IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORP. and BOSTON SCIENTIFIC SCIMED, INC., Plaintiffs, v. EDWARDS LIFESCIENCES CORP., Defendant.	C.A. No. 16-275-SLR-SRF
EDWARDS LIFESCIENCES CORP., EDWARDS LIFESCIENCES PVT, INC., and EDWARDS LIFESCIENCES LLC, Counterclaim and Third-Party Plaintiffs, v. BOSTON SCIENTIFIC CORPORATION, BOSTON SCIENTIFIC SCIMED, INC., and SADRA MEDICAL, INC., Counterclaim and Third-Party Defendants.	

DECLARATION OF PROFESSOR STEPHEN J.D. BRECKER IN SUPPORT OF BOSTON SCIENTIFIC'S REPLY CLAIM CONSTRUCTION BRIEF

I, Stephen J.D. Brecker, state and declare as follows:

1. I am over the age of 21 and am competent to make this declaration.

2. I am an interventional cardiologist with a special interest in adult structural heart disease and valvular intervention. I have over 25 years of medical experience as a practicing interventional cardiologist. I am the Chief of Cardiology at St. George's University Hospitals in

London, U.K. I have performed over one thousand transcatheter aortic valve replacement ("TAVR") procedures.

3. I graduated from St. Thomas' Hospital, London, in 1984. Subsequently, I completed senior house officer posts at the Hammersmith Hospital, the Brompton Hospital, and the National Hospital for Nervous Diseases. I then completed registrar training in cardiology at St. Thomas' Hospital and the London Chest Hospital, before taking up a British Heart Foundation Junior Research Fellowship at the Royal Brompton Hospital. I was also a visiting fellow at Johns Hopkins Hospital, Baltimore, before becoming a Consultant Cardiologist and Honorary Senior Lecturer at St. George's in 1996. I am now Professor of Cardiology and Chief of Cardiology Clinical Academic Group at St. George's University Hospitals.

4. My full qualifications are set forth in my CV, attached hereto at Exhibit A.

5. I have proctored over 600 TAVR procedures in which I assist and teach other physicians how to perform TAVR. I have been and remain a Global proctor for Medtronic since 2010 at approximately 80 centers worldwide, including over 50 medical centers in the USA for the US Pivotal Trial of the Corevalve product. I have also proctored the TAVR procedure in the UK, Denmark, Belgium, Japan, India, Israel, Holland, Austria, Greece, and South Korea.

6. I have performed TAVR procedures with Medtronic's Corevalve and Evolut R products, as well as Boston Scientific's Lotus product and Edwards's Sapien products.

7. I have been active in the field of TAVR as a clinician, researcher, teacher, and innovator, and I have performed over 1,000 percutaneous TAVR procedures since 2007.

8. I have been a practicing cardiologist since 1996 and I am aware of the technological advances since then.

9. I am a named inventor on one patent, describing a specific TAVR guidewire, acquired by Medtronic, and two patent applications, one for a transcatheter mitral valve, and one for a novel temporary pacing wire.

10. I am a Fellow of the Royal College of Physicians, the European Society of Cardiology, the American College of Cardiology, the British Cardiovascular Society, and the British Cardiovascular Intervention Society.

11. I am the author or co-author of four books, 16 book chapters, and more than 100 peer-reviewed articles.

12. For my time, I am being compensated at $800 per hour, my standard rate for this type of consulting activity. My compensation is in no way contingent on the results of these or any other legal proceedings.

Opinions Regarding Dr. Buller's Declaration And The '608 Patent

13. I have reviewed U.S. Patent No. 8,992,608 (the "'608 patent"), the parties' claim construction briefs, and Dr. Buller's declaration regarding the '608 patent. I provide the following opinions regarding these materials.

14. In Paragraph 27 of Dr. Buller's declaration, he sets out his instructions regarding the interpretation of claim terms in a patent. (Buller ¶ 27.) I have followed these same instructions in coming to my opinions in this Declaration.

15. In Paragraph 28 of Dr. Buller's declaration, he sets out his instructions regarding the standard of evaluating whether a patent claim is indefinite. (Buller ¶ 28.) I have followed these same instructions in coming to my opinions in this Declaration.

16. In Paragraph 31 of Dr. Buller's declaration, he opines that a person of ordinary skill in the art would have been an "interventional cardiologist with a working knowledge of

heart valve designs and endovascular prostheses, including expandable stents, stent-grafts, and transcatheter heart valves, including transcatheter aortic heart valves. This person of ordinary skill in the art would, where necessary, work as a team in combination with a medical device engineer to fabricate a THV device." (Buller ¶ 31.) I agree generally with this definition, however, it is my opinion that a person of ordinary skill in the art could also include a cardiac surgeon with experience implanting aortic valve prosthesis in the heart.

17. Dr. Buller asserts that "wrinkling or pleating can involve several variables. In my opinion, three of those variables are particularly important for purposes of determining whether the phrases 'flaps' and 'pockets' as used in the '608 patent inform, with reasonable certainty, those skilled in the art about the scope of the invention: **magnitude**, **orientation**, and **formation.**" (Buller ¶ 49.) I disagree that any of these "variables" need to be known in advance or quantified in order to determine whether a device has "flaps" or "pockets" within the meaning of the claims of the '608 patent. The word "flaps" in the claim and in the context of the description in the specification is clear and means fabric that projects from the anchor. To determine whether a device has "flaps" or "pockets," it is not necessary to determine whether the fabric projects a little or a lot, whether it is oriented in a certain direction, or how the fabric flap is formed. Instead, the fabric simply needs to project from the anchor in order to form flaps. Of course, the claim also requires the fabric flaps to (i) be part of a fabric seal and (ii) extend into the gaps formed by the native valve leaflets.

18. Dr. Buller describes several pieces of prior art that show what he considers to be flaps and pockets. The stent graft shown in paragraph 45 of Dr. Buller's declaration (the EVT endograft) does not appear to have flaps or pockets that project away from the anchor. (Buller ¶ 45.) To be sure, there are wrinkles shown in the left-most diagram of paragraph 45, but

it is not clear whether the wrinkles extend inwardly into the holes between the anchor's struts or whether they project away from the anchor. Regardless, persons of ordinary skill in the art would not have considered the covering around an endograft like the EVT endograft to have been suitable as a fabric seal in highly diseased and calcified locations, such as in a diseased aortic annulus. The covering around the EVT endograft shown in Dr. Buller's declaration does not form flaps and pockets that would extend into the gaps form by native aortic valve leaflets.

19. Dr. Buller points to several other pieces of prior art that he contends show "flaps and pockets" (Buller ¶¶ 46-48), but I do not believe this is relevant to the question of whether the terms "flaps" and "pockets" in the '608 patent are indefinite. I have not yet considered whether the prior art shows "flaps" and "pockets."

20. Dr. Buller provides three specific bases for his opinion that the term "flaps" is indefinite: he asserts that a person of ordinary skill in the art would not know the magnitude, orientation, and formation of the claimed "flaps." (Buller ¶ 49.) I disagree.

21. *First*, Dr. Buller asserts that "[a]ny fabric covering with wrinkles, for example, could be said to have portions that project from the anchor slightly along the wrinkles. Even very smooth fabric seals could project from the anchor at least in those areas along the open cells of the anchor due to the crimping process and the subsequent expansion of the valve, much like the wrinkles that form in clothing. The person of ordinary skill is thus left to guess whether any not-smooth portions of the fabric constitute 'flaps.'" (Buller ¶ 50.) I disagree with Dr. Buller's suggestion that a flap must project from the anchor by a predetermined distance in order to be a flap. The claims of the '608 patent require that the flaps be part of a "fabric seal," and, therefore, they are designed to "seal" the spaces between the anchor and the native aortic annulus. Additionally, the claims require that the flaps extend into the gaps formed by the native valve

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.