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Paper No. 7
March 29, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION,
Petitioner,

v.

BOSTON SCIENTIFIC SCIMED, INC.,
Patent Owner.

Case IPR2017-00060
Patent 8,992,608 B2

Before NEIL T. POWELL, JAMES A. TARTAL, and ROBERT L. KINDER, *Administrative Patent Judges*.

TARTAL, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Edwards Lifesciences Corporation ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting institution of *inter partes* review of claims 1–4 of U.S. Patent No. 8,992,608 B2 (Ex. 1001, "the '608 patent"). Boston Scientific Scimed, Inc. ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted "unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

Upon consideration of the Petition and the Preliminary Response, we conclude the information presented shows there is a reasonable likelihood that Petitioner would prevail in showing the unpatentability of challenged claims 1–4. Accordingly, we authorize an *inter partes* review to be instituted as to claims 1–4 of the '608 patent. Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far (prior to Patent Owner's Response). This is not a final decision as to patentability of claims for which *inter partes* review is instituted. Any final decision will be based on the record, as fully developed during trial.

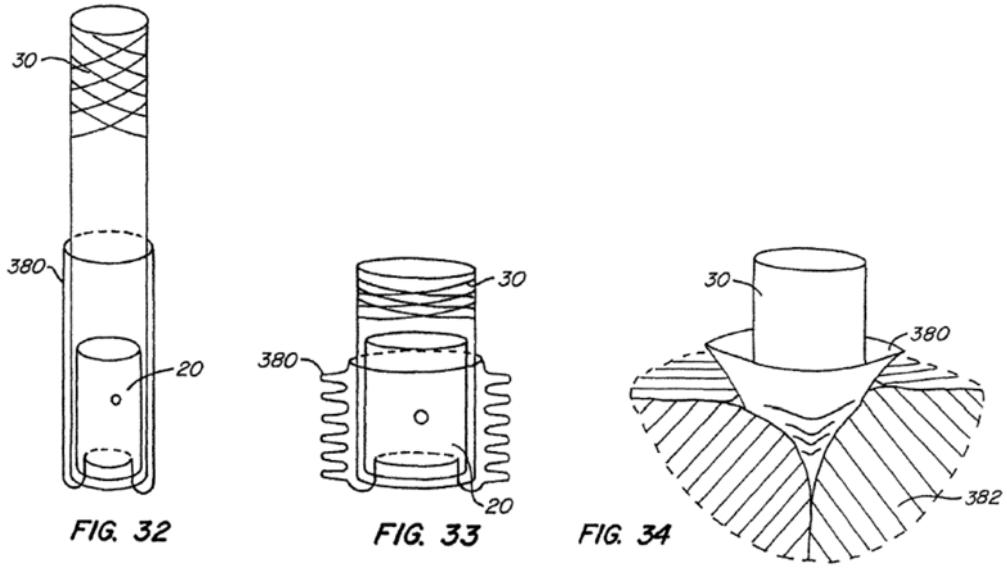
II. BACKGROUND

A. The '608 Patent

The '608 patent, titled "Everting Heart Valve," issued March 31, 2015, from U.S. Application No. 12/492,512 (the '512 application), filed June 26, 2009. Ex. 1001. The '512 application was a divisional of U.S. Application No. 12/269,213, filed on November 12, 2008 (issued as U.S. Patent No. 8,668,733), which was a continuation of U.S. Application

No. 10/870,340, filed on June 16, 2004 (issued as U.S. Patent No. 7,780,725). *Id.* The '608 patent generally relates to "methods and apparatus for endovascularly replacing a patient's heart valve." Ex. 1001, Abstract.

Figures 32, 33, and 34 of the '608 patent are reproduced below.



An embodiment of the replacement heart valve and anchor is illustrated in Figure 32 in an undeployed configuration, and in Figure 33 in a deployed configuration. Ex. 1001 4:38–42. Figure 34 illustrates the replacement heart valve deployed in a patient's heart valve. *Id.* at 4:43–44. The '608 patent further explains:

> 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.

Id. at 14:21–29.

Figure 3B of the '608 patent is reproduced below.

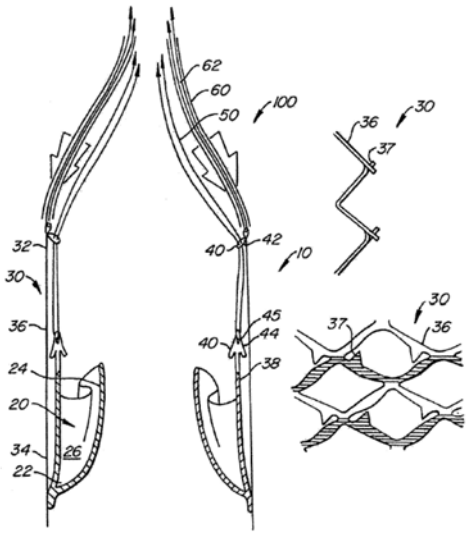


FIG. 3B

Figure 3 B illustrates the deployment of a replacement heart valve. Of particular note for purposes of this Decision, "[a]nnular 60 base 22 of replacement valve 20 preferably is coupled to skirt region 34 of anchor 30, while commissures 24 of replacement valve leaflets 26 are coupled to and supported by posts 38." Ex. 1001, 5:60–63. "Replacement valve 20 is preferably made from biologic tissues, e.g. porcine valve leaflets or bovine or equine pericardium tissues or human cadaver tissue." *Id.* at 5:51–53.

B. Illustrative Claim

Challenged claim 1 is the sole independent claim challenged, from which challenged claims 2–4 depend. Claim 1 is illustrative of the claimed subject matter and is reproduced below:

> 1. A system for replacing a heart valve, comprising:
> an expandable anchor having a collapsed delivery configuration and an expanded configuration, the expandable anchor comprising a distal end;
> a replacement valve commissure support element attached to the expandable anchor;

> a commissure portion of a replacement valve leaflet attached to the commissure support element; and
>
> a fabric seal at least partially disposed around an exterior portion of the expandable anchor when the anchor is in the expanded configuration, the fabric seal having 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;
>
> wherein 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.

Ex. 1001, 22:22–42.

C. Related Proceedings

According to the parties the ’608 patent is a subject of a case captioned *Boston Scientific Corp. et al. v. Edwards Lifesciences Corp.*, Case No. 1:16-cv-00275 (D. Del.). Pet. 25; Paper 4, 2. Petitioner also states that “there is at least one pending U.S. patent application, serial number 14/873,462, that claims priority to the ’608 patent.” *Id.* at 26.

D. Real Parties in Interest

Petitioner identifies Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences AG as real parties in interest. Pet. 25. Patent Owner identifies Boston Scientific Scimed, Inc. and Boston Scientific Corp. as real parties in interest. Paper 4, 2.

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–4 of the '608 patent on the following grounds:

Reference(s)	Basis	Claims challenged
Spenser[1]	§ 102	1–4
Spenser and Elliot[2]	§ 103	1–4
Spenser and Thornton[3]	§ 103	1–4
Spenser and Cook[4]	§ 103	1–4
Spenser and De Paulis[5]	§ 103	1–4
Cribier[6]	§ 102	1–4
Cribier and Spiridigliozzi[7]	§ 103	1–4
Cribier and Elliot	§ 103	1–4
Cribier and Thornton	§ 103	1–4
Cribier and Cook	§ 103	1–4
Cribier and De Paulis	§ 103	1–4

Petitioner supports its challenge with a Declaration by Nigel P. Buller, M.D., dated October 10, 2016 (Ex. 1007).

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[1] WO 03/047468 A1, published June 12, 2003 (Ex. 1004, "Spenser"). Citations to Spenser are to the original pagination.
[2] U.S. Patent App. Pub. No. 2003/0236567 A1, published December 25, 2003 (Ex. 1005, "Elliot").
[3] U.S. Patent No. 6,015,431, issued January 18, 2000 (Ex. 1019, "Thornton").
[4] U.S. Patent App. Pub. No. 2004/0082989 A1, published April 29, 2004 (Ex. 1006, "Cook").
[5] U.S. Patent No. 6,352,554 B2, issued March 5, 2002 (Ex. 1021, "De Paulis").
[6] WO 98/29057, published July 9, 1998 (Ex. 1003, "Cribier"). Citations to Cribier are to the original pagination.
[7] U.S. Patent App. Pub. No. 2004/0033364 A1, published February 19, 2004 (Exhibit 1010, "Spiridigliozzi").

III. ANALYSIS

A. Claim Construction

Claim 1 recites "the fabric seal comprises flaps." Ex. 1001, 22:34. Claim 2 depends from claim 1 and further recites "the fabric seal defines a plurality of pockets." *Id.* at 22:43–44. Petitioner contends that "flaps" should be construed to mean "circumferentially oriented folds or unattached ends." Pet. 43. Petitioner further contends that "pockets" should be construed to mean "open spaces or cavities formed by flaps of the fabric seal." *Id.* at 45. Patent Owner argues that Petitioner's proposed constructions are not the broadest reasonable, but proposes no alternative. Prelim. Resp. 4. Instead, Patent Owner contends that the Petition should be denied under Petitioner's proposed constructions. *Id.* We determine no terms require express construction for purposes of this Decision. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999): "only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy."

B. Asserted Anticipation by Spenser

Petitioner contends that the challenged claims of the '608 patent are anticipated by Spenser. Pet. 74–75. Spenser, titled "Implantable Prosthetic Valve," describes a valve prosthesis comprised of a support stent and valve assembly. Ex. 1004, Abstract.

Figure 1 of Spenser is reproduced below.

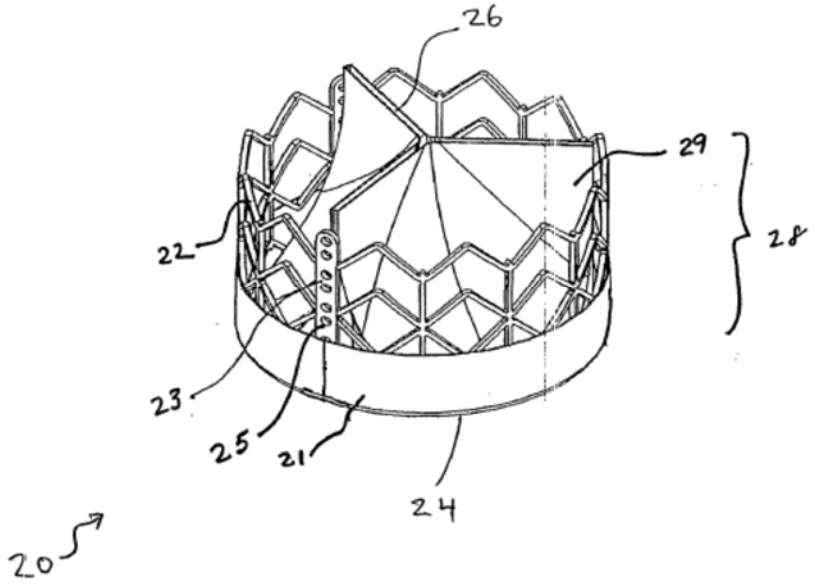

Figure 1 illustrates an implantable prosthetic tricuspid valve suitable for deployment by a stent. Ex. 1004, 14. Tricuspid implantable prosthetic valve 20 includes valve assembly 28, with inlet 24, outlet 26, and outer walls consisting of collapsible pliant material 29. *Id.* at 22. Valve assembly 28 is attached to annular support stent 22 at bores 25 on support beams 23. *Id.* "[C]uff portion 21 of the valve assembly 28 is wrapped around support stent 22 at inlet 24 to enhance the stability." *Id.* "Preferably cuff portion 21 of valve material 28 is attached to support beams 23." *Id.* Spenser describes as an "important feature" the constant length of the support beams 23 such that "there is no need for slack material as the attachment points (25) remain at constant distance regardless of the position of the valve device (crimped or deployed)." *Id.* at 23.

First, Petitioner argues that if claim 1 is not construed to be limited to "circumferential 'flaps'," then Spenser discloses "flaps" because "excess fabric would surround the prosthesis," forming longitudinal pleats if

deployed short of its "maximum diameter." Pet. 74. The only support Petitioner cites is an ambiguous reference to "*See supra* Section II.D" of the Petition, which spans eleven pages. Presumably of particular note in that portion of the Petition, Petitioner contends (apparently with respect to stents in general) that under certain conditions "unless the covering is completely elastic," if a stent is deployed "short of its maximum diameter," it "typically results in the formation of longitudinally oriented pleats." Pet. 10–11, *citing*, *inter alia*, Lawrence,[8] 358).

As Patent Owner notes, Spenser depicts a cuff portion of the prosthesis that is taught with no flaps. Prelim. Resp. 23–24 (citing Ex. 1004 Fig. 1). Indeed, Petitioner appears to acknowledge that "Spenser does not explicitly disclose whether the fabric seal, in the deployed state, comprises circumferential 'flaps' . . . as claimed by the '608 patent." Pet. 71. Thus, Petitioner's argument is premised on an alleged inherent disclosure by Spenser of "flaps," as required by claim 1 of the '608 patent.

> To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted) (internal quotation marks omitted). By merely asserting what "typically" occurs under certain conditions with stents in general, Petitioner fails to

[8] Lawrence *et al.*, "Percutaneous Endovascular Graft: Experimental Evaluation," Radiology, 163(2): 357–60 (May 1987) (Ex. 1029, "Lawrence").

adequately contend, much less show that "flaps" are "necessarily present" in the prosthetic described by Spenser to support Petitioner's inherency argument.

Second, Petitioner argues that Spenser applies a crimping device to the prosthetic to compress the valve for delivery, which "[a]s Patent Owner asserts, . . . will form a pleated structure that remains pleated after re-expansion." Pet. 74. Petitioner identifies no persuasive support for its contention that pleats forming flaps are "necessarily present" in the prosthetic described by Spenser. Instead, Petitioner's argument is largely premised on Patent Owner's alleged infringement contentions in another proceeding. *See* Ex. 1007 ¶¶ 106, 195 (rather than unambiguously stating his own opinion, Petitioner's Declarant instead states that "[a]s Boston Scientific asserts, this will form a pleated structure that remains pleated after re-expansion.").

As further support, Petitioner ambiguously provides a citation to "*see also supra* Section V" of the Petition, which spans nineteen pages. Pet. 75. Presumably of particular note in that portion of the Petition, Petitioner contends U.S Patent No. 5,855,601 (Ex. 1033, "Bessler") "details a compressed, self-expanding THV with a pleated seal." *See id.* at 33–34. Petitioner, however, does not adequately explain the significance of Bessler to Spenser. To the contrary, as Petitioner makes clear, Bessler explicitly illustrates a device with pleating and Spenser does not. *Id.* at 33–34, 66. Petitioner directs us to no sufficient disclosure in Spencer, or elsewhere, to support its contention that pleats, and therefore "flaps," are necessarily present in the prosthetic described by Spenser. Petitioner's reliance on Bessler (or Lawrence), suggests, at most, a possibility that pleats might be

formed by the prosthetic of Spenser under some conditions, which is an insufficient showing to demonstrate anticipation. *See Robertson*, 169 F.3d at 745. Accordingly, the information provided by Petitioner does not show a reasonable likelihood of prevailing in showing that claim 1 of the '608 patent, or any of claims 2–4 which depend from claim 1, is anticipated by Spenser.

C. Asserted Obviousness over Spenser and Other Prior Art

Petitioner contends claims 1–4 of the '608 patent would have been obvious over the combination of Spenser and either Elliot, Thornton, Cook, or De Paulis. Pet. 66–74. In each ground, we determine that Petitioner sufficiently asserts that Spenser discloses the claimed features other than "flaps" and "pockets" based on the current record, and focus our discussion on the additional references and the rational for the combinations. *See id.*

1. Elliot

Elliot, titled "Implantable Prosthesis with Displaceable Skirt," relates to "tubular prostheses, including, but not limited to, endovascular grafts and stent-grafts, for maintaining patency of blood vessels and treating aneurysms (e.g., aortic aneurysms), and tubular conduits for maintaining patency in other bodily passageways." Ex. 1005 ¶ 1. Elliot describes the use of "at least one skirt" that extends from a tubular body. *Id.* ¶ 24. The skirt has a peripheral edge that is free and displaceable to a greater diameter than the diameter of the tubular body, such that it "can be displaced to contact, and form a seal with a surrounding wall." *Id.* "Irregularities and/or wall displacement . . . can be responded to by the skirt [] in minimizing endoleaks about the prosthesis." *Id.*

Figure 7 of Elliot is reproduced below.

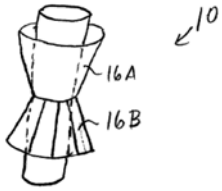

FIG. 7

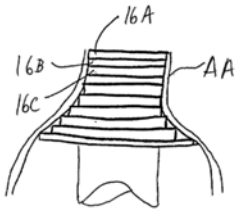

FIG. 8

Figure 7 illustrates prosthesis 10, including skirts 16a and 16b, and Figure 8 illustrates a plurality of skirts 16A, 16B, 16C. *Id.* ¶ 40. Petitioner contends that the structure formed by the skirts disclosed by Elliot corresponds to the claimed "flaps" and "pockets." Pet. 57–59, 71.

Patent Owner argues that Elliot is insufficient because "it has nothing to do with valves," and instead is directed to forming a seal with a surrounding wall. Prelim. Resp. 42–43. Petitioner, however, relies on Spenser as disclosing a prosthetic valve. Pet. 66. Patent Owner's argument improperly attacks Elliott individually, when Petitioner asserts that Spenser in combination with Elliott discloses the claimed features. *See In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (cautioning against attacking references individually when obviousness is predicated upon a combination of prior art disclosures). We are persuaded, based on the present record, that Petitioner has sufficiently identified how the combination of Elliot and Spenser allegedly teaches every claim feature, including those not disclosed by Spenser alone.

2. Thornton

Thornton, titled "Endolumenal Stent-Graft with Leak-Resistant Seal," relates to an implantable medical device, including a tubular member and one or more sealing members secured to an outer surface of the tubular

member, which is expandable to engage an endolumenal wall. Ex. 1019, Abstract.

Figure 1 of Thornton is reproduced below:

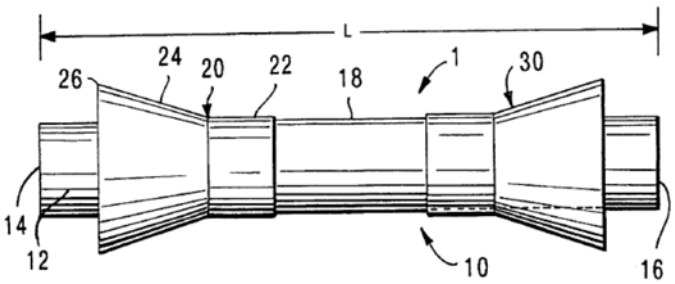

FIG.1

Figure 1 illustrates tubular member 10, including tubular wall 12 and seal member 20. *Id.* at 7:14–20. Thornton further explains:

> Seal member (20) is shown in FIG. l as an occlusive cuff, which has a first cuff end (22) secured to outer surface (18) of tubular wall (12), and which also has a second cuff end (24) at least a portion which is unsecured to form a flange (26). In this configuration, flange (26) forms a one-way valve that circumferentially surrounds tubular member (10) and occludes flow around tubular wall (12) in the direction from the first cuff end (22) to the second cuff end (24) when tubular member (10) is deployed with in a radially confining endolumenal space.

Ex. 1019, 7:20–29. Petitioner contends that the structure formed by the seal member disclosed by Thornton corresponds to the claimed "flaps" and "pockets." Pet. 60–61, 71.

Patent Owner argues that Thornton is insufficient because "it has nothing to do with valves," and instead engages the vascular wall. Prelim. Resp. 45–47. Petitioner, however, relies on Spenser as disclosing a prosthetic valve. Pet. 66. Patent Owner's argument improperly attacks Thornton individually, when Petitioner asserts that Spenser in combination with Thornton discloses the claimed features. *See In re Merck & Co.*,

800 F.2d at 1097. We are persuaded, based on the present record, that Petitioner has sufficiently identified how the combination of Thornton and Spenser allegedly teaches every claim feature, including those not disclosed by Spenser alone.

3. Cook

Cook, titled "Stent Graft with Improved Proximal End," relates to a stent graft prosthesis comprising a main body portion and a cuff that "comprises an external sealing zone that extends around the outer main body portion to help prevent leakage of fluids." Ex. 1006, Abstract.

Figures 2 and 6 of Cook are reproduced below.

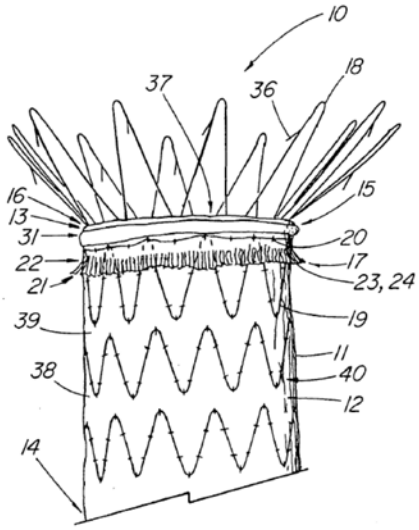

FIG. 2

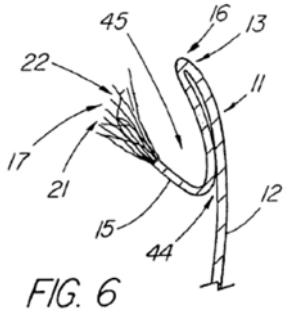

FIG. 6

Figure 2 illustrates graft prosthesis 10, including cuff portion 15 with frayed portion 22. Ex. 1006 ¶¶ 26, 30. As shown in Figure 6, according to Cook, sealing zone 21, including frayed portion 22, may be "configured such that the free edge 17 of the cuff portion 15 is directed proximally (toward the first or folded edge 16), 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 ¶ 36. Petitioner contends that the structure formed by the sealing zone disclosed by Cook corresponds to the claimed "flaps" and "pockets." Pet. 62–64, 71.

Patent Owner argues that Cook is insufficient because "it has nothing to do with valves," and instead engages the vessel wall. Prelim. Resp. 48–49. Petitioner, however, relies on Spenser as disclosing a prosthetic valve. Pet. 66. Patent Owner's argument improperly attacks Cook individually, when Petitioner asserts that Spenser in combination with Cook discloses the claimed features. *See In re Merck & Co.*, 800 F.2d at 1097. We are persuaded, based on the present record, that Petitioner has sufficiently identified how the combination of Cook and Spenser allegedly teaches every claim feature, including those not disclosed by Spenser alone.

4. De Paulis

De Paulis, titled "Prosthetic Tubular Aortic Conduit and Method for Manufacturing the Same," relates to a prosthetic aortic conduit for replacing a root portion of an aorta. Ex. 1021, Abstract.

Figure 2 of De Paulis is reproduced below.

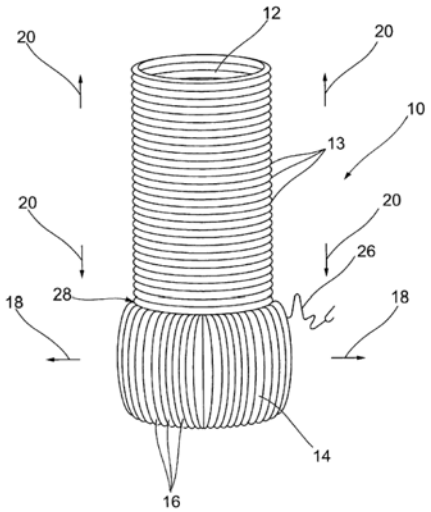

Fig. 2

Figure 2 illustrates conduit 10 with upper portion 12 with circumferentially extending corrugations 13 and second lower portion 14 with longitudinally extending pleats or corrugations 16. Ex. 1021, 4:62–5:6. Petitioner contends that the circumferentially extending corrugations or pleats disclosed by De Paulis correspond to the claimed "flaps" and "pockets." Pet. 64–65, 73.

5. Motivation for Asserted Combinations

a. Spenser in Combination with Either Elliot, Thornton, or Cook

Petitioner argues that it would have been obvious to modify Spenser in view of Elliot, Thornton, or Cook for the same following reasons: (1) to further improve the sealing function of the fabric seal to further minimize the risk of paravalvular leaks, and (2) because the use of external skirts to prevent endoleaks was a known technique from either Elliot, Thornton, or Cook that would have improved the similar device of Spenser in the same way, yielding predictable results. Pet. 59–62, 64, 71–73.

Patent Owner argues that there was no motivation to combine Spenser and either Elliot, Thornton, or Cook because none of the references recognized or solved the problem of paravalvular leakage solved by the '608 patent. Prelim. Resp. 53–58. Patent Owner also argues that Spenser and either Elliot, Thornton, or Cook are incompatible because Spenser discourages slack in the cuff while Elliot, Thornton, and Cook disclose skirts or flanges extending outward. *Id.* at 54, 56, 58. Patent Owner's arguments are insufficiently supported on the present record to persuade us that Petitioner's rationale for the asserted combinations is insufficient for purposes of institution. Accordingly, we are persuaded that the information provided by Petitioner demonstrates a reasonable likelihood of prevailing in

showing that claims 1–4 of the ’608 patent would have been obvious over Spenser and either Elliot, Thornton, or Cook.

a. Spenser in Combination with De Paulis

With regard to De Paulis, Petitioner contends a combination with Spenser would have been obvious because the structure of De Paulis would have been “an obvious design choice” and would permit “the seal to significantly increase in length.” Pet. 73. According to Petitioner, “[a]lthough the support beams taught by Spenser preferably remain constant in length, the remainder of the stent structure undergoes a degree of foreshortening.” *Id.* (citing Ex. 1004 at 23; Ex. 1007 ¶¶ 83, 191).

Rather than support Petitioner’s contention, the portion of Spenser cited by Petitioner states that:

> The valve assembly is attached to the support stent at the support beams, and due to their constant length there is no need for slack material as the attachment points (25) remain at constant distances regardless of the position of the valve device (crimped or deployed).

Ex. 1004, 23. In further support of Petitioner, Dr. Buller states that:

> The support beams (25) 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. [Ex. 1004] at pp. 34–35.

Ex. 1007 ¶ 83. Dr. Buller does not identify what “remaining portions” of the Spenser prosthetic “undergo a degree of foreshortening” or otherwise provide any explanation for such a conclusion. We are not persuaded that

the portion of Spenser cited by Dr. Buller sufficiently supports such a contention to show it is not merely conclusory. Spenser states:

> [T]he length of the attaching means (the height of the valve) remains at all times constant; thus suitable for serving as the pliable valve assembly's anchorage. The leaflets are attached to the support frame at the attaching means, and due to their constant length there is no need for slack material as these attachment points that remain at constant distances regardless of the position of the valve assembly (crimped or deployed). This is an important feature for this means that the manufacturer of the valve device can make sure the valve assembly is secured and fastened to the support frame at all times.

Ex. 1004, 34–35. No portion of Spenser cited by Petitioner or Dr. Buller indicates that foreshortening occurs with the prosthetic. Further, by merely arguing a combination is an "obvious design choice," without further explanation, Petitioner has not provided sufficiently the "articulated reasoning with some rational underpinning" required to support the legal conclusion of obviousness. *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 418 (2007). Accordingly, the information provided by Petitioner does not show a reasonable likelihood of prevailing in showing that any of claims 1–4 would have been obvious over Spenser and De Paulis.

D. Asserted Anticipation by Cribier

Petitioner contends that the challenged claims of the '608 patent are anticipated by Cribier. Pet. 47–54. Cribier, titled "Valve Prosthesis for Implantation in Body Channels," describes a valve prosthesis comprised of a collapsible valvular structure and an expandable frame. Ex. 1003, Abstract.

Figures 4a and 4b of Cribier are reproduced below.

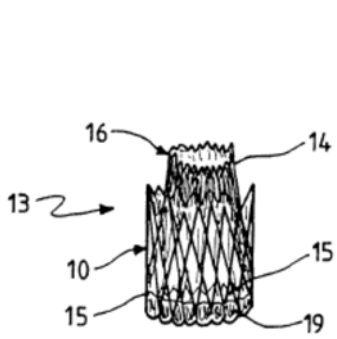

FIG_4a

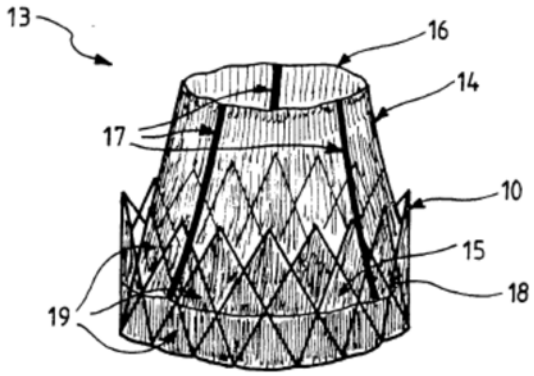

FIG_4b

Figures 4a and 4b illustrate an implantable valve ("IV") 13, as disclosed by Cribier, in the compressed position and the expanded position, respectively. Ex. 1003, 18:1–4. The implantable valve is made of an "expand[a]ble but substantially rigid structure made of the frame 10," and "a soft and mobile tissue constituting the valvular structure 14 exhibiting a continuous surface truncated between a base 15 and an upper extremity 16." *Id.* at 18:13–18. The tissue has rectilinear struts 17 to "strengthen it" and "to induce a patterned movement between its open and closed state." *Id.* at 18:22–25. The valvular structure includes internal cover 19 to be fixed on the internal wall of frame 10 to prevent "any passage of blood through the spaces between the bars 11 of the frame," and to strengthen the fastening of valvular structure 14 to frame 10. *Id.* at 20:26–21:3.

Figure 6d of Cribier is reproduced below.

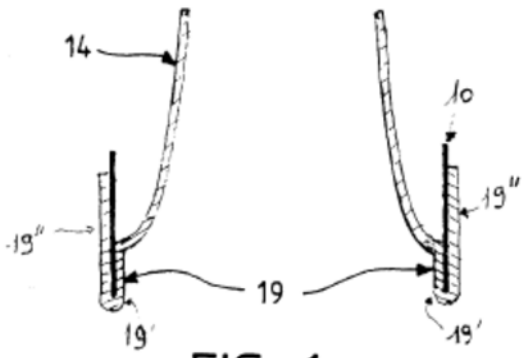

FIG_6d

Figure 6d illustrates a sectional view of the implantable valve showing the internal cover and the external cover of the valvular structure overlapping the frame bars. Ex. 1003, 11:18–21. According to Cribier:

> At Figure 6d, the internal cover 19 is extended at its lower end 19' to an external cover 19'' which is rolled up to be applied on the external wall of the stent 10. The internal and external cover are molded, glued or soldered to the bars of the stent 10.

Id. at 22:23–26. Cribier further explains that "[t]he internal cover makes a sort of 'sleeve' below the fastening of the valvular structure on the internal surface of the frame, covering the spaces between the frame bars of the frame at this level, thus preventing any regurgitation of blood through these spaces." *Id.* at 22:17–20.

The Court of Appeals for the Federal Circuit summarized the analytical framework for determining whether prior art anticipates a claim as follows:

> To anticipate a claim, a single prior art reference must expressly or inherently disclose each claim limitation. *Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998). But disclosure of each element is not quite enough—this court has long held that "[a]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention

> *arranged as in the claim*." *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) (citing *Soundscriber Corp. v. United States*, 175 Ct. Cl. 644, 360 F.2d 954, 960 (1966) (emphasis added)).

Finisar Corp. v. DirecTV Grp., Inc., 523 F.3d 1323, 1334–35 (Fed. Cir. 2008). "Thus, it is not enough that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention." *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 n.5 (Fed. Cir. 2008). "The requirement that the prior art elements themselves be 'arranged as in the claim' means that claims cannot be 'treated . . . as mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning.'" *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1332 (Fed. Cir. 2010) (quoting *Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1459 (Fed.Cir.1984)).

Claim 1 requires "a replacement valve commissure support element attached to the expandable anchor." Petitioner contends struts 17 of Cribier correspond to this limitation. Pet. 48 (citing Ex. 1003, 18:18–28, Fig. 4a, 4b). Claim 1 further requires "a commissure portion of a replacement valve leaflet attached to the commissure support element." According to Petitioner:

> 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* [Ex. 1003] 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.

Pet. 48–49. Petitioner fails to identify any feature shown in Figure 4b that corresponds to the claimed "a commissure portion of a replacement valve leaflet." Moreover, the portion of Cribier cited by Petitioner does not address "a commissure portion of a replacement valve leaflet," and Petitioner does not otherwise explain how it contends that disclosure corresponds to "a commissure portion of a replacement valve leaflet," as claimed. *See* Ex. 1003, 18:18–28 (teaching "a valvular structure 14 exhibiting a *continuous surface* truncated between a base 15 and an upper extremity 16") (emphasis added).

Patent Owner argues that although "Cribier discloses 'several types' of valvular structures – as depicted in Figures 4-5 and 9-11 – none of these includes any 'replacement valve leaflets.'" Prelim. Resp. 15. Instead, Cribier criticizes a prior art cardiac valve prosthesis that used "a semi-lunar leaflet design" as "inherently fragile," and "not strong enough." Ex. 1003, 4:3–13.

We determine that Cribier's reference to "any type of valvular structure" is not a sufficient disclosure of any specific structure, particularly one that expressly includes "a commissure portion of a replacement valve leaflet," as required by claim 1 of the '608 patent. Similarly, Cribier's statement that "porcine leaflets" may be used to make a valvular structure suggests a material to be used, but does not disclose the form of the valvular structure, much less that the valvular structure, itself, has "a commissure portion of a replacement valve leaflet." Therefore, we agree with Patent

Owner that Petitioner has not shown that Cribier discloses all elements of claim 1 of the '608 patent, arranged as in the claim. That Cribier allegedly "contemplates" undisclosed elements, as Petitioner contends, is of no moment to an anticipation analysis. Accordingly, the information provided by Petitioner does not show a reasonable likelihood of prevailing in showing that claim 1 of the '608 patent, or any of claims 2–4 which depend from claim 1, is anticipated by Cribier.

E. Asserted Obviousness over Cribier and Other Prior Art

Petitioner contends that claims 1–4 would have been obvious over Cribier and either Spiridigliozzi, Elliot, Thornton, Cook, or De Paulis. Pet. 54–66. For each ground Petitioner relies only on Cribier as disclosing "a commissure portion of a replacement valve leaflet attached to the commissure support element," as required by claim 1. *See id.* As discussed above, Petitioner fails to show that Cribier discloses this feature for purposes of demonstrating anticipation. Moreover, although Cribier discusses deficiencies in prior art designs that employed leaflets, Petitioner does not argue that it would have been obvious to modify the implantable valve taught by Cribier to include "a commissure portion of a replacement valve leaflet," and does not rely on any other asserted references as disclosing the same. Accordingly, the information provided by Petitioner does not show a reasonable likelihood of prevailing in showing that any of claims 1–4 would have been obvious over Cribier in combination with either Spiridigliozzi, Elliot, Thornton, Cook, or De Paulis.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that *inter partes* review is *instituted* in IPR2017-00060 with respect to the following grounds of unpatentability:

claims 1–4 as obvious over Spenser and Elliot under 35 U.S.C. § 103(a),

claims 1–4 as obvious over Spenser and Thornton under 35 U.S.C. § 103(a),

claims 1–4 as obvious over Spenser and Cook, under 35 U.S.C. § 103(a);

FURTHER ORDERED that no ground other than those specifically instituted above is authorized for the *inter partes* review;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the ’608 patent is hereby instituted in IPR2017-00060 commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

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