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1 Pursuant to the Federal Rules of Civil Procedure 26 and 33, Defendant 2 Edwards Lifesciences Corporation ("Edwards") hereby supplements its response 3 to Interrogatory No. 8 of Plaintiffs Boston Scientific Corporation and Boston 4 Scientific Scimed, Inc. (collectively, "BSC").

### PRELIMINARY STATEMENT

Edwards hereby incorporates, in full, the Preliminary Statement set forth in its Responses to BSC's First Set of Interrogatories served on August 26, 2016.

#### **GENERAL OBJECTIONS**

10 Edwards hereby incorporates, in full, the General Objections set forth in its Responses to BSC's First Set of Interrogatories served on August 26, 2016.

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# **INTERROGATORY NO. 8:**

13 For each Patent-in-Suit, state all factual and legal bases for any contention 14 that non-infringing alternatives regarding any Accused Product were or are 15 available and acceptable, including an identification of all persons who have 16 knowledge of such contention and all documents related to such contention.

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**RESPONSE TO INTERROGATORY NO. 8:** 

Subject to its General and Specific Objections, Edwards responds as 19 follows:

20 Edwards responds that acceptable non-infringing alternatives to the 21 Accused Products exist. For example, at least some customers would choose to 22 purchase the following transcatheter heart valve systems for use in 23 transcathether aortic valve replacement or implantation if they could not 24 purchase products from Edwards: CoreValve Evolut R System, CoreValve 25 Evolut System, CoreValve ReValving System, Medtronic CoreValve System, 26 Medtronic Engager System, St. Jude Medical Portico Transcatheter Aortic 27 Valve Replacement System, Symetis Acurate neo System, Symetis Acurate neo 28 Suctam Sumatic Acurata TE Suctam Sumatic Acurata TA Suctam Diract Flow

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Medical Transcatheter Aortic Valve System, and JenaValve System. Edwards
is unaware of any allegations by BSC that any of the transcatheter heart valve
systems sold by these companies infringe any of the patents-in-suit. Because
Edwards' investigation of this matter is ongoing, Edwards reserves the right to
supplement or amend this response, and to rely on additional documents,
witnesses, or other evidence.

The above response is subject to Edwards' General Objections, each 7 8 of which is fully incorporated herein, as well as the following Specific 9 Objections: Edwards objects to this Interrogatory as premature, because fact 10 discovery is ongoing and Edwards' investigation of this matter continues. 11 Edwards objects to this Interrogatory as overly broad and not proportional to the needs of this case to the extent that it seeks information about Edwards' non-12 13 accused products or for products that BSC has identified as infringing but for 14 which it has not provided sufficiently (or any) particularized and detailed 15 infringement contentions. Edwards objects to this Interrogatory because it 16 presumes that the Accused Products infringe the Patents-in-Suit, which they 17 do not. Therefore, Edwards does not need to identify any non-infringing alternatives to the Accused Products. Edwards objects to this Interrogatory 18 to the extent it seeks expert testimony or Edwards' contentions at trial. 19 20Edwards will disclose any expert opinions or trial contentions as required by 21 the Federal Rules of Civil Procedure, the Local Rules, and the Court's 22 Scheduling Order. Edwards objects to this Interrogatory as premature and 23 calling for legal conclusions to the extent it seeks information concerning 24 the meaning of claim terms that have yet to be construed. Edwards objects 25 to this Interrogatory as overly broad, unduly burdensome, and not 26 proportional to the needs of this case to the extent it seeks "all factual and legal bases" for any such contention. Edwards objects to this Interrogatory 27 to the extent it seeks information that is publicly available, and therefore, of 28

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no greater burden for BSC to obtain than Edwards. Edwards objects to this
 Interrogatory as seeking information protected from disclosure by a
 privilege or immunity, including without limitation, the attorney-client
 privilege, the work-product doctrine, and the common interest privilege.

# **SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 8:**

6 Edwards hereby incorporates, in full, its response, including Specific
7 Objections, set forth in its Response to Interrogatory No. 8 served on August 26,
8 2016. Subject to its General and Specific Objections, Edwards responds that, in
9 addition to the products identified in its original response, Edwards had
10 noninfringing designs that were available and acceptable alternatives to the
11 following accused products:

<u>NovaFlex family and Commander</u>: For the asserted claims of the '543,
'548, '962, '827, '234, and '062 patents, Edwards had several acceptable noninfringing alternative designs that do not use the balloon insert in the NovaFlex
or the coil in the Commander, which Boston accuses of satisfying the
"mounting body" and other similar claim limitations. These designs would have
provided adequate retention force on the valve.

18 One option, which Edwards considered in June 2008, was to instruct 19 doctors to add a small amount of fluid to the inflation balloon after the valve is 20aligned over the inflation balloon. By this time, doctors had commonly added a 21 small amount of fluid to balloon-expandable catheters before deploying the 22balloon, and doctors had commonly done so with Edwards' Retroflex delivery 23 systems. Edwards tested this solution in June 2008, and determined that it 24 provided a 7.3 lb. retention force, which was greater than the approximately 4.78 lb. force provided by the balloon insert. See EWL 00373671-72; EWL 25 00397057; May 24, 2017 Deposition Transcript of Tri Tran at 164-172. 26 It would have taken Edwards no additional time to develop this solution, and it 27 28 would not have cost any more to manufacture than the commercial NovaFlex

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and Commander products that Edwards sold. Edwards could have
commercialized this alternative by the same time that it commercialized its
accused NovaFlex and Commander products.

- 4 A second option, which Edwards considered by September 2008, was to 5 add unidirectional stoppers. This option would have prevented the valve from 6 moving after the valve alignment step and before the valve deployment step. See EWL 00350069; June 2, 2017 Deposition Transcript of Ronaldo Cayabyab at 7 8 88-91, 96-97; May 24, 2017 Deposition Transcript of Tri Tran at 164-172. It 9 would have taken Edwards approximately 10-12 weeks and less than \$25,000 to develop this design. Edwards could have manufactured this alternative for the 10 11 same cost as the accused NovaFlex and Commander products. Edwards could 12 have commercialized this alternative by the same time that it commercialized its 13 accused NovaFlex and Commander products.
- 14 A third option would have been to redesign the tip of the flex catheter so 15 that it could expand and break away during inflation. This design would allow 16 the flex tip to support the proximal end of the valve as the valve crossed the 17 native annulus and during initial inflation. It would have taken Edwards approximately 10-12 weeks and less than \$25,000 to develop this design. 18 19 Edwards could have manufactured this alternative for the same cost as the 20accused NovaFlex and Commander products. Edwards could have 21 commercialized this alternative by the same time that it commercialized its 22 accused NovaFlex and Commander products.
- Each alternative to using a balloon insert would have retained the valve as
  effectively as the balloon insert. Thus, the alternative would have been equally
  acceptable to doctors using the delivery system. These options could have fit
  into the same size sheath as the accused products, and therefore could have
  served the same patient population.

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