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EDWARDS LIFESCIENCES CORPORATION and  
13 EDWARDS LIFESCIENCES LLC  
14  
15

16 IN THE UNITED STATES DISTRICT COURT  
17 FOR THE CENTRAL DISTRICT OF CALIFORNIA

18  
19 EDWARDS LIFESCIENCES  
CORPORATION, a Delaware  
20 corporation, and EDWARDS  
LIFESCIENCES LLC, a Delaware  
21 corporation

22 Plaintiff,

23 v.

24 ABBOTT CARDIOVASCULAR  
SYSTEMS, INC., a California  
25 corporation, ABBOTT  
LABORATORIES, INC., a  
26 Delaware Corporation, and  
EVALVE, INC., a Delaware  
27 Corporation

28 Defendants.

Case No. 8:19-cv-345

**FIRST AMENDED COMPLAINT  
FOR PATENT INFRINGEMENT**

**DEMAND FOR JURY TRIAL**

1 Plaintiffs Edwards Lifesciences Corporation and Edwards Lifesciences  
2 LLC, for their complaint against Defendants Abbott Cardiovascular Systems,  
3 Inc., Abbott Laboratories, Inc., and Evalve, Inc. allege as follows:

4 **I. THE PARTIES**

5 1. Plaintiff Edwards Lifesciences Corporation is a corporation  
6 organized and existing under the laws of the State of Delaware, with its  
7 principal place of business at One Edwards Way, Irvine, California 92614.

8 2. Plaintiff Edwards Lifesciences LLC is a corporation organized and  
9 existing under the laws of the State of Delaware, with its principal place of  
10 business at One Edwards Way, Irvine, California 92614.

11 3. Defendant Abbott Cardiovascular Systems, Inc. is a corporation  
12 organized and existing under the laws of the State of California, with its  
13 principal place of business at 3200 Lakeside Drive, Santa Clara, California  
14 95054.

15 4. Defendant Abbott Laboratories, Inc. is a corporation organized and  
16 existing under the laws of the State of Delaware, with its principal place of  
17 business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

18 5. Defendant Evalve, Inc. is a corporation organized and existing  
19 under the laws of the State of Delaware, with its principal place of business at  
20 4045 Campbell Avenue, Menlo Park, California 94025.

21 6. Edwards Lifesciences Corporation and Edwards Lifesciences LLC  
22 shall be collectively referred to herein as “Plaintiffs” or “Edwards Lifesciences.”  
23 Abbott Cardiovascular Systems, Inc., Abbott Laboratories, Inc., and Evalve,  
24 Inc. shall be referred to herein as “Defendants” or “Abbott.”

25 **II. JURISDICTION AND VENUE**

26 7. This is an action for patent infringement arising under the patent  
27 laws of the United States of America, Title 35, United States Code. This Court  
28 has original jurisdiction over the subject matter of this action pursuant to 28

1 U.S.C. §§ 1331 and 1338(a).

2 8. Defendants are engaged in the business of manufacturing, selling,  
3 offering for sale, exporting, and/or importing mitral valve repair devices sold  
4 under the names MitraClip, MitraClip NT, MitraClip NTR, and MitraClip XTR  
5 (collectively, the “Accused Products”) in the United States, including within this  
6 District.

7 9. Venue is proper in this District pursuant to 28 U.S.C. § 1400(b),  
8 because the Defendants have committed acts of infringement in this District,  
9 and because Defendants Abbott Cardiovascular Systems and Abbott  
10 Laboratories, Inc. have several established places of business in this district,  
11 including in Temecula, California. For purposes of this lawsuit, Evalve, Inc.  
12 and Abbott Laboratories, Inc. consent to venue in the Central District of  
13 California.

14 10. This Court has personal jurisdiction over Defendants. The  
15 Defendants have committed acts of infringement in this District, including  
16 manufacturing, selling, offering for sale, exporting, and/or importing the  
17 Accused Products in this District.

### 18 **III. THE PATENTS-IN-SUIT**

19 11. On April 13, 2004, the United States Patent and Trademark Office  
20 issued United States Patent No. 6,719,767 (“the ’767 Patent”) entitled “Device  
21 and a Method for Treatment of Atrioventricular Regurgitation,” a true and  
22 correct copy of which is attached as Exhibit 1.

23 12. Edwards Lifesciences Corporation is the assignee of all rights to  
24 the ’767 Patent, including the right to sue for and recover all past and present  
25 damages for infringement of the ’767 Patent. Edwards Lifesciences LLC is the  
26 exclusive licensee of the ’767 Patent.

27 13. On March 14, 2006, the United States Patent and Trademark Office  
28 issued United States Patent No. 7,011,669 (“the ’669 Patent”) entitled “Device

1 and a Method for Treatment of Atrioventricular Regurgitation,” a true and  
2 correct copy of which is attached as Exhibit 2.

3 14. Edwards Lifesciences Corporation is the assignee of all rights to  
4 the ’669 Patent, including the right to sue for and recover all past and present  
5 damages for infringement of the ’669 Patent. Edwards Lifesciences LLC is the  
6 exclusive licensee of the ’669 Patent.

7 15. On November 22, 2011, the United States Patent and Trademark  
8 Office issued United States Patent No. 8,062,313 (“the ’313 Patent”) entitled  
9 “Device and a Method for Treatment of Atrioventricular Regurgitation,” a true  
10 and correct copy of which is attached as Exhibit 3.

11 16. Edwards Lifesciences Corporation is the assignee of all rights to  
12 the ’313 Patent, including the right to sue for and recover all past and present  
13 damages for infringement of the ’313 Patent. Edwards Lifesciences LLC is the  
14 exclusive licensee of the ’313 Patent.

15 17. The ’767 Patent, the ’669 Patent, and the ’313 Patent are  
16 collectively referred to herein as the Asserted Patents.

17 **IV. COUNT 1 – INFRINGEMENT OF THE ’767 PATENT**

18 18. Edwards Lifesciences incorporates paragraphs 1 through 17 as  
19 though fully set forth herein.

20 19. Defendants have made, used, sold, and/or offered for sale the  
21 Accused Products in the United States, imported the Accused Products into the  
22 United States, and/or exported from the United States all or a substantial portion  
23 of the components of the Accused Products for which no substantial  
24 noninfringing use exists, including within this District.

25 20. Defendants have directly infringed at least Claim 14 of the ’767  
26 Patent either literally or under the doctrine of equivalents by manufacturing,  
27 selling, offering for sale, and/or importing the Accused Products, in violation of  
28 35 U.S.C. § 271(a).

1           21. By way of example, and not limitation, Defendants' direct  
2 infringement of Claim 14 of the '767 Patent is shown in the claim chart in  
3 Exhibit 4, attached hereto and incorporated herein by reference, which compares  
4 exemplary Claim 14 to the Accused Products.

5           22. Each version of the MitraClip implant requires a clip delivery  
6 system, including a catheter, for implantation. The clip delivery system is  
7 especially made for use with the MitraClip. The MitraClip Instructions for Use  
8 instruct clinicians to use the clip delivery system to implant the MitraClip.

9           23. One or more Defendants have also infringed at least Claim 14 of  
10 the '767 Patent by supplying or causing to be supplied from the United States all  
11 or a substantial portion of the components of the Accused Products, including  
12 the MitraClip implant and/or the clip delivery system, in such a manner as to  
13 actively induce the combination of the components outside the United States in  
14 a manner that would infringe if the combination occurred within the United  
15 States, in violation of 35 U.S.C. § 271(f)(1).

16           24. One or more Defendants have also infringed at least Claim 14 of  
17 the '767 Patent by supplying components of the Accused Products, including  
18 the MitraClip and/or the clip delivery system, that are especially made or  
19 adapted for use in the Accused Products and are not a staple article or  
20 commodity of commerce suitable for substantial noninfringing use, with  
21 knowledge that the components are so made or adapted and intending that the  
22 components will be combined outside the United States in a manner that would  
23 infringe the patent if such combination occurred within the United States, in  
24 violation of 35 U.S.C. § 271(f)(2).

25           25. Defendants had actual knowledge of the '767 Patent prior to the  
26 filing of this Complaint. For example, on September 22, 2004 during the  
27 prosecution of U.S. Patent No. 7,335,213, Defendant Abbott Cardiovascular  
28 Systems cited the '767 Patent in an information disclosure statement to the

1 United States Patent and Trademark Office. As an additional example, on  
2 January 30, 2010, during the prosecution of U.S. Patent No. 7,736,388,  
3 Defendant Evalve, Inc. cited the '767 Patent in an information disclosure  
4 statement to the United States Patent and Trademark Office. Abbott  
5 Laboratories, Inc. had actual knowledge of the '767 Patent at least as early as  
6 February 22, 2019, when Edwards filed their Complaint in this case.

7 26. Edwards Lifesciences has been damaged by Defendants' infringing  
8 activities in an amount to be determined at trial, but in no event less than a  
9 reasonable royalty.

10 **V. COUNT 2 – INFRINGEMENT OF THE '669 PATENT**

11 27. Edwards Lifesciences incorporates paragraphs 1 through 26 as  
12 though fully set forth herein.

13 28. Defendants have induced infringement of the '669 Patent under 35  
14 U.S.C. § 271(b), by, for example, instructing clinicians to use the Accused  
15 Products in a manner that constitutes direct infringement of the '669 Patent.

16 29. Defendants have also contributed to the infringement of the '669  
17 Patent under 35 U.S.C. § 271(c) by, for example, offering for sale, selling,  
18 and/or importing the Accused Products for use in practicing the patented process  
19 of the '669 Patent, where the Accused Products constitute a material part of the  
20 invention, and are not a staple article or commodity of commerce suitable for  
21 substantial non-infringing use, and are known by Defendants to be especially  
22 adapted for use in an infringement of the '669 Patent. As a result, the Accused  
23 Products have been used by customers and clinicians in a manner that directly  
24 infringes at least claim 1 of the '669 Patent.

25 30. For example, in the MitraClip Instructions For Use (attached hereto  
26 as Exhibit 5), Defendants instruct clinicians to use the Accused Products in a  
27 manner that infringes, either literally or under the doctrine of equivalents, one or  
28 more claims of the '669 Patent, including at least Claim 1.

1           31. When clinicians perform the method of using the Accused  
2 Products, as described at least in Exhibit 5, they are directly infringing at least  
3 Claim 1 of the '669 Patent as described in the claim chart in Exhibit 6, attached  
4 hereto and incorporated herein by reference.

5           32. Defendants knew that clinicians would infringe the '669 Patent by  
6 using the Accused Products during the term of the '669 Patent. For example,  
7 Defendants provide Instructions for Use (Exhibit 5) to clinicians with the  
8 Accused Products. The Instructions for Use instruct the clinician to perform a  
9 method of using the Accused Products that would constitute direct infringement  
10 of at least Claim 1 of the '669 Patent. Defendants also knew that the Accused  
11 Products were not a staple article or commodity of commerce for substantial  
12 non-infringing use.

13           33. Defendants had the specific intent to induce and did induce  
14 clinicians to infringe the '669 Patent under 35 U.S.C. § 271(b), by, for example,  
15 causing clinicians to use the Accused Products in a manner that constitutes  
16 direct infringement of at least Claim 1 of the '669 Patent during the term of the  
17 '669 Patent, including by providing marketing materials and instructions for  
18 use, such as for example the Instructions for Use (Exhibit 5), to clinicians that  
19 instruct the clinicians to perform a method of using the Accused Products that  
20 infringes at least Claim 1 of the '669 Patent.

21           34. Defendants had actual knowledge of the '669 Patent prior to the  
22 filing of this Complaint. For example, on July 25, 2018 during the prosecution  
23 of U.S. Patent No. 10,188,392, Defendant Abbott Cardiovascular Systems cited  
24 the '669 Patent in an information disclosure statement to the United States  
25 Patent and Trademark Office. As an additional example, on April 17, 2007,  
26 during the prosecution of U.S. Patent No. 7,736,388, Defendant Evalve, Inc.  
27 cited the '669 Patent in an information disclosure statement to the United States  
28 Patent and Trademark Office. Abbott Laboratories, Inc. had actual knowledge



1 of the '669 Patent at least as early as February 22, 2019, when Edwards filed  
2 their Complaint in this case.

3 35. Edwards Lifesciences has been damaged by Defendants' infringing  
4 activities in an amount to be determined at trial, but in no event less than a  
5 reasonable royalty.

6 **VI. COUNT 3 – INFRINGEMENT OF THE '313 PATENT**

7 36. Edwards Lifesciences incorporates paragraphs 1 through 35 as  
8 though fully set forth herein.

9 37. Defendants have made, used, sold, and/or offered for sale the  
10 Accused Products in the United States, imported the Accused Products into the  
11 United States, and/or exported from the United States all or a substantial portion  
12 of the components of the Accused Products for which no substantial  
13 noninfringing use exists, including within this District.

14 38. Defendants have directly infringed at least Claim 1 of the '313  
15 Patent either literally or under the doctrine of equivalents by manufacturing,  
16 selling, offering for sale, and/or importing the Accused Products, in violation of  
17 35 U.S.C. § 271(a).

18 39. By way of example, and not limitation, Defendants' direct  
19 infringement of Claim 1 of the '313 Patent is shown in the claim chart in  
20 Exhibit 7, attached hereto and incorporated herein by reference, which compares  
21 exemplary Claim 1 to the Accused Products.

22 40. Each version of the MitraClip implant requires a clip delivery  
23 system, including a catheter, for implantation. The clip delivery system is  
24 especially made for use with the MitraClip. The MitraClip Instructions for Use  
25 instruct clinicians to use the clip delivery system to implant the MitraClip.

26 41. One or more Defendants have also infringed at least Claim 1 of the  
27 '313 Patent by supplying or causing to be supplied from the United States all or  
28 a substantial portion of the components of the Accused Products, including the



1 MitraClip implant and/or the clip delivery system, in such a manner as to  
2 actively induce the combination of the components outside the United States in  
3 a manner that would infringe if the combination occurred within the United  
4 States, in violation of 35 U.S.C. § 271(f)(1).

5 42. One or more Defendants have also infringed at least Claim 1 of the  
6 '313 Patent by supplying components of the Accused Products, including the  
7 MitraClip and/or the clip delivery system, that are especially made or adapted  
8 for use in the Accused Products and are not a staple article or commodity of  
9 commerce suitable for substantial noninfringing use, with knowledge that the  
10 components are so made or adapted and intending that the components will be  
11 combined outside the United States in a manner that would infringe the patent if  
12 such combination occurred within the United States, in violation of 35 U.S.C. §  
13 271(f)(2).

14 43. Defendants had actual knowledge of the patent application that  
15 issued as the '313 Patent prior to the filing of this Complaint. For example, on  
16 July 25, 2018, during the prosecution of U.S. Patent No. 10,188,392, Defendant  
17 Abbott Cardiovascular Systems cited the patent application that issued as the  
18 '313 Patent in an information disclosure statement to the United States Patent  
19 and Trademark Office. As an additional example, on January 31, 2010 during  
20 the prosecution of U.S. Patent No. 8,052,592, Defendant Evalve, Inc. cited the  
21 patent application that issued as the '313 Patent in an information disclosure  
22 statement to the United States Patent and Trademark Office. Defendants had  
23 actual knowledge of the '313 Patent prior to the filing of this Complaint.  
24 Defendants are sophisticated companies that monitor the patents of its  
25 competitors and as a result of this monitoring learned that the '313 Patent issued  
26 from the patent application. Abbott Laboratories, Inc. had actual knowledge of  
27 the '313 Patent at least as early as February 22, 2019, when Edwards filed their  
28 Complaint in this case.

1           44. Edwards Lifesciences has been damaged by Defendants' infringing  
2 activities in an amount to be determined at trial, but in no event less than a  
3 reasonable royalty.

4                                   **VII. PRAYER FOR RELIEF**

5 WHEREFORE, Edwards Lifesciences requests the following relief:

6           45. A judgment in favor of Edwards Lifesciences that Defendants have  
7 infringed one or more claims of the '767 Patent;

8           46. A judgment in favor of Edwards Lifesciences that Defendants have  
9 induced others to infringe one or more claims of the '669 Patent;

10          47. A judgment in favor of Edwards Lifesciences that Defendants have  
11 contributed to the infringement by others of one or more claims of the '669  
12 Patent;

13          48. A judgment in favor of Edwards Lifesciences that Defendants have  
14 infringed one or more claims of the '313 Patent;

15          49. A judgment in favor of Edwards Lifesciences that this case is  
16 exceptional under 35 U.S.C. § 285 and awarding Edwards Lifesciences its  
17 attorneys' fees;

18          50. A judgment and order requiring Defendants to pay Edwards  
19 Lifesciences damages adequate to compensate for infringement under 35 U.S.C.  
20 § 284, which damages in no event shall be less than a reasonable royalty for the  
21 use made of the inventions of the Asserted Patents, including supplemental  
22 damages for any continuing post-verdict infringement up until the entry of  
23 judgment, with an accounting, as needed, pre- and post-judgment interest and  
24 costs, including expenses and disbursements;

25          51. A judgment in favor of Edwards Lifesciences, and against  
26 Defendants, that interest, costs, and expenses be awarded in favor of Edwards  
27 Lifesciences; and

28       ///



**VIII. DEMAND FOR TRIAL BY JURY**

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs Edwards Lifesciences Corporation and Edwards Lifesciences LLC hereby demand a trial by jury on all issues so triable.

Respectfully submitted,  
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: November 7, 2019 By: /s/ Hans L. Mayer

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