

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC,  
AND EDWARDS LIFESCIENCES AG  
Petitioners

v.

BOSTON SCIENTIFIC SCIMED, INC.  
Patent Owner

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Case IPR2017-00060  
Patent 8,992,608

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**SUPPLEMENTAL DECLARATION OF NIGEL P. BULLER, M.D.  
SUBMITTED ON BEHALF OF PETITIONERS EDWARDS LIFESCIENCES  
CORPORATION, EDWARDS LIFESCIENCES LLC, AND  
EDWARDS LIFESCIENCES AG**

I, Dr. Nigel P. Buller, declare as follows:

1. I have been retained on behalf of Edwards Lifesciences Corporation, Edwards Lifesciences LLC and Edwards Lifesciences AG (“Edwards”), and its counsel, Jeffer Mangels Butler & Mitchell, LLP, as an expert in this proceeding. I am personally knowledgeable about the matters stated herein and am competent to make this declaration.

2. I have been informed that the Patent Owner objected to my qualifications as an expert as of the asserted June 2004 priority date of U.S. Patent No. 8,992,608 (the “’608 Patent”) on “any technical matter relevant to transcatheter aortic heart valves, including, engineering devices for sealing spaces formed by native valve leaflets and fluid dynamics associated with paravalvular leakage of transcatheter aort heart valves,” whether the claims of the ’608 Patent are valid, whether a person of ordinary skill would have been motivated to combine prior art references to disclose the inventions claimed in the ’608 patent, the construction and application of claim terms from the ’608 patent, and whether I have any first-hand knowledge, experience, or perceptions regarding these issues sufficient to render any lay testimony or opinions on these matters. As such, I have been asked to provide additional explanation regarding these topics.

3. First, I incorporate by reference herein the discussion of my Background and Qualifications set forth at Paragraphs 5-26 of my Declaration, as well as my

*Curriculum Vitae* attached as Exhibit A to my Declaration, which was submitted as Exhibit 1007 to IPR2017-00060.

4. As noted in paragraph 23 of my Declaration, throughout the 1990s, I served on scientific advisory boards, including Patent Owner Boston Scientific's scientific advisory board, where I discussed and debated concepts and development of a variety of medical devices for use in interventional procedures, including stent-based devices.

5. In June of 2004, the asserted priority date of the '608 Patent, only a handful of physicians in the world had hands-on experience with transcatheter heart valve technology, namely interventional cardiologists Dr. Alain Cribier and his team with respect to aortic transcatheter heart valves and Dr. Philipp Bonhoeffer and his team with respect to pulmonary transcatheter heart valves. As such, a person of ordinary skill in the art for purposes of the '608 Patent would not be limited to interventional cardiologists with hands-on experience with transcatheter heart valves. Instead, as set forth in my Declaration at Paragraph 36, a person of ordinary skill in the art as of June 2004 would be an interventional cardiologist with a working knowledge of heart valve designs and endovascular prostheses, including expandable stents and stent-grafts. My Declaration provides summations of my expertise in the areas of heart valve designs and endovascular prostheses, including expandable stents and stent-grafts. *See Ex. 1007 at Paragraphs 5-26.*

6. I further provide that I have been qualified as an expert in a number of matters involving transcatheter heart valve technology, most recently in a matter where I served as an expert on behalf of Petitioner Edwards Lifesciences in litigation against Patent Owner Boston Scientific involving the European counterpart patents to the '608 Patent, the patent subject here to *inter partes* review. This and other matters in which I've both submitted expert reports and testified at trial on transcatheter heart valve technology are provided below:

- a. *Edwards Lifesciences LLC v. Boston Scientific Scimed, Inc.*, Case No. HC-2015-004574 (High Court of Justice Chancery Division, United Kingdom). The Approved Judgment in this matter, attached as Exhibit 1036 hereto, confirms that I was qualified as an expert witness on transcatheter heart valve technology. *See, e.g.*, Exhibit 1036 at ¶¶ 47-48.
- b. *CoreValve Inc. v. Edwards Lifesciences AG*, Case No. HC-07-C01243 (High Court of Justice Chancery Division, United Kingdom). The Judgment in this matter, attached as Exhibit 1037 hereto, confirms that I was qualified as an expert witness on transcatheter heart valve technology. *See, e.g.*, Exhibit 1037 at ¶¶ 40-44.
- c. *Edwards Lifesciences AG v. Cook Biotech Inc.*, Case No. HC08-00934 (High Court of Justice Chancery Division, United Kingdom). The Approved Judgment in this matter, attached as Exhibit 1038 hereto,

confirms that I was qualified as an expert witness on transcatheter heart valve technology. *See, e.g.*, Exhibit 1038 at ¶¶ 5-6.

d. *Edwards Lifesciences AG v. CoreValve, Inc.*, C.A. No. 08-091 (GMS) (D. Del.). The Court's post-trial memorandum opinion in this matter, attached as Exhibit 1039 hereto, confirms that I was qualified as an expert witness on transcatheter heart valve technology. *See, e.g.*, Exhibit 1039 at 7.

e. *Edwards Lifesciences LLC v. Medtronic CoreValve LLC*, C.A. No. 12-023 (GMS) (D. Del.). There is no post-trial opinion in this matter as it settled prior to issuance of any such opinion, but Edwards' post-trial brief in support of its motion for enhanced damages, attached hereto as Exhibit 1040, confirms that I was qualified as an expert witness on transcatheter heart valve technology. *See, e.g.*, Exhibit 1040 at 12-13.

7. I have been informed that the Patent Owner also objected to Exhibit 1015, Excerpts from Vossoughi *et al.*, Stent Graft Update (2000), submitted on October 12, 2016 in the Petition for *Inter Partes* Review, and I have been asked to provide additional information regarding this Exhibit. This textbook is accepted by those of ordinary skill in the art and in the field of interventional cardiology generally as a reliable authority and it also is relied on by persons of ordinary skill in the art and in the field of interventional cardiology. Exhibit 1041 is a true and correct copy of the complete Stent Graft Update textbook.

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