IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDOHEART AG *Plaintiff,* v. EDWARDS LIFESCIENCES CORPORATION, *Defendant*.	Civil Action No. _____ **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff Endoheart AG ("Endoheart) for its Complaint herein against Edwards Lifesciences Corporation ("Edwards") avers as follows:

JURISDICTION AND VENUE

1. This is an action for patent infringement arising under the Patent Laws of the United States, Title 35, United States Code.

2. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

3. Venue within this Judicial District is proper under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

THE PARTIES

4. Plaintiff Endoheart is a Swiss corporation with a principal place of business at Hegifeldstrasse 9, 8404 Winterhur, Canton Zurich, Switzerland.

5. On information and belief, defendant Edwards is a Delaware corporation with a principal place of business in Irvine, California.

6. Huber U.S. Patent 8,182,530 ("the '530 patent"), entitled "METHODS AND DEVICES FOR REPAIR OR REPLACEMENT OF HEART VALVES OR ADJACENT TISSUE WITHOUT THE NEED FOR FULL CARDIOPULMONARY SUPPORT," was duly and legally issued to Endoheart on May 22, 2012. Since that date, Endoheart has been and still is the owner of all right, title and interest in and to the '530 patent, including the right to sue and to recover for past infringements thereof. A copy of the '530 patent is attached as Exhibit A to this Complaint.

7. The provisional application for the '530 patent was filed on October 2, 2004 and the non-provisional application for the '530 patent was filed on December 28, 2004. The non-provisional application for the '530 patent was published on April 6, 2006 as Publication 2006/0074484 ("the '530 publication").

8. On information and belief, Edwards has been aware of the '530 publication since at least October 27, 2010, when Edwards listed the '530 publication in an Information Disclosure Statement filed in connection with Application 11/280,063, which issued as United States Patent 8,764,820 and states that it is assigned to Edwards.

9. On information and belief, Edwards has been aware of the '530 patent since at least September 2012, when Endoheart notified Edwards of the '530 patent in connection with communications between Endoheart and Edwards concerning the '530 patent and the applicability of the claims of the '530 patent to methods that use Edwards devices in transcatheter aortic valve replacement procedures using a transapical approach.

10. On information and belief, Edwards received pre-market approval from the United States Food and Drug Administration on October 19, 2012 for transapical delivery for the Edwards Sapien Transcatheter Heart Valve and accessories, including the Ascendra Delivery

System, the Ascendra Balloon Aortic Valvuloplasty Catheter, the Ascendra Introducer Sheath Set and the Edwards Crimper.

11. On information and belief, Edwards has actively induced infringement of the ‘530 patent by selling Edwards devices, including at least the Ascendra Delivery System, the Ascendra Balloon Aortic Valvuloplasty Catheter, the Ascendra Introducer Sheath Set, the Sapien Transcatheter Heart Valve and the Edwards Crimper, and by actively inducing others, including at least physicians at TAVR Centers, to use such devices to perform transcatheter aortic valve replacement procedures using a transapical approach as claimed by at least claims 1 and 6 of the ‘530 patent.

12. On information and belief, Edwards has intended, and continues to intend, to induce infringement by third parties and has had knowledge that its inducing acts would cause infringement or has been willfully blind to the possibility that its inducing acts would cause infringement. For example, on information and belief, Edwards has instructed physicians to perform, and is aware that physicians will infringe the ‘530 patent by performing, a method that uses Edwards devices in connection with performing transcatheter aortic valve replacement procedures using a transapical approach, including the steps of:

A. Using a needle to gain access to the left ventricular apex of a patient’s heart by piercing the myocardium;

B. Inserting a soft guidewire through the needle and crossing the aortic valve with the soft guidewire, where the guidewire is configured to move with the blood flow and follows the blood flow through the aortic valve of the heart;

C. Exchanging the needle for an Ascendra Introducer Sheath Set, which has at least one valve for preventing bleeding through the Sheath Set;

D. Inserting the Ascendra Balloon Catheter of an Ascendra Delivery System through an Ascendra Introducer Sheath Set, with a Sapien Transcatheter Heart Valve crimped onto the Balloon Catheter with the inflow of the Sapien Transcatheter Heart Valve towards the proximal end of the Balloon Catheter for delivery in an antegrade direction relative to blood flow; and

E. Installing a Sapien Transcatheter Heart Valve within the diseased aortic valve.

13. On information and belief, Edwards' infringement is willful and deliberate. On information and belief, Edwards has been aware of the '530 patent since at least September 2012, and has actively induced infringement of the '530 patent by selling devices and by actively inducing physicians to use those devices to perform the methods claimed by at least claims 1 and 6 of the '530 patent since Edwards received pre-market approval from the United States Food and Drug Administration on October 19, 2012 for transapical delivery for the Edwards Sapien Transcatheter Heart Valve and accessories, including the Ascendra Delivery System, the Ascendra Balloon Aortic Valvuloplasty Catheter, the Ascendra Introducer Sheath Set and the Edwards Crimper, despite an objectively high likelihood that its actions constituted infringement, and with knowledge that its acts would cause infringement.

14. Endoheart has been suffering, and will continue to suffer damages, as a result of Edwards' infringing acts.

PRAYER FOR RELIEF

WHEREFORE, plaintiff Endoheart requests a judgment:

A. That Endoheart is the owner of all right, title and interest in and to U.S. Patent 8,182,530, together with all rights of recovery under the patent;

B. The Edwards has infringed one or more claims of U.S. Patent 8,182,530;

C. That U.S. Patent 8,182,530 is valid and enforceable in law;

D. Awarding to Endoheart its damages caused by Edwards' infringement, together with prejudgment and post-judgment interest;

E. That Edwards' infringement is and has been willful and said damages be trebled pursuant to 35 U.S.C. § 284;

F. That this is an exceptional case and awarding to Endoheart its costs, expenses and reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

G. Awarding to Endoheart such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury of all issues so triable.

Dated: December 10, 2014

/s/ Kenneth L. Dorsney

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