

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

	)	
AORTIC INNOVATIONS LLC,	)	
	)	
Plaintiff,	)	Case No. 1:21-cv-01377-JPM
	)	
v.	)	
	)	
EDWARDS LIFESCIENCES	)	
CORPORATION, EDWARDS	)	
LIFESCIENCES LLC, and EDWARDS	)	
LIFESCIENCES (U.S.) INC.,	)	
	)	
Defendants.	)	

DEFENDANTS' PRELIMINARY INVALIDITY CONTENTIONS

Pursuant to the Local Patent Rules and the Court's Scheduling Order, Defendants Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences (U.S.) Inc. (collectively, "Defendants" or "Edwards") submit these preliminary invalidity contentions with respect to the Asserted Claims of U.S. Patent Nos. 10,881,538 (the "'538 patent"); 10,966,846 (the "'846 patent"); 10,987,236 (the "'236 patent"); and 11,129,735 (the "'735 patent") (collectively, the "Asserted Patents."). These Contentions are made in response to Aortic Innovations LLC's ("Aortic") assertion of infringement by Edwards of claims 1-8, 10-18, and 20 of the '538 patent; claim 6 of the '846 patent; claims 1-4 of the '236 patent; and claims 1-10 and 12 of the '735 patent (the "Asserted Claims").

These Contentions are based upon information that is currently available to Edwards, including Edwards' present understanding of the Asserted Patents, the Asserted Claims, the prior

Some of the prior art refers to or discusses other prior art, illustrating the close technical relationship among the prior art.

Therefore, the Asserted Claims are invalid as obvious under 35 U.S.C. § 103 in view of Wen alone and/or Wen in combination with one or more of Spenser, Cribier, Hariton, Cribier '321, Levi, Walther, Spenser II, Cheung, Birdsall, Spenser III, Greenberg, Magovern, Essinger, McLean, Essinger '157, Hariton, Braidó, Braidó '802, Navia, Snyders, Ryan, Norris, Greenhalgh, Cook, Hartley, Fogarty, Dehdashtian, Letort, Chuter, Baker, Rhodes, Baker '356, Elliot, Staudemneir, and/or Letort '926. *See* Exhibits B-E.

Q. Cribier-Edwards MIS Aortic Bioprosthesis Model 9000MIS

Cribier-Edwards MIS Aortic Bioprosthesis Model 9000MIS (“9000MIS”) was implanted within the diseased aortic valve of patients at least as early as 2006. The 9000MIS was publicly known in the United States at least as early as 2009, the publication date of an article by Dr. Anson Cheung published in the *Annals of Thoracic Surgery* entitled “Transapical Transcatheter Mitral Valve-in-Valve Implantation in a Human,” which discloses and describes the 9000MIS. The 9000MIS was also disclosed and describe in an article published in April 2011 by Dr. Thomas Walther and colleagues in the *European Journal of Cardio-thoracic Surgery* entitled, “Trans-catheter valve-in-valve implantation: in vitro hydrodynamic performance of SAPIEN + cloth trans-catheter heart valve in the Carpentier-Edwards Perimount valves.” The 9000MIS therefore qualifies as prior art to the Asserted Patents under at least pre-AIA 35 U.S.C. § 102(a).

The Cribier-Edwards MIS Aortic Bioprosthesis Model 9000MIS (“9000MIS”) discloses or renders obvious the limitations of the Asserted Claims as detailed in Exhibits B-E. A POSITA would have understood that the 9000MIS could have been delivered endovascularly through at least the common iliac artery. A POSITA would have also found it obvious to modify the 9000MIS

to enable endovascular delivery through the common femoral artery. POSITA's would have been motivated to endovascularly deliver the 9000MIS through the femoral artery. Many POSITAs considered the transfemoral approach "as the technique of first choice" and safer than the transapical approach, which was associated with "more adverse events and higher mortality rates." Conradi at 515-516; Yuksel at 52; Kainuma at 275. POSITAs would have had access to a range of suitable cloths having varying thicknesses and densities and could have selected an appropriately dimensioned cloth for endovascular delivery through, for example, the femoral artery. Examples of such cloths are disclosed in at least Levi, Walther, Spenser II, Cheung, Birdsall, Spenser III, Greenberg, Magovern, Essinger, McLean, Essinger '157, Hariton, Braido, Braido '802, Navia, Snyders, Norris, Greenhalgh, Cook, Hartley, Fogarty, Dehdashtian, Letort, Chuter, Baker, Rhodes, Baker '356, Elliot, Staudemneir, and/or Letort '926. *See* Exhibits B-E. Additionally, by 2012, Edwards had developed delivery systems having smaller diameters than those initially used with the SAPIEN valve. Nietlispach at 295-297; Le at [0005]-[0006]. These delivery systems permitted POSITAs to crimp valves to smaller diameters and thus endovascularly deliver valves having additional components, such as an outer seal. Also, by 2012, Edwards had developed a variety of ways to adapt a heart valve's outer frame and leaflets to create additional space for an outer seal. *See e.g.*, Levi at 6:31-49, 16:24-17:18. POSITAs would have found it obvious to utilize one or more of these known strategies to make the 9000MIS suitable for endovascular delivery, and particularly for transfemoral delivery. To the extent that the 9000MIS does not disclose or render obvious any limitation of the Asserted Claims, a POSITA would have found it obvious to combine 9000MIS with the teachings of one or more of Spenser, Cribier, Hariton, Cribier '321, and/or Levi, which disclose well-known features of THVs as detailed in Exhibits B-E. Such combinations would merely entail the application known elements

that would be reasonably likely to maintain their respective properties once combined and would be well within the ordinary creativity and common sense of a POSITA. *See id.* at 417-421.

Therefore, the 9000MIS anticipates the Asserted Claims under 35 U.S.C. § 102. Additionally, the Asserted Claims are invalid as obvious under 35 U.S.C. § 103 in view of the 9000MIS alone and/or the 9000MIS in combination with one or more of Spenser, Cribier, Hariton, Cribier '321, Levi, Walther, Spenser II, Cheung, Birdsall, Spenser III, Greenberg, Magovern, Essinger, McLean, Essinger '157, Braido, Hariton, Braido '802, Navia, Snyders, Ryan, Norris, Greenhalgh, Cook, Hartley, Fogarty, Dehdashtian, Letort, Chuter, Baker, Rhodes, Baker '356, Elliot, Staudemneir, and/or Letort '926. *See* Exhibits B-E.

R. '735 Patent – Proximal Apices Limitations

As detailed in Exhibit E, the prior art discloses the limitations of the Asserted Claims of the '735 patent requiring “wherein an end of the apices of the outer frame that are most proximal are uncovered by the outer seal and the graft covering” and “wherein the end of the most proximal apices of the outer frame extends more proximally than a proximal end of the outer seal.” Additionally, to the extent any prior art reference does not expressly disclose these limitations, a POSITA would have found it obvious to adjust the size and placement of the outer fibrous sealing material so that the ends of the proximal apices extend more proximally than the outer sealing material and are uncovered by both the sealing material and the graft covering. POSITAs were motivated to routinely adjust the size and shape of outer cloths to maximize sealing while minimizing the profile of the valve. The variety of outer seals disclosed in the prior art, as detailed in Exhibit E, illustrates this point. As explained above, persons of ordinary skill in the art had access to many suitable cloths having varying thicknesses and densities and naturally tried different cloths having different dimensions and placements. The prior art detailed in Exhibit E reflects that POSITAs knew how to attach different types and shapes of outer cloths to heart valves. POSITAs would have been

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/s/ Joshua J. Stowell

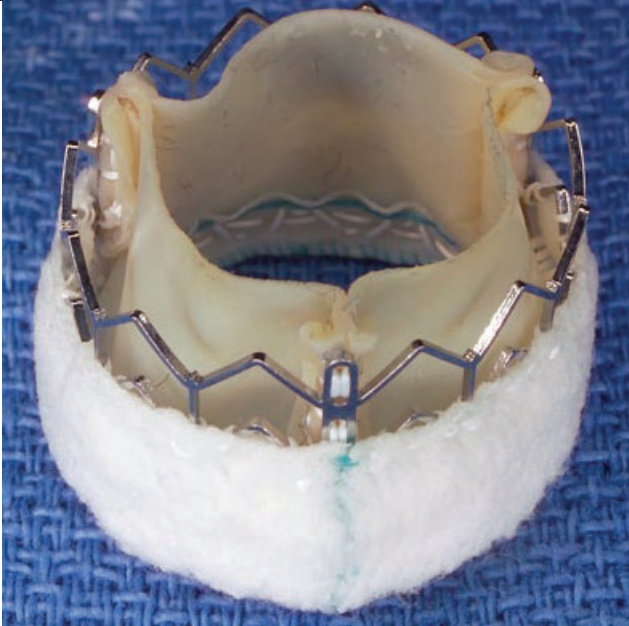
John B. Sganga, Jr.
Craig S. Summers
Christy G. Lea
Joshua J. Stowell
Brian C. Barnes
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, Fourteenth Floor
Irvine, CA 92614
(949) 760-0404
John.Sganga, Jr.@knobbe.com
Craig.Summers@knobbe.com
Christy.Lea@knobbe.com
Joshua.Stowell@knobbe.com
Brian.Barnes@knobbe.com

Brian C. Horne
KNOBBE, MARTENS, OLSON & BEAR, LLP
1925 Century Park East, Suite 600
Los Angeles, CA 90067
(310) 551-3450
Brian.Horne@knobbe.com

Brian P. Egan (#6227)
Anthony D. Raucci (#5948)
MORRIS, NICHOLS, ARSHT & TUNNELL LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
began@morrisnichols.com
araucci@morrisnichols.com

Attorneys for Defendants

'538 Patent Claim Element	Prior Art Disclosure
	the closed valve.” <i>See also</i> Wen, [0027]. The Cribier-Edwards Model 9000 MIS has been used in a method wherein the transcatheter aortic valve assembly has a radially compressed orientation and a radially expanded orientation, as shown below: Crimped Valve: 33 F Apogee Gen 1b Greinecker 041305 (EDWARDS_AI013346-EDWARDS_AI013368) at EDWARDS_AI013351.
1.4 wherein the transcatheter aortic valve assembly includes an outer frame, wherein the outer frame is formed from a metallic material and defines an	Under Plaintiffs’ view of this claim limitation (as reflected in Plaintiffs’ infringement contentions), at least the following prior art references disclose wherein the transcatheter aortic valve assembly includes an outer frame, wherein the outer frame is formed from a metallic material and defines an open cell configuration. Cribier, 348: “The Edwards-Sapien® Transcatheter Heart Valve (THV) consists of a tubular slotted

'538 Patent Claim Element	Prior Art Disclosure
	 Apogee Gen 1b Greinecker 041305 at EDWARDS_AI013350. – Balloon-expandable, stainless steel stent Apogee Update Feb 05 at EDWARDS_AI013389.
1.5 wherein the transcatheter includes an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending graft covering extending at least partially radially outwardly of the prosthetic	Under Plaintiffs’ view of this claim limitation (as reflected in Plaintiffs’ infringement contentions), at least the following prior art references disclose wherein the transcatheter includes an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve. Cribier, 348: “The Edwards-Sapien® Transcatheter Heart Valve (THV) consists of a tubular slotted stainless-steel balloon-expandable stent with an integrated unidirectional trileaflet bovine tissue valve with a polyethylene terephthalate (PET) fabric cuff (Figure 1).” Figure 1 of Cribier shows the fabric

CERTIFICATE OF SERVICE

I certify that I caused to be served copies of the foregoing **DEFENDANTS'**
PRELIMINARY INVALIDITY CONTENTIONS on August 3, 2022, upon the following in
the manner indicated:

Adam W. Poff, Esquire
Robert M. Vrana
YOUNG CONAWAY STARGATT & TAYLOR, LLP
Rodney Square
1000 North King Street
Wilmington, DE 19801
apoff@ycst.com
rvrana@ycst.com

VIA ELECTRONIC MAIL

John Campbell, Esquire
John F. Garvish, Esquire
Joel L. Thollander, Esquire
Caroline E. Burks
McKOOOL SMITH, P.C.
303 Colorado, Suite 2100
Austin, TX 78701
jcampbell@mckoolsmith.com
jgarvish@mckoolsmith.com
jthollander@mckoolsmith.com
cburks@mckoolsmith.com

VIA ELECTRONIC MAIL

Alan P. Block, Esquire
McKOOOL SMITH, P.C.
300 South Grand Ave., Suite 2900
Los Angeles, CA 90071
ablock@mckoolsmith.com

VIA ELECTRONIC MAIL

Casey Shomaker
McKOOOL SMITH, P.C.
300 Crescent Court, Suite 1500
Dallas, TX 75201
jyang@mckoolsmith.com
cshomaker@mckoolsmith.com

VIA ELECTRONIC MAIL

Attorneys for Plaintiff



Linda P. Dunn

55875194