imported into this term to limit the material and positioning of the internal cover. (D.I. 70 at 16.) Specifically, and with respect to the defendants' assertion that "internal cover" should be restricted to being "fastened solely to the internal surface of the frame," the asserted Claims 1 and 14 state that the internal cover may, in fact, be "sewn on the lower extremity of the frame along a zig-zag line," which would permit it to contact any portion (inside, outside, top, or bottom) of the lower zig-zag extremity of the frame in order to secure the internal cover to the frame. As set forth in the '825 Patent specification:

> Preferably, an internal cover is coupled or is integral to the valvular structure and placed between said valvular structure and the internal wall of the frame to prevent any passage of the body fluid through said frame. Therefore, there is no regurgitation of blood as it would be the case if there were any space between the valvular structure fastened on the frame and the zone of application of the frame on the aortic annulus. The internal cover makes a sort of "sleeve" at least below the fastening of the valvular structure covering the internal surface of the frame and thus prevents any regurgitation of blood through the frame.

'825 Patent at col. 5, ll. 32-42. The court, therefore, finds that the defendants' proposed construction including limitations from related Application No. 11/942,690 is inappropriate as the recited language "internal cover extending only along the internal surface and only between the valvular structure and the inlet end of the stent" does not appear in the asserted claims of the '825 Patent. *See Saunders Grp., Inc. v. Comfortrac, Inc.*, 492 F.3d 1326, 1333-34 (Fed. Cir. 2007) ("When the purported disclaimers are directed to specific claim terms that have been omitted or materially altered in subsequent applications (rather than to the invention itself), those disclaimers do not apply."); *see also Ventana Med. Sys. v. Biogenex Labs.*, 473 F3d 1173, 1182 (Fed. Cir. 2006); *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1078 (Fed. Cir. 2005). Further, the plaintiffs correctly note that an embodiment represented in Figure 6d shows the internal cover extending below the area the defendants' construction would allow. *See On-Line Techs., Inc.*, 386 F.3d at 1138 ("A claim interpretation that excludes a preferred embodiment form the scope of the claim is rarely, if ever, correct.")

9. The term "comprises a concave shape profile" and "shape comprising a concave profile" is construed to mean "a portion of the frame having a concave shape."[9]

10. The term "wherein the frame is configured to be expanded by a balloon" is construed to mean "the frame is capable of being increased in diameter by the expansion of a balloon."[10]

Dated: April 23, 2013

CHIEF, UNITED STATES DISTRICT JUDGE

[9] The court agrees with the plaintiffs' proposed construction of this term. *See* D.I. 53 at 1; *see also* Tr. at 50:9-23 (revising its original proposed construction to use the word "concave" rather than "waist"). Specifically, the court concludes that the defendants' proposed construction, "the portion of the frame that is within the stenosed aortic valve expands to a concave shape profile" (D.I. 56 at 18) or, alternatively, "a concave shape for implanting within the aortic annulus" (Tr. at 92:1-8), improperly imports limitations requiring the concave portion of the frame to be located "within" the stenosed aortic valve. (D.I. 70 at 18.) Notably, the plain language of the asserted claims does not impose such a limitation or require actual implantation of the device. (*Id.*) In addition, the plaintiffs correctly note that the frame of the asserted claims is not limited to a concave profile only "within" the stenosed aortic valve. (*Id.*) In particular, the Patent specification, while describing a preferred embodiment of a concave frame, states that a concave shape profile can be used to "reinforc[e] the embedding of the IV in the aortic orifce," which anatomically is beyond the native stenosed aortic valve. *See* '825 Patent at col. 8, ll. 51-58. Thus, the concave profile of the frame should not be limited to a concave profile that exists only "within the stenosed aortic valve" or that is a "concave shape for implanting within the stenosed aortic valve." *See On-Line Techs., Inc.*, 386 F.3d at 1138 ("A claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever, correct.")

[10] *See supra* note 5.