

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and)	
EDWARDS LIFESCIENCES LLC,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 09-873 (GMS)
)	
MEDTRONIC, INC., MEDTRONIC)	DEMAND FOR JURY TRIAL
COREVALVE, LLC, and MEDTRONIC)	
VASCULAR, INC.)	
)	
Defendants.)	

SECOND AMENDED COMPLAINT

Plaintiffs Edwards Lifesciences AG (“Edwards AG”) and Edwards Lifesciences LLC (“Edwards LLC”) (collectively, “Plaintiffs”), for their Second Amended Complaint (“Complaint”) against Defendants Medtronic, Inc. (“Medtronic”), Medtronic CoreValve, LLC (“Medtronic CoreValve”), and Medtronic Vascular, Inc. (“Medtronic Vascular”) (collectively, “Defendants”), allege as follows:

JURISDICTION AND VENUE

1. This action arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* This Court has jurisdiction over the subject matter of this action based on 28 U.S.C. §§ 1338(a) and 1331. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

THE PARTIES

Edwards

2. Plaintiff Edwards AG is a corporation organized and existing under the laws of Switzerland and having its principal executive offices in Nyon, Switzerland.

3. Plaintiff Edwards LLC is a limited liability company organized and existing under the laws of the State of Delaware and having its principal executive offices in Irvine, California.

4. Edwards AG is the assignee of the following United States Patents covering pioneering percutaneous heart valve products: U.S. Patent No. 7,618,446 (“the ‘446 Patent”), U.S. Patent No. 5,411,552 (“the ‘552 Patent”), and U.S. Patent No. 6,582,462 (“the ‘462 Patent”) (collectively, “the Patents”). The Patents disclose and claim, *inter alia*, collapsible and expandable tissue valve prostheses that replace human heart valves using minimally invasive catheterization procedures.

5. Edwards LLC is the exclusive licensee of the Patents for the field of all cardiovascular applications.

Medtronic

6. Upon information and belief, Defendant Medtronic is a corporation organized and existing under the laws of the State of Minnesota and having its principal place of business in Minneapolis, Minnesota.

7. Upon information and belief, Medtronic is registered to do business in Delaware, and is doing business in Delaware.

8. Upon information and belief, Medtronic has been and is now manufacturing, using, importing, selling and/or offering to sell in the United States heart valve prostheses, including heart valve prostheses known as “Medtronic CoreValve Percutaneous System,” “CoreValve transcatheter aortic valve system,” and/or the “ReValving” system (hereinafter collectively the “ReValving” system), and/or supplying or causing to be supplied in

or from the United States one or more components of such heart valve prostheses, which activities infringe the '446 Patent, the '552 Patent and the '462 Patent.

9. Upon information and belief, Medtronic has been and is now knowingly and actively inducing others to infringe the '446 Patent, the '552 Patent and the '462 Patent and continues to do so.

Medtronic CoreValve

10. Upon information and belief, Defendant Medtronic CoreValve is a corporation organized and existing under the laws of the State of Delaware and having its principal place of business in Irvine, California.

11. Upon information and belief, Medtronic CoreValve is a wholly owned subsidiary of, and controlled by, Medtronic.

12. Upon information and belief, Medtronic CoreValve has been and is now manufacturing, using, importing, selling and/or offering to sell in the United States heart valve prostheses, including heart valve prostheses known as the ReValving system, and/or supplying or causing to be supplied in or from the United States one or more components of such heart valve prostheses, which activities infringe the '446 Patent and the '462 Patent.

13. On April 1, 2010, in *Edwards Lifesciences AG et al. v. Medtronic CoreValve, LLC et al.*, C.A. No. 08-91 (D. Del.) (GMS), a jury returned a verdict that Medtronic CoreValve literally and willfully infringed the '552 Patent by manufacturing the ReValving system in the United States.

14. Upon information and belief, Medtronic CoreValve is now supplying or causing to be supplied in or from the United States one or more components of heart valve prostheses, including the ReValving system, which activities infringe the '552 Patent.

15. Upon information and belief, Medtronic CoreValve has been and is now knowingly and actively inducing others to infringe the '446 Patent, the '552 Patent and/or the '462 Patent and continues to do so.

Medtronic Vascular

16. Upon information and belief, Defendant Medtronic Vascular is a corporation organized and existing under the laws of the State of Delaware and having its principal place of business in Santa Rosa, California.

17. Upon information and belief, Medtronic Vascular is a wholly owned subsidiary of, and controlled by, Medtronic.

18. Upon information and belief, Medtronic Vascular has been and is now manufacturing, using, importing, selling and/or offering to sell in the United States heart valve prostheses, including heart valve prostheses known the ReValving system, and/or supplying or causing to be supplied in or from the United States one or more components of such heart valve prostheses, which activities infringe the '446 Patent, the '552 Patent and the '462 Patent.

19. Upon information and belief, Medtronic Vascular has been and is now knowingly and actively inducing others to infringe the '446 Patent, the '552 Patent and the '462 Patent and continues to do so.

**FIRST CAUSE OF ACTION
(Infringement of the '446 Patent)**

20. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 19 above.

21. On November 17, 2009, the '446 Patent (Exhibit 1), entitled "A Valve Prosthesis for Implantation in the Body and a Catheter for Implanting Such Valve Prosthesis," was duly and legally issued to Drs. Henning Rud Andersen, John Michael Hasenkam, and Lars

Lyhne Knudsen. Edwards AG is the assignee, and Edwards LLC is the exclusive licensee of the '446 Patent for the field of all cardiovascular applications. Plaintiffs are the owners of all rights, title and interest in and to the '446 Patent, including all rights to recover for any and all past infringement thereof, in the field of all cardiovascular applications.

22. Upon information and belief, and in violation of 35 U.S.C. § 271(a), Medtronic, Medtronic CoreValve and Medtronic Vascular have been and are now infringing the '446 Patent by manufacturing, using, importing, selling and/or offering to sell heart valve prostheses covered by one or more claims of the '446 Patent, including products designated as the ReValving system.

23. Upon information and belief, and in violation of 35 U.S.C. § 271(b), Medtronic, Medtronic CoreValve and Medtronic Vascular have been and are now infringing the '446 Patent, including at least by their knowing and active inducement of the manufacture, use, importation, sale and/or offer to sell of heart valve prostheses covered by one or more claims of the '446 Patent, including products designated as the ReValving system.

24. Upon information and belief, and in violation of 35 U.S.C. § 271(f)(1), Medtronic, Medtronic CoreValve and Medtronic Vascular are now infringing the '446 Patent by supplying or causing to be supplied in or from the United States all or a substantial portion of the components of the invention claimed in the '446 Patent, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside the United States in a manner that would infringe the '446 Patent if such combination occurred within the United States.

25. Upon information and belief, and in violation of 35 U.S.C. § 271(f)(2), Medtronic, Medtronic CoreValve and Medtronic Vascular are now infringing the '446 Patent by

supplying or causing to be supplied in or from the United States one or more components of the invention claimed in the '446 Patent, that is or are especially made or especially adapted for use in the invention claimed in the '446 Patent and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component or components is or are uncombined in whole or in part, knowing that such component or components is or are so made or adapted and intending that such component or components will be combined outside of the United States in a manner that would infringe the '446 Patent if such combination occurred within the United States.

26. Defendants' foregoing infringement has been willful and deliberate, rendering this case exceptional within the meaning of 35 U.S.C. § 285.

27. Plaintiffs have been damaged and will be irreparably injured by Defendants' past and continuing infringement, for which Plaintiffs have no adequate remedy at law. Defendants' infringement will continue unless enjoined by this Court.

**SECOND CAUSE OF ACTION
(Infringement of the '552 Patent)**

28. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 27 above.

29. On May 2, 1995, the '552 Patent (Exhibit 2 hereto), entitled "Valve Prosthesis for Implantation in the Body and a Catheter for Implanting such Valve Prosthesis," was duly and legally issued to Drs. Henning Rud Andersen, John Michael Hasenkam, and Lars Lyhne Knudsen. Edwards AG is the assignee, and Edwards LLC is the exclusive licensee of the '552 Patent for the field of all cardiovascular applications. Plaintiffs are the owners of all rights, title and interest in and to the '552 Patent, including all rights to recover for any and all past infringement thereof, in the field of all cardiovascular applications.

30. Upon information and belief, and in violation of 35 U.S.C. § 271(a), Medtronic and Medtronic Vascular have been and are now infringing the '552 Patent by manufacturing, using, importing, selling and/or offering to sell heart valve prostheses covered by one or more claims of the '552 Patent, including products designated as the ReValving system.

31. Upon information and belief, and in violation of 35 U.S.C. § 271(b), Medtronic, Medtronic CoreValve and Medtronic Vascular have been and/or are now infringing the '552 Patent, including at least by their knowing and active inducement of the manufacture, use, importation, sale and/or offer to sell of heart valve prostheses covered by one or more claims of the '552 Patent, including products designated as the ReValving system.

32. Upon information and belief, and in violation of 35 U.S.C. § 271(f)(1), Medtronic, Medtronic CoreValve and Medtronic Vascular are now infringing the '552 Patent by supplying or causing to be supplied in or from the United States all or a substantial portion of the components of the invention claimed in the '552 Patent, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside the United States in a manner that would infringe the '552 Patent if such combination occurred within the United States.

33. Upon information and belief, and in violation of 35 U.S.C. § 271(f)(2), Medtronic, Medtronic CoreValve and Medtronic Vascular are now infringing the '552 Patent by supplying or causing to be supplied in or from the United States one or more components of the invention claimed in the '552 Patent, that is or are especially made or especially adapted for use in the invention claimed in the '552 Patent and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component or components is or are uncombined in whole or in part, knowing that such component or components is or are so made

or adapted and intending that such component or components will be combined outside of the United States in a manner that would infringe the '552 Patent if such combination occurred within the United States.

34. Defendants' foregoing infringement has been willful and deliberate, rendering this case exceptional within the meaning of 35 U.S.C. § 285.

35. Plaintiffs have been damaged and will be irreparably injured by Defendants' past and continuing infringement, for which Plaintiffs have no adequate remedy at law. Defendants' infringement will continue unless enjoined by this Court.

**THIRD CAUSE OF ACTION
(Infringement of the '462 Patent)**

36. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 35 above.

37. On June 24, 2003, the '462 Patent (Exhibit 3 hereto), entitled "Valve Prosthesis for Implantation in the Body and a Catheter for Implanting such Valve Prosthesis," was duly and legally issued to Drs. Henning Rud Andersen, John Michael Hasenkam, and Lars Lyhne Knudsen. Edwards AG is the assignee, and Edwards LLC is the exclusive licensee of the '462 Patent for the field of all cardiovascular applications. Plaintiffs are the owners of all rights, title and interest in and to the '462 Patent, including all rights to recover for any and all past infringement thereof, in the field of all cardiovascular applications.

38. Upon information and belief, and in violation of 35 U.S.C. § 271(a), Medtronic, Medtronic CoreValve and Medtronic Vascular have been and are now infringing the '462 Patent by manufacturing, using, importing, selling and/or offering to sell heart valve prostheses covered by one or more claims of the '462 Patent, including products designated as the ReValving system.

39. Upon information and belief, and in violation of 35 U.S.C. § 271(b), Medtronic, Medtronic CoreValve and Medtronic Vascular have been and are now infringing the '462 Patent, including at least by their knowing and active inducement of the manufacture, use, importation, sale and/or offer to sell of heart valve prostheses covered by one or more claims of the '462 Patent, including products designated as the ReValving system.

40. Upon information and belief, and in violation of 35 U.S.C. § 271(f)(1), Medtronic, Medtronic CoreValve and Medtronic Vascular are now infringing the '462 Patent by supplying or causing to be supplied in or from the United States all or a substantial portion of the components of the invention claimed in the '462 Patent, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside the United States in a manner that would infringe the '462 Patent if such combination occurred within the United States.

41. Upon information and belief, and in violation of 35 U.S.C. § 271(f)(2), Medtronic, Medtronic CoreValve and Medtronic Vascular are now infringing the '462 Patent by supplying or causing to be supplied in or from the United States one or more components of the invention claimed in the '462 Patent, that is or are especially made or especially adapted for use in the invention claimed in the '462 Patent and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component or components is or are uncombined in whole or in part, knowing that such component or components is or are so made or adapted and intending that such component or components will be combined outside of the United States in a manner that would infringe the '462 Patent if such combination occurred within the United States.

42. Defendants' foregoing infringement has been willful and deliberate, rendering this case exceptional within the meaning of 35 U.S.C. § 285.

43. Plaintiffs have been damaged and will be irreparably injured by Defendants' past and continuing infringement, for which Plaintiffs have no adequate remedy at law. Defendants' infringement will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE Plaintiffs demand judgment as follows:

- (a) Finding that Defendants have infringed the '446 Patent, the '552 Patent and the '462 Patent;
- (b) Finding that Defendants' infringement of the '446 Patent, the '552 Patent and the '462 Patent has been willful and deliberate;
- (c) Preliminarily and permanently enjoining and restraining Defendants and their officers, agents, servants, employees and attorneys, all parent, subsidiary and affiliate corporations and other related business entities, and all other persons or entities acting in concert, participation or in privity with Defendants, and their successors and assigns, from infringing, contributing to the infringement of, or inducing others to infringe the '446 Patent, the '552 Patent and the '462 Patent;
- (d) Awarding Plaintiffs damages, in an amount to be determined at trial, together with interest and costs as fixed by the Court;
- (e) Awarding Plaintiffs enhanced damages under 35 U.S.C. § 284;
- (f) Awarding Plaintiffs their reasonable attorneys' fees and their costs and disbursements in this action, as provided by 35 U.S.C. § 285; and
- (g) Granting Plaintiffs such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable in this Complaint.

MORRIS NICHOLS ARSHT & TUNNELL LLP

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April 23, 2010

CERTIFICATE OF SERVICE

I hereby certify that on April 23, 2010, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

John W. Shaw, Esquire
Karen E. Keller, Esquire
YOUNG CONAWAY STARGATT & TAYLOR, LLP

I further certify that I caused copies of the foregoing document to be served on April 23, 2010, upon the following in the manner indicated:

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