OBLON
SPIVAK

ATTORNEYS AT LAW

Docket No.: 372336US68SD

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

RE: Application Serial No.: 08/261,235
Applicants: HENNING R. ANDERSEN, ET AL.
Filing Date: JUNE 14, 1994
For: VALVE PROTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROTHESIS
Group Art Unit: 3308
Examiner: WILLSE, DAVID H.

SIR:

Attached hereto for filing are the following papers:

APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156 AND 37 C.F.R. §§ 1.710 ET SEQ. WITH EXHIBITS A-E THREE COPIES

DISCLOSURE PURSUANT TO 35 U.S.C. § 156(D)(4) AND 37 C.F.R. § 1.765 WITH EXHIBITS A-J THREE COPIES

Credit card payment is being made online (if electronically filed), or is attached hereto (if paper filed), in the amount of **$1,120.00** to cover any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. **15-0030**. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time.

Respectfully submitted,

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DOCKET NO: 372336US0-SD **MAIL STOP HATCH-WAXMAN PTE**

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF	:
HENNING R. ANDERSEN, ET AL.	: GROUP ART UNIT: 3308
SERIAL NO: 08/261,235	: EXAMINER: WILLSE, DAVID H.
FILED: JUNE 14, 1994	: PATENT NO.: 5,411,552
FOR: VALVE PROTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROTHESIS	: ISSUED: MAY 2, 1995

APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156 AND 37 C.F.R. §§ 1.710 ET SEQ.

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

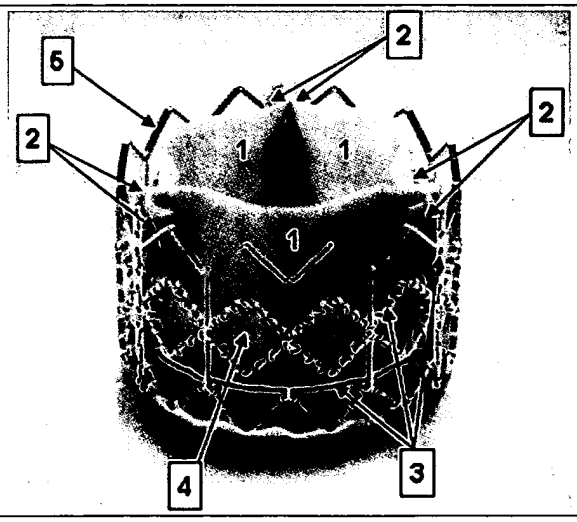
This is an application for extension of patent term under 35 U.S.C. § 156 and 37 C.F.R. §§ 1.710 et seq. for U.S. Patent No. 5,411,552 ("the '552 patent").

This application is being made by Edwards Lifesciences AG ("Edwards"), having a place of business at Route de l'etraz 70, Nyon, Switzerland 1260. Edwards is the owner of the '552 patent by way an assignment recorded with the U.S. Patent and Trademark Office at reel 019984, frame 0799. The undersigned is authorized to act on behalf of Edwards as pertains to the '552 patent and this application for extension of patent term.

Two additional copies of this application (for a total of three copies) are being submitted herewith (37 C.F.R. § 1.740(b)). A disclosure statement pursuant to 35 U.S.C. § 156(d)(4) and 37 C.F.R. § 1.765 is being filed concurrently.

I. Complete Identification of Approved Product (37 C.F.R. § 1.740(a)(1)).

The approved product is SAPIEN. The Edwards SAPIEN Transcatheter Heart Valve 9000TFX (SAPIEN) includes bioprosthetic valve technology for transfemoral implantation in patients with symptomatic severe aortic stenosis (AS), who have excessively high operative risk. The bioprosthesis is an integrated unidirectional trileaflet tissue valve comprised of an expandable support structure (frame), bovine pericardial leaflets, and a fabric skirt.



1. Bovine Pericardium Leaflet
2. Stainless Steel 5-hole Bars with cloth covers
3. Sutures
4. Fabric Skirt
5. Stainless Steel Frame

II. Complete Identification of Federal Statute under which Regulatory Review Occurred (37 C.F.R. § 1.740(a)(2)).

Regulatory permission to sell SAPIEN was granted under 21 U.S.C. § 360 (section 520 of the Federal Food, Drug, and Cosmetic Act).

III. Identification of Date on which Product Received Permission for Commercial Marketing or Use (37 C.F.R. § 1.740(a)(3)).

Regulatory approval for SAPIEN was granted on November 2, 2011.

IV. Identification of Each Active Ingredient in Product and Statement That Each Active Ingredient Has Not Been Previously Approved for Commercial Marketing or Use (37 C.F.R. § 1.740(a)(4)).

SAPIEN is a medical device and, thus, the requirements of 37 C.F.R. § 1.740(a)(4) are not applicable.

V. Statement that Application Is Being Submitted within Sixty Day Period and Identification of Date of Last Day on which Application Could Be Submitted (37 C.F.R. § 1.740(a)(5)).

This application is being submitted within the sixty day period specified by 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f). The last day on which this application could be submitted is January 1, 2012.

VI. Complete Identification of Patent for which Extension Is Being Sought by Name of Inventor, Patent Number, Date of Issue, and Date of Expiration (37 C.F.R. § 1.740(a)(6)).

The patent for which extension of patent term is sought is U.S. Patent No. 5,411,552 ("the '552 patent"), which names Henning R. Andersen, John M. Hasenkam, and Lars L. Knudsen as inventors, which issued on May 2, 1995, from U.S. Patent Application Serial No. 08/261,235, and which, prior to grant of extension, is due to expire on May 2, 2012.

VII. Copy of Patent for which Extension Is Being Sought (37 C.F.R. § 1.740(a)(7)).

A copy of the '552 patent is attached hereto as Exhibit A.

VIII. Copy of Any Disclaimer, Certificate of Correction, Receipt of Maintenance Fee Payment, or Reexamination Certificate Issued in Patent (37 C.F.R. § 1.740(a)(8)).

Edwards states on the record that no disclaimers have been filed in the '552 patent, and no certificates of correction have been requested or issued in the '552 patent.

A reexamination certificate (No. 8463) issued in the '552 patent on August 16, 2011. In the reexamination certificate, the patentability of claim 1 of the '552 patent is confirmed. During reexamination, claim 1 of the '552 patent was not amended. Claims 2-8 of the '552 patent were not reexamined. A copy of the reexamination certificate is attached hereto as Exhibit B.

A copy of the receipts of maintenance fee payments for the first, second and third maintenance fees in the '552 patent are attached hereto as Exhibit C.

IX. Statement that Patent Claims Approved Product and Showing which Lists Each Applicable Patent Claim and Demonstrates Manner in which at least One Such Patent Claim Reads On Approved Product (37 C.F.R. § 1.740(a)(9)).

The approved product, SAPIEN, is claimed in at least claim 1 of the '552 patent.

The relationship between claim 1 of the '552 patent and the approved product is set forth in TABLE 1 below.

TABLE 1

Claim 1 of the '552 Patent	SAPIEN
1. A valve prosthesis for implantation in a body channel, the valve prosthesis comprising a collapsible elastical valve which is mounted on an elastical stent, the elastical valve having a plurality of commissural points, wherein the stent comprises:	SAPIEN is a device for implantation in patients with symptomatic severe aortic stenosis (AS). The three bovine pericardium leaflets of SAPIEN form a collapsible elastical valve having a plurality of commissural points that is mounted on the stainless steel frame of SAPIEN, which forms an elastical stent.
cylindrical support means which is radially collapsible for introduction within the body channel and which has a plurality of circumferentially-expandable sections such that the cylindrical support means is radially expandable for being secured within the body channel; and	The stainless steel frame of SAPIEN includes cylindrical support means which is radially collapsible for introduction within a body channel and which has a plurality of circumferentially-expandable sections such that the cylindrical support means is radially expandable for being secured within the body channel.

a plurality of commissural supports projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof for supporting the commissural points of the collapsible valve, at least one circumferentially-expandable section of the cylindrical support means lying between each of the commissural supports, such that the collapsible valve may be collapsed and expanded together with the cylindrical support means for implantation in the body channel by means of a technique of catheterization.	The stainless steel frame of SAPIEN includes a plurality of commissural supports projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof for supporting the commissural points of the collapsible valve. At least one circumferentially-expandable section of the cylindrical support means lies between each of the commissural supports, such that the collapsible valve may be collapsed and expanded together with the cylindrical support means for implantation in the body channel by means of a technique of catheterization.

X. Statement Beginning on New Page of Relevant Dates and Information to Enable the Secretary of Health and Human Services to Determine Applicable Regulatory Review Period (37 C.F.R. § 1.740(a)(10)(v)).

(A) The effective date of the investigational device exemption (IDE) and the IDE number, if applicable, or the date on which the applicant began the first clinical investigation involving the device, if no IDE was submitted, and any available substantiation of that date (37 C.F.R. § 1.740(a)(10)(v)(A)).

The effective date of the investigational device exemption (IDE) application for SAPIEN was March 24, 2003. The IDE number is G030069.

(B) The date on which the application for product approval or notice of completion of a product development protocol under Section 515 of the Federal Food, Drug and Cosmetic Act was initially submitted and the number of the application (37 C.F.R. § 1.740(a)(10)(v)(B)).

The premarket approval (PMA) application for the approved product was initially submitted on October 29, 2010. The PMA number is P100041.

(C) The date on which the application was approved or the protocol declared to be completed (37 C.F.R. § 1.740(a)(10)(v)(C)).

PMA P100041 was approved on November 2, 2011.

XI. Brief Description Beginning on New Page of Significant Activities Undertaken by Marketing Applicant during Applicable Regulatory Review Period with respect to Approved Product and Significant Dates Applicable to Such Activities (37 C.F.R. § 1.740(a)(11)).

A list of significant activities undertaken by the marketing applicant during the regulatory review period and the significant dates applicable thereto is provided in TABLES 2A and 2B below.

TABLE 2A (IDE Correspondence)

Date	Document Type	Action	Action Detail
2003-03-24	Pre-IDE Materials	IDE number assigned (FDA)	Notification that number has been assigned by FDA
2003-04-23	Pre-IDE Materials	Disapproval (FDA)	
2003-08-28	Pre-IDE Materials	Approval (FDA)	Approval of compassionate use (FDA)
2003-12-05	Pre-IDE Materials	Request for additional information (FDA)	
2003-12-19	Pre-IDE Materials	Disapproval (FDA)	
2004-06-09	Pre-IDE Materials	Request for additional information (FDA)	
2004-07-28	IDE - Letter from FDA	Disapproval (FDA)	
2004-07-29	IDE - Letter from FDA	Acknowledge of IDE transfer (FDA)	
2004-11-03	IDE - Letter from FDA	Disapproval (FDA)	
2005-01-26	IDE - Letter from FDA	Conditional Approval (FDA)	
2005-03-02	IDE - Letter from FDA	Response to FDA	ELS Response to FDA letter dated 1/26/05 and email dated 02/09/05
2005-03-11	IDE - Letter to FDA	Notification	Current Investigator List
2005-03-18	IDE- Supplement	5-Day Notice	5-Day Notice of IDE Change
2005-03-18	IDE - Adverse Event Report	Notification	
2005-03-22	IDE- Supplement	Change request	Developmental Change to the Delivery System for the PHV

Date	Document Type	Action	Action Detail
2005-04-01	IDE - Letter from FDA	Conditional Approval (FDA)	
2005-04-11	IDE- Supplement		
2005-04-14	IDE - Letter from FDA	Request for additional information (FDA)	AE Report - Additional information required
2005-04-14	IDE- Supplement		
2005-04-19	IDE - Letter from FDA	Request for additional information (FDA)	
2005-04-20	IDE - Letter from FDA	Disapproval (FDA)	
2005-04-28	IDE- Supplement	Response to FDA	R-202-01 FG Euroscore printout, Surgical consult note, Post-procedure echo, STS risk
2005-05-10	IDE - Letter to FDA	Acknowledge of receipt (FDA)	Confirmation of receipt of electronic information
2005-05-12	IDE - Supplement	Response to FDA	ELS Response to FDA Letter for G030069/S001 Dated April 1,2005
2005-05-19	IDE - Supplement	Response to FDA	ELS Response to FDA Letter for G030069/S001 Dated April 1,2005
2005-05-20	IDE - Supplement		
2005-05-20	IDE - Supplement		
2005-06-15	IDE - Letter from FDA	Conditional Approval (FDA)	
2005-06-24	IDE - Meeting Minutes/Notes/Agendas	Meeting (with FDA)	Meeting w/FDA RE: Revival
2005-06-24	IDE - Supplement		
2005-06-24	IDE – Supplement	Response to FDA	ELS Response to FDA Letter for IDE Supplement S5 Dated April 20, 2005
2005-07-20	IDE - Letter from FDA	Request for additional information (FDA)	
2005-07-20	IDE – Supplement		IDE Supplement for Alternative Manufacturing
2005-07-27	IDE - Letter from FDA	Approval (FDA)	

Date	Document Type	Action	Action Detail
2005-07-27	IDE – Supplement	Response to FDA	ELS Response to FDA Letter Dated June 15, 2005, for G030069/S11 and S12
2005-08-09	IDE – Supplement	Response to FDA	ELS Response to FDA Letter Dated June 15, 2005, for G030069/S11 and S12
2005-08-22	IDE – Supplement	Response to FDA	Response to FDA Letter Dated June 24, 2005, for G030069/S15
2005-08-26	IDE - Letter from FDA	Conditional Approval (FDA)	
2005-08-26	IDE – Supplement		
2005-09-02	IDE – Supplement	Response to FDA	ELS Response to FDA Letter Dated June 15, 2005 for G030069/S11 and S12
2005-09-09	IDE - Letter from FDA	Conditional Approval (FDA)	
2005-09-12	IDE – Supplement	Response to FDA	ELS Response to FDA Letter Dated June 15, 2005 for G030069/S11 and S12 – Add'l
2005-09-20	IDE – Supplement	Response to FDA	Response to FDA Letter Dated June 24, 2005 for G030069/S15, item #8
2005-09-22	IDE - Letter from FDA		
2005-09-30	IDE - Letter from FDA	Conditional Approval (FDA)	
2005-10-05	IDE – Supplement	Request for Compassionate Use	
2005-10-06	IDE - Letter from FDA	Disapproval (FDA)	
2005-10-06	IDE - Electronic/E-mail	ELS Response (to FDA)	ELS email to FDA Regarding Request for Compassionate Use
2005-10-10	IDE – Supplement	Request for Extension of time	
2005-10-13	IDE - Letter from FDA	Approval (FDA)	Request for extension to submit granted (FDA)
2005-10-21	IDE – Supplement	Request for Extension of time	

Date	Document Type	Action	Action Detail
2005-10-26	IDE - Letter from FDA	Disapproval (FDA)	Not approved (request for compassionate use) (FDA)
2005-10-27	IDE – Supplement	Response to FDA	ELS Response to FDA Letters dated Oct 6,2005 and Aug 26, 2005
2005-11-04	IDE - Letter from FDA	Approval (FDA)	Request for extension to submit granted (FDA)
2005-11-11	IDE – Supplement	Response to FDA	ELS Response to FDA Letter dated Oct 26, 2005
2005-11-11	IDE – Supplement	Response to FDA	ELS Response to FDA Letter dated Oct 6, 2005 for G030069/S21
2005-11-11	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2005-11-11	IDE – Supplement	Response to FDA	ELS Response to Letters dated Aug 26, 2005 and Sept 9, 2005
2005-11-14	IDE – Supplement	Request for Extension of time	
2005-11-14	IDE – Supplement	Response to FDA	ELS Response to Letters dated Aug 26, 2005 and Sept 9, 2005
2005-11-22	IDE - Letter to FDA	Response to FDA	FDA Request for Additional Information by phone on Nov 22, 2005
2005-11-25	IDE - Letter from FDA	Approval (FDA)	Request for compassionate use approved (FDA)
2005-11-28	IDE - Electronic/E-mail	Response to FDA	ELS response to request for additional information re: Supp 34
2005-11-30	IDE - Letter from FDA	Conditional Approval (FDA)	
2005-11-30	IDE – Supplement	Response to FDA	ELS Response to FDA Letter dated Sept 30, 2005

Date	Document Type	Action	Action Detail
2005-12-01	IDE – Supplement	Response to FDA	ELS Response to FDA Letters dated Nov 11,2005 and Sept 9, 2005
2005-12-09	IDE – Supplement	IRB Approval Letter	
2005-12-12	IDE – Letter from FDA	Conditional Approval (FDA)	
2005-12-12	IDE – Letter from FDA	Acknowledge of receipt (FDA)	
2005-12-14	IDE – Supplement	Certification	IRB Approval
2005-12-16	IDE – Letter from FDA	Conditional Approval (FDA)	
2005-12-22	IDE – Letter from FDA	Conditional Approval (FDA)	
2005-12-29	IDE – Letter from FDA	Conditional Approval (FDA)	
2006-01-06	IDE – Supplement	Response to FDA	
2006-01-17	IDE – Letter from FDA	Request for Extension of time	Request for Annual Report Submission Date Extension
2006-01-19	IDE – Letter from FDA	Approval (FDA)	Time extension request accepted (FDA)
2006-01-27	IDE – Letter from FDA	Request for Extension of time	
2006-02-03	IDE – Letter from FDA	Approval (FDA)	Time extension request accepted (FDA)
2006-02-06	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change – new supplier
2006-02-08	IDE – Letter from FDA	Conditional Approval (FDA)	
2006-02-08	IDE – Supplement	Notification	Certification of Institutional Review Board
2006-02-13	IDE – Supplement	Notification (to FDA)	Adverse Event Report
2006-02-22	IDE – Supplement	Request for additional information (FDA)	
2006-02-22	IDE – Supplement		Information on Forthcoming Supplement to IDE G030069
2006-03-03	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change – Device modifications

Date	Document Type	Action	Action Detail
2006-03-07	IDE – Supplement	Request for Extension of time	Annual Report Submission Date Extension
2006-03-08	IDE – Letter from FDA		
2006-03-09	IDE – Letter from FDA	Approval (FDA)	
2006-03-09	IDE – Letter from FDA	Notification of IRB approval (FDA acknowledgement)	
2006-03-09	IDE – Letter from FDA	Request for additional information (FDA)	Patient death review request for additional information (FDA)
2006-03-30	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change- Device modifications
2006-03-31	IDE – Supplement	Response to FDA	Response to FDA letter for G030069/S31, S33. S37
2006-03-31	IDE – Supplement	Response to FDA	Response to FDA letter for G030069/S36
2006-03-31	IDE – Supplement	Change request	Change in Biological Tissue Component
2006-03-31	IDE – Supplement	Change request	Change in Biological Tissue Component
2006-04-07	IDE – Letter from FDA		
2006-04-25	IDE – Annual Report	Submission/ Attachments & Response	2006 IDE Annual Progress Report and Response to FDA March, 9 2006 letter re: Supp
2006-04-25	Letters	Response to FDA	Response to FDA Letter dated Feb. 8, 2006
2006-04-28	Letters	Certification	IRB Approval
2006-04-28	IDE – Adverse Event Report	Notification	
2006-05-03	IDE – Letter from FDA	Conditional Approval (FDA)	
2006-05-03	Letters		
2006-05-03	Letters		
2006-05-18	Letters	5-Day Notice	5-Day Notice of IDE Change – Device modifications
2006-05-19	Letters	ELS Response (to FDA)	

Date	Document Type	Action	Action Detail
2006-05-23	IDE – Letter from FDA	Conditional Approval (FDA)	
2006-05-24	IDE – Letter from FDA	No response necessary (FDA)	
2006-05-24	IDE – Letter from FDA	No response necessary (FDA)	
2006-05-30	IDE – Letter from FDA	Request for additional information (FDA)	Adverse Event report additional information required (FDA)
2006-06-09	Letters		
2006-06-14	IDE – Letter from FDA	No response necessary (FDA)	
2006-06-20	IDE – Letter from FDA	Conditional Approval (FDA)	
2006-06-26	IDE – Supplement	Response to FDA	
2006-06-30	Letters	Response to FDA	Response to May 30, 2006 FDA letter for G030069/S57
2006-07-11	IDE – Letter from FDA	Conditional Approval (FDA)	
2006-07-12	Letters	5-Day Notice	5-Day Notice of IDE Change
2006-07-13	IDE – Letter from FDA	Compassionate Use Request	
2006-07-26	IDE – Letter from FDA	Conditional Approval (FDA)	
2006-07-28	IDE – Letter from FDA	Approval (FDA)	Approved (compassionate use) FDA
2006-08-03	Letters	Request for Extension of time	Request for Two-Week Extension
2006-08-04	IDE – Letter from FDA	Approval (FDA)	Approval of request for additional time
2006-08-16	Letters	5-Day Notice	5-Day Notice of IDE Change
2006-08-16	Letters	5-Day Notice	5-Day Notice of IDE Change
2006-08-17	Letters	Response to FDA	Response to June 20, 2006 FDA letter
2006-08-23	Letters	Response to FDA	Response to July 26, 2006 FDA Letter
2006-08-24	Letters	Request for Extension of time	

Date	Document Type	Action	Action Detail
2006-08-24	Letters	Request for Extension of time	
2006-08-28	Letters	Response to FDA	Response to July 11m, 2006
2006-08-30	IDE – Supplement	Request (to FDA)	Request for Addition of Subjects to REVIVAL-2 Clinical Trial
2006-08-31	IDE – Adverse Event Report	Notification	
2006-09-01	Letters	Request for live case	Columbia University Medical
2006-09-01	Letters	Addition of Transapical Procedure Utilizing	
2006-09-05	IDE – Adverse Event Report	Notification	
2006-09-13	IDE – Letter from FDA	Conditional Approval (FDA)	
2006-09-15	IDE – Adverse Event Report	Notification	
2006-09-15	IDE – Adverse Event Report	Notification	
2006-09-22	IDE – Letter from FDA	Approval (FDA)	
2006-09-27	IDE – Letter from FDA	Conditional Approval (FDA)	
2006-09-28	IDE – Letter from FDA	Disapproval (FDA)	
2006-09-29	IDE – Letter from FDA	Approval (FDA)	
2006-10-05	IDE – Letter from FDA	Disapproval (FDA)	
2006-10-13	Letters	Response to FDA	Response to October 5, 2006 FDA letter for G030069/S76
2006-11-06	Letters	Response to FDA	Response to Sept. 27, 2006 FDA letter
2006-11-07	IDE – Letter from FDA	Notification	Summary Information of Patient Outcomes of Compassionate Use
2006-11-15	IDE – Letter from FDA	Conditional Approval (FDA)	
2006-11-28	IDE – Supplement		
2006-11-29	Letters	Response to FDA	Response to Nov. 15th FDA letter
2006-11-29	IDE – Supplement		
2006-11-30	Letters	5-Day Notice	5-Day Notice of IDE Change

Date	Document Type	Action	Action Detail
2006-12-04	Letters	Certification	IRB Approval, IRB approval of Informed Consent
2006-12-05	IDE – Adverse Event Report	Notification	
2006-12-07	IDE – Letter from FDA	Request for additional information (FDA)	
2006-12-08	IDE – Letter from FDA	Approval (FDA)	
2006-12-12	IDE – Letter from FDA		Letter stating copies being provided
2006-12-12	IDE – Adverse Event Report	Notification	
2006-12-12	Letters	Certification	IRB Approval
2006-12-21	IDE – Letter from FDA	Disapproval (FDA)	
2006-12-21	Letters	5-Day Notice	5-Day Notice of IDE Change
2006-12-22	Letters	Certification	IRB Approval
2006-12-22	Letters	Certification	IRB Approval
2006-12-22	Letters	Certification	IRB Approval
2006-12-28	IDE – Letter from FDA	Disapproval (FDA)	
2006-12-28	IDE – Letter from FDA	Conditional Approval (FDA)	
2006-12-28	IDE – Letter from FDA	Conditional Approval (FDA)	
2006-12-29	IDE – Letter from FDA	Conditional Approval (FDA)	
2007-01-10	IDE – Letter from FDA	Conditional Approval (FDA)	Conditional approval for S84, S87, S91
2007-01-16	IDE – Supplement	Request for Extension of time	
2007-01-17	IDE – Letter from FDA	Approval (FDA)	Extension request approval from FDA - 2nd IDE annual report
2007-01-19	IDE – Letter from FDA	Approval (FDA)	
2007-01-26	IDE – Supplement		
2007-02-06	IDE – Supplement	Request for Extension of time	
2007-02-08	IDE – Supplement	Response to FDA	Response to Letter dated Dec. 29, 2006 for G030069/S86

Date	Document Type	Action	Action Detail
2007-02-13	IDE – Supplement	Response to FDA	Response from ELS to FDA on disapproval letter dated Dec. 28,2006
2007-02-22	IDE – Supplement	Response to FDA	Response from ELS to FDA dated Dec. 28, 2006 and Jan. 10, 2007
2007-03-12	IDE – Letter from FDA	Approval (FDA)	
2007-03-12	IDE – Letter from FDA	Approval (FDA)	
2007-03-14	IDE – Letter from FDA	Approval (FDA)	Approval (FDA) corrects previous letter
2007-03-16	IDE – Letter from FDA	Conditional Approval (FDA)	
2007-03-20	IDE – Annual Report		IDE Annual Progress Report
2007-03-22	IDE – Supplement		
2007-03-23	IDE – Letter from FDA	Conditional Approval (FDA)	
2007-04-05	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change – Device modifications
2007-04-16	IDE – Supplement	Response to FDA	Response from ELS to FDA on letter dated Dec. 8, 2006
2007-04-20	IDE – Letter from FDA	Approval (FDA)	
2007-04-20	IDE – Supplement	Response to FDA	Response from ELS to FDA on letter dated Mar. 16, 2007
2007-04-20	IDE – Supplement	Certification	IRB Approval, IRB approval of Informed Consent
2007-05-16	IDE – Letter from FDA	Approval (FDA)	
2007-05-17	IDE – Letter from FDA	Approval (FDA)	
2007-05-27	IDE – Supplement	Certification	IRB Approval, IRB approval of Informed Consent
2007-06-18	IDE – Supplement	Certification	IRB Approval, IRB approval of Informed Consent
2007-06-21	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change

Date	Document Type	Action	Action Detail
2007-06-21	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change – multiple categories
2007-06-27	IDE – Letter from FDA	Disapproval (FDA)	
2007-07-06	IDE – Supplement	Response to FDA	Response from ELS to FDA on letter dated June 27, 2007
2007-07-06	IDE – Supplement	Response to FDA	Response from ELS to FDA on letter dated May 17, 2007
2007-07-09	IDE – Supplement	Certification	IRB Approval
2007-07-10	IDE – Supplement	Request (to FDA)	Request for Addition of Subjects
2007-07-17	IDE - Electronic/E-mail	Notification	Appropriate for 5-day notice
2007-07-19	IDE – Supplement		
2007-07-20	IDE – Letter from FDA	Approval (FDA)	
2007-08-03	IDE – Supplement	Submission/Attachments	6-Month Investigator List
2007-08-09	IDE – Letter from FDA	Denial/Approval/Conditional approval (FDA)	Denial/Approval/Conditional approval for different sections submitted (FDA)
2007-08-14	IDE – Adverse Event Report	Notification	
2007-08-16	IDE – Supplement	Certification	IRB Approval
2007-08-16	IDE – Supplement	Certification	IRB Approval
2007-08-23	IDE – Letter from FDA	Disapproval/approval (FDA)	Change #1 – Disapproved Approval of additional 20 transapical subjects (FDA)
2007-09-06	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2007-09-12	IDE – Letter from FDA	Approval (FDA)	
2007-09-12	IDE – Supplement	Response to FDA	Response to Aug. 9, 2007 FDA letter for G030069/S111
2007-09-25	IDE – Supplement	Request for live case	Columbia University Medical
2007-09-26	IDE – Supplement	Certification	IRB Approval

Date	Document Type	Action	Action Detail
2007-09-28	IDE – Supplement	Change request	Request for Use of an Alternate Source Material
2007-10-08	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2007-10-10	IDE – Supplement	Certification	IRB Approval
2007-10-12	IDE – Letter from FDA	Conditional Approval (FDA)	
2007-10-12	IDE – Letter from FDA	Conditional Approval (FDA)	
2007-10-19	IDE – Letter from FDA	Approval (FDA)	
2007-10-19	IDE – Supplement	Notification of Device Disposition	
2007-10-19	IDE – Supplement	Response to FDA	Response from ELS to FDA on letter dated Aug. 09, 2007 for G030069/S111
2007-10-30	IDE – Letter from FDA	Approval (FDA)	
2007-11-08	IDE – Letter from FDA	Conditional Approval (FDA)	
2007-11-14	IDE – Letter from FDA	Approval (FDA)	
2007-11-14	IDE – Adverse Event Report	Notification	
2007-12-03	IDE – Letter from FDA	Request for additional information (FDA)	Adverse Event report additional information required (FDA)
2007-12-05	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2007-12-06	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2007-12-07	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2007-12-10	IDE – Adverse Event Report	Notification	
2007-12-17	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2007-12-19	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2007-12-20	IDE – Supplement	Response to FDA	ELS Response to FDA letters dated 08/09/07, 08/23/07 and 10/12/07.
2008-01-03	IDE – Supplement		

Date	Document Type	Action	Action Detail
2008-01-07	IDE – Letter to FDA	Request for Extension of time	
2008-01-10	IDE – Letter from FDA	Approval (FDA)	Approval of extension to file annual progress report (FDA)
2008-01-10	IDE – Supplement		
2008-01-10	IDE – Electronic/E-mail correspondence	Approval (FDA)	Approval of Request for Annual Submission Date Extension
2008-01-12	IDE – Letter from FDA	Request for additional information (FDA)	
2008-01-16	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2008-01-16	IDE – Supplement	Response to FDA	Response to December 3, 2007 FDA letter for Supplement 128
2008-01-21	IDE – Supplement		
2008-01-25	IDE – Letter from FDA	Conditional Approval (FDA)	
2008-02-01	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2008-02-14	IDE – Supplement		
2008-02-15	IDE – Supplement	Request for Extension of time	
2008-02-20	IDE – Letter from FDA	Approval (FDA)	Approval of request for extension to respond to January 12, 2008 conditional
2008-02-20	IDE – Electronic/E-mail correspondence	Approval (FDA)	Approval of request for extension to respond to January 12, 2008
2008-02-22	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2008-02-25	IDE – Supplement		
2008-02-28	IDE – Supplement		
2008-03-04	IDE – Supplement		
2008-03-05	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change – process changes
2008-03-07	IDE – Supplement		
2008-03-10	IDE – Supplement		
2008-03-11	IDE – Supplement		
2008-03-14	IDE – Supplement		

Date	Document Type	Action	Action Detail
2008-04-08	IDE – Letter from FDA	Conditional Approval (FDA)	
2008-04-09	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2008-04-16	IDE – Letter from FDA	Request for additional information (FDA)	IDE annual progress report review need additional information (FDA)
2008-05-07	IDE – Letter from FDA	No response necessary (FDA)	
2008-05-21	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2008-05-27	IDE – Supplement		
2008-06-02	IDE – Supplement		
2008-06-06	IDE – Supplement		
2008-06-20	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change – Device modifications
2008-06-25	IDE – Letter from FDA	Conditional Approval (FDA)	
2008-07-02	IDE – Letter from FDA	Request for additional information (FDA)	Response from ELS to FDA on deficiency letter for annual progress report request for
2008-07-18	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2008-07-24	IDE – Supplement		
2008-08-07	IDE – Supplement	Request for Extension of time	
2008-08-13	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2008-08-18	IDE – Supplement	ELS Request (to FDA)	Request to videotape a case at Cleveland Clinic for Potential Media Release
2008-08-18	IDE – Supplement	Request for Extension of time	
2008-09-04	IDE – Supplement		
2008-09-05	IDE – Letter to FDA	ELS Request (to FDA)	Request for a Transfemoral Aortic Live Case for IDE G030069 at Emory University

Date	Document Type	Action	Action Detail
2008-09-11	IDE – Supplement	ELS Request (to FDA)	Request for Live Cases at Columbia University Medical Center
2008-09-18	IDE – Letter from FDA	Disapproval (FDA)	
2008-09-24	IDE – Supplement		
2008-09-30	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2008-10-08	IDE – Letter from FDA	Disapproval (FDA)	
2008-10-24	IDE – Letter from FDA	Conditional Approval (FDA)	
2008-10-24	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change – Device modifications
2008-11-25	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change – Device modifications
2008-12-05	IDE – Supplement		
2008-12-17	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change – Device modifications
2009-01-05	IDE – Letter from FDA		
2009-01-13		Meeting (with FDA)	Pre-PMA presentation by ELS
2009-01-19	IDE – Letter to FDA	Notification	Temporary suspension of enrollment at an investigational site
2009-01-30	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2009-02-19	IDE – Supplement		
2009-02-27	IDE – Letter from FDA	Request for additional information (FDA)	Request for additional information (FDA) – Annual report review
2009-02-27	IDE – Supplement		
2009-02-27	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2009-03-06	IDE – Supplement	Change request	Request for continued access for PARTNER study Cohort b
2009-03-06	IDE – Supplement	Request for Extension of Continued Access	
2009-03-12	IDE – Supplement		
2009-03-20	IDE – Letter from FDA	Approval (FDA)	

Date	Document Type	Action	Action Detail
2009-03-26	IDE – Letter from FDA	Conditional Approval (FDA)	Requested enrollment rate exceeds the current enrollment rate during the
2009-03-26	IDE – Letter from FDA		
2009-03-26	IDE – Letter from FDA	Request for additional information (FDA)	Adverse Event report additional information required (FDA)
2009-03-31	IDE – Letter from FDA	Conditional Approval (FDA)	
2009-04-10	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2009-04-10	IDE – Supplement		
2009-04-15	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2009-04-24	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2009-05-07	IDE – Supplement		
2009-05-08		Response to FDA	ELS agrees to conduct the continued access study within the modified limit, i.e., 23
2009-05-08	IDE – Supplement		
2009-05-14	IDE – Supplement		
2009-05-14	IDE – Supplement		
2009-05-28	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2009-06-02	IDE – Letter from FDA	Approval (FDA)	Deficiencies in March 26, 2009 FDA conditional approval letter have been addressed.
2009-06-02	IDE – Letter from FDA		
2009-06-09	IDE – Letter from FDA	Approval (FDA)	
2009-07-07	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2009-07-09	IDE – Letter to FDA	Request (to FDA)	Request for continued access for PARTNER Study Cohort A
2009-07-09	IDE – Supplement	Request for Extension of Continued Access	
2009-07-20	IDE – Supplement		

Date	Document Type	Action	Action Detail
2009-08-12	IDE – Letter from FDA	Conditional Approval (FDA)	Requested enrollment rate exceeds the current enrollment rate during the
2009-08-12	IDE – Letter from FDA	Conditional Approval (FDA)	
2009-08-31	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2009-09-17	IDE – Meeting Minutes/Notes/Agendas	Meeting (with FDA)	SAP for PARTNER Study Cohort B
2009-09-23	IDE – Letter to FDA	Change request	ELS agrees to conduct the continued access study within the modified limit, i.e. 23
2009-09-23	IDE – Supplement		
2009-10-19	IDE – Letter from FDA	Approval (FDA)	Deficiencies in August 12, 2009 FDA conditional approval letter have been addressed.
2009-10-19	IDE – Letter from FDA	Approval (FDA)	
2009-10-30	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change
2009-11-24	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change – process changes
2009-12-22	IDE – Supplement	5-Day Notice	5-Day Notice of IDE Change – Device modifications
2009-12-23	IDE – Supplement	Request for Extension for Continued Access	
2010-01-27	IDE – Letter from FDA	Approval (FDA)	FDA agrees to expansion of continued access as proposed, i.e. 23 institutions and 468
2010-01-28	IDE – Annual Report		
2010-02-01	IDE – Minutes from Phone Conversations	Information Only	Teleconference (with FDA) – Trial enrollment rates for continued access
2010-02-04	IDE – Letter to FDA		5-Day Notice of Change for Investigational Device Exemption

Date	Document Type	Action	Action Detail
2010-02-18	IDE – Meeting Minutes/Notes/Agendas	Meeting (with FDA)	Trial enrollment rates for continued access
2010-03-05	IDE - Electronic/Email Correspondence	Proposal (by FDA)	Create 2-month enrollment blocks rather than 1-month blocks
2010-03-09	IDE - Letter to FDA	Change request	Request for new allotment plan for continued access for PARTNER Study
2010-03-09	IDE - Letter to FDA	Change request	ELS Supplement (Request for modification of continued access enrollment rates
2010-03-10	IDE - Letter to FDA	Proposal (by ELS)	Request for PARTNER Cohort B SAP review and feedback
2010-03-10	IDE - Supplement	Request for FDA Review	Request for FDA review - SAP for Cohort B or PARTNER Trial
2010-03-11	IDE - Supplement	5-Day Notice	5-Day Notice of IDE Change - Updated regulatory contacts
2010-03-16	IDE - Letter from FDA	Approval (FDA)	
2010-03-25	IDE - Letter to FDA	Notification	
2010-04-30	IDE - Supplement	5-Day Notice	5-Day Notice of IDE Change - Device modifications
2010-04-30	IDE - Supplement	Information Only	Appendix A
2010-04-30	IDE - Supplement	Information Only	Appendix B
2010-04-30	IDE - Supplement	Information Only	Appendix C
2010-05-10	IDE - Supplement	Request (to FDA)	Crossover provision for Cohort B
2010-05-19	IDE - Letter from FDA	Approval (FDA)	
2010-05-26	IDE - Electronic/Email correspondence		
2010-06-04	IDE - Letter to FDA	5-Day Notice	5-Day Notice of IDE Change - Device modifications
2010-07-16	IDE - Letter to FDA	5-Day Notice	5-Day Notice of IDE Change

Date	Document Type	Action	Action Detail
2010-07-29	IDE - Letter to FDA	Information Only	6-Month Investigator List
2010-08-04	IDE - Letter to FDA	Request for Extension of Continued Access	
2010-08-25	IDE - Supplement	Request for Extension of Continued Access	
2010-08-31	IDE - Supplement	5-Day Notice	5-Day Notice of IDE Change - Device modifications
2010-11-08	IDE - Supplement	5-Day Notice	5-Day Notice of IDE Change - Device modifications
2010-12-20	IDE - Supplement	5-Day Notice	5-Day Notice of IDE Change - Device modifications
2011-02-07	IDE - Supplement	Request for Extension of Continued Access	
2011-02-10	IDE - Supplement	Information Only	Emergency Use
2011-02-16	IDE - Letter from FDA	Disapproval/approval (FDA)	Continued Access Approval
2011-02-24	IDE - Supplement	5-Day Notice	5-Day Notice of IDE Change - Device modifications
2011-03-28	IDE - Supplement	Notification	Annual Report
2011-04-20	IDE - Supplement	5-Day Notice	Changes to Delivery Systems and Crimper
2011-06-17	IDE - Supplement	5-Day Notice	Changes to Ascendra Delivery System
2011-07-25	IDE - Supplement	Notification	6-Month Investigator List
2011-07-29	IDE - Supplement	5-Day Notice	Changes to Delivery Systems and Crimper
2011-08-05	IDE - Supplement	Request (to FDA)	Request for Continued Access Extension
2011-08-11	IDE - Letter from FDA	Approval (FDA)	FDA Approval of Continued Access
2011-09-08	IDE - Supplement	5-Day Notice	Changes to Delivery Systems
2011-09-29	IDE - Supplement	Notification (to FDA)	Investigation Plan Deviation

TABLE 2B (PMA Correspondence)

2010-01-06	PMA - Pre-PMA Submission	Notification	Modular PMA Shell Application
2010-01-21	PMA - Letter from FDA	Notification	Original Shell Application Approval
2010-03-05	PMA - Original Module	Submission/Attachments	Manufacturing Module
2010-05-28	PMA - Letter from FDA	Approval (FDA)	Original Approval letter for Module 1
2010-07-26	PMA - Letter from FDA	Approval (FDA)	Revised Approval letter for Module 1
2010-08-02	PMA - Letter from FDA	Acknowledge of receipt (FDA)	Revised Shell Application Approval
2010-09-30	PMA - Original Module	Submission/Attachments	Non-clinical Study Module
2010-10-24	PMA - Letter from FDA	Notification	Expedited Review Approval
2010-10-29	PMA - Original Module	Submission/Attachments	Clinical Module
2010-12-23	PMA - Amendment	Submission/Attachments	Addition of Draper Facility
2011-01-20	PMA - Letter from FDA	Notification	FDA Deficiency Letter for Modules 2 and 3
2011-01-28	PMA - Letter from FDA	Notification	FDA Deficiency Letter for A001
2011-02-28	PMA - Amendment	Response to FDA	Response to FDA Letter Dated 01/28/2011
2011-03-23	PMA - Letter from FDA	Notification	FDA Deficiency Letter for A002
2011-04-05	PMA - Amendment	Response to FDA	Response to FDA questions sent on 03/23/2011
2011-04-13	PMA - Amendment	Response to FDA	Response to FDA questions sent on 02/09/2011 and 02/24/2011
2011-04-18	PMA - Amendment	Response to FDA	Response to FDA Questions sent 04/01/2011
2011-04-29	PMA - Amendment	Response to FDA	Response to FDA Questions sent 04/21/2011 and 04/22/2011

2011-05-13	PMA - Amendment	Response to FDA	Response to FDA Questions sent 05/06/2011
2011-05-23	PMA - Amendment	Response to FDA	Response to Clinical Questions on FDA Letter Dated 01/20/2011
2011-05-27	PMA - Amendment	Response to FDA	Response to Engineering Questions on FDA Letter Dated 01/20/2011
2011-05-29	PMA - Amendment	Response to FDA	Response to In-Vitro Questions on FDA Letter Dated 01/20/2011
2011-06-06	PMA - Amendment	Response to FDA	Response to FDA Questions sent 05/17/2011 and 05/18/2011
2011-06-07	PMA - Amendment	Response to FDA	Response to FDA Questions sent 06/02/2011
2011-06-14	PMA - Amendment	Response to FDA	Response to FDA Questions sent 06/11/2011 and 06/13/2011
2011-11-02	Correspondence	Approval	Approval of PMA P100041

XII. Statement Beginning on New Page that in Opinion of Applicant Patent Is Eligible for Extension and Statement as to Length of Extension Claimed, Including How Length of Extension Was Determined (37 C.F.R. § 1.740(a)(12)).

In the opinion of Edwards, the '552 patent is eligible for extension. In the opinion of the Edwards, the '552 patent is entitled to be extended by 1,757 days, i.e., the '552 patent is entitled to an extended expiration date of February 22, 2017. The extension was calculated by the method described in 37 C.F.R. § 1.777.

The number of days by which the '552 patent should be extended was calculated as follows:

A. The minimum number of days in the regulatory review period was calculated according to 37 C.F.R. § 1.777(c) and reduced as appropriate pursuant to 37 C.F.R. §§ 1.777(d)(1)-(6).

B. The minimum number of days in the regulatory review period was calculated by adding the number of days pursuant to 37 C.F.R. § 1.777(c)(1) and the number of days pursuant to 37 C.F.R. § 1.777(c)(2).

C. The number of days pursuant to 37 C.F.R. § 1.777(c)(1) was calculated as the number of days in the period starting from the effective date of IDE G030069, March 24, 2003, and ending on the date PMA P100041 was submitted, October 29, 2010, and determined to be at least 2,776 days.

D. The number of days pursuant to 37 C.F.R. § 1.777(c)(2) was calculated as the number of days in the period starting from the date PMA P100041 was submitted, October 29, 2010, and ending on the date of approval of PMA P100041, November 2, 2011, and determined to be at least 369 days.

E. Thus, the number of days in the regulatory review period was calculated by adding 2,776 days to 369 days and determined to be at least 3,145 days.

F. The number of days to be subtracted from the regulatory review period under 37 C.F.R. § 1.777(d)(1) was calculated by determining the number of days pursuant to each of 37 C.F.R. §§ 1.777(d)(1)(i)-(iii).

G. Since the regulatory review period began on March 24, 2003, and since the '552 patent issued on May 2, 1995, 0 days in the regulatory review period were on or before the date on which the '552 patent issued. Thus, the number of days pursuant to 37 C.F.R. § 1.777(d)(1)(i) was determined to be 0.

H. As set forth above, Applicant has acted with due diligence during the entire regulatory review period. Thus, the number of days pursuant to 37 C.F.R. § 1.777(d)(1)(ii) was determined to be 0.

I. The number of days pursuant to 37 C.F.R. § 1.777(d)(1)(iii) was calculated by first subtracting the number of days pursuant to 37 C.F.R. §§ 1.777(d)(1)(i) and 1.777(d)(1)(ii), 0 days, from the number of days pursuant to 37 C.F.R. § 1.777(c)(1), 2,776 days, to obtain 2,776 days and then dividing that number of days in half and determined to be 1,388 days.

J. The number of days pursuant to 37 C.F.R. § 1.777(d)(1) was calculated by subtracting the number of days calculated pursuant to 37 C.F.R. §§ 1.777(d)(1)(i) and 1.777(d)(1)(ii), 0 days, and the number of days calculated pursuant to 37 C.F.R. § 1.777(d)(1)(iii), 1,388 days, from the number of days calculated pursuant to 37 C.F.R. § 1.777(c), 3,145 days, and determined to be 1,757 days.

K. The term of the '552 patent as extended as determined by 37 C.F.R. § 1.777(d)(2) was calculated by adding the number of days calculated pursuant to 37 C.F.R. § 1.777(d)(1),

1,757 days, to the original term of the '552 patent (original expiration date May 2, 2012) and determined to be February 22, 2017.

L. The term of the '552 patent as extended as determined by 37 C.F.R. § 1.777(d)(3) was calculated by adding 14 years to the date of approval, November 2, 2011, and determined to be November 2, 2025.

M. The term of the '552 patent as extended as determined by 37 C.F.R. § 1.777(d)(4) was calculated by comparing the dates calculated pursuant to 37 C.F.R. § 1.777(d)(2) and 37 C.F.R. § 1.777(d)(3) and selecting the earlier date and determined to be February 22, 2017.

N. The term of the '552 patent as extended as determined by 37 C.F.R. § 1.777(d)(5)(i) was calculated by adding five years to the original expiration date of the '552 patent (May 2, 2012) and determined to be May 2, 2017.

O. The term of the '552 patent as extended as determined by 37 C.F.R. § 1.777(d)(5)(ii) was calculated by selecting the earlier date pursuant to 37 C.F.R. § 1.777(d)(4) and 37 C.F.R. § 1.777(d)(5)(i) and determined to be February 22, 2017.

P. Since the '552 patent issued after September 24, 1984, no adjustment was made under 37 C.F.R. § 1.777(d)(6).

XIII. Statement that Applicant Acknowledges Duty to Disclose to Director of United States Patent and Trademark Office and Secretary of Health and Human Services Any Information which Is Material to Determination of Entitlement to Extension Sought (37 C.F.R. §§ 1.740(a)(13) and 1.765).

Edwards acknowledges a duty to disclose to the Director of the United States Patent and Trademark Office and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to the determination of entitlement to the extension sought.

It is understood that the duty of candor and good faith toward the Patent and Trademark Office and the Secretary of Health and Human Services or the Secretary of Agriculture rests on the patent owner or its agent, on each attorney or agent who represents the patent owner and on every other individual who is substantively involved on behalf of the patent owner in a patent term extension proceeding. All such individuals who are aware, or become aware, of material information adverse to a determination of entitlement to the extension sought, which has not been previously made of record in the patent term extension proceeding must bring such information to the attention of the Office or the Secretary, as appropriate, as soon as it is practical to do so after the individual becomes aware of the information. Information is material where there is a substantial likelihood that the Office or the Secretary would consider it important in determinations to be made in the patent term extension proceeding. 37 C.F.R. § 1.765(a).

It is also understood that disclosures pursuant to this section must be accompanied by a copy of each written document which is being disclosed. The disclosure must be made to the Office or the Secretary, as appropriate, unless the disclosure is material to determinations to be made by both the Office and the Secretary, in which case duplicate copies, certified as such,

must be filed in the Office and with the Secretary. Disclosures pursuant to this section may be made to the Office or the Secretary, as appropriate, through an attorney or agent having responsibility on behalf of the patent owner or its agent for the patent term extension proceeding or through a patent owner acting on his or her own behalf. Disclosure to such an attorney, agent or patent owner shall satisfy the duty of any other individual. Such an attorney, agent or patent owner has no duty to transmit information which is not material to the determination of entitlement to the extension sought. 37 C.F.R. § 1.765(b).

It is further understood that no patent will be determined eligible for extension and no extension will be issued if it is determined that fraud on the Office or the Secretary was practiced or attempted or the duty of disclosure was violated through bad faith or gross negligence in connection with the patent term extension proceeding. If it is established by clear and convincing evidence that any fraud was practiced or attempted on the Office or the Secretary in connection with the patent term extension proceeding or that there was any violation of the duty of disclosure through bad faith or gross negligence in connection with the patent term extension proceeding, a final determination will be made that the patent is not eligible for extension. 37 C.F.R. § 1.765(c).

XIV. Prescribed Fee for Receiving and Acting upon Application for Extension (37 C.F.R. § 1.740(a)(14)).

The fee as prescribed in 37 C.F.R. § 1.20(j) is attached hereto in the from of a credit card form for the amount of $1,120.00. Additionally, please charge any additional fees that may be

required for the processing of this application, or credit any overpayments, to Deposit Account No. 15-0030.

XV. Name, Address, and Telephone Number of Person to Whom Inquiries and Correspondence Relating to Application for Patent Term Extension are to be Directed (37 C.F.R. § 1.740(a)(15)).

All inquiries and correspondence should be sent to:

Customer Number: 22850

Which corresponds to:

Oblon, Spivak, McClelland, Maier & Neustadt, LLP.
(Stephen G. Baxter or Jacob A. Doughty)
1940 Duke Street
Alexandria, VA 22314

Telephone: 703-413-3000
Facsimile: 703-413-2220

XVI. Patent Term Extension Applicant (M.P.E.P. § 2752).

As indicated above, this application is being made by Edwards, the owner of the '552 patent, and the undersigned is authorized to act on behalf of Edwards as pertains to the '552 patent and this application for extension of patent term.

Edwards was not the marketing applicant before the Food and Drug Administration in IDE G030069 or PMA P100041. Dr. William O'Neill, on behalf of Percutaneous Valve Technologies, Inc. (PVT), was the marketing applicant in IDE G030069 from institution until July 29, 2004. On July 29, 2004, Edwards Lifesciences, LLC, became the marketing applicant in

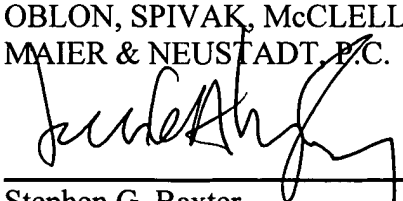
IDE G030069. On October 29, 2010, Edwards Lifesciences, LLC, filed PMA P100041. Edwards Lifesciences, LLC, was the marketing applicant in PMA P100041 through approval. Attached as Exhibit D is a letter from Dr. William O'Neill to the U.S. Patent and Trademark Office authorizing Edwards to rely on his activities as the marketing applicant before the Food and Drug Administration in IDE G030069. Attached as Exhibit E is a letter from an authorized representative of Edwards Lifesciences, LLC, to the U.S. Patent and Trademark Office authorizing Edwards to rely on its activities as the marketing applicant before the Food and Drug Administration in IDE G030069 and PMA P100041.

* * * *

In view of the foregoing, Edwards submits that the present patent is entitled to the requested extension of patent term, and early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



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Attachment:
Exhibits A to E

Exhibit A

US005411552A

United States Patent [19]

Andersen et al.

[11] Patent Number: 5,411,552

[45] Date of Patent: May 2, 1995

[54] **VALVE PROTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROTHESIS**

[76] Inventors: **Henning R. Andersen**, Dalvangen 37A, DK-8270 Hoejbjerg; **John M. Hasenkam**, Aprilvej 8, DK-8210 Aarhus V; **Lars L. Knudsen**, RudolfWulffsgade 6,4.mf., DK-8000 Aarhus C, all of Denmark

[21] Appl. No.: **261,235**

[22] Filed: **Jun. 14, 1994**

Related U.S. Application Data

[63] Continuation of Ser. No. 961,891, Jan. 11, 1993, abandoned.

[30] **Foreign Application Priority Data**

May 18, 1990 [DK] Denmark 1246/90

[51] **Int. Cl.**[6] **A61F 2/24**

[52] **U.S. Cl.** **623/2**; 623/900; 137/343; 137/844; 251/358

[58] **Field of Search** 623/2, 900; 137/343, 137/844, 316; 251/358; 606/108

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,671,979	6/1972	Moulopoulos .	
4,038,703	8/1977	Bokros	623/2
4,056,854	11/1977	Boretos et al.	623/2
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Primary Examiner—David H. Willse
Attorney, Agent, or Firm—Watson, Cole, Grindle & Watson

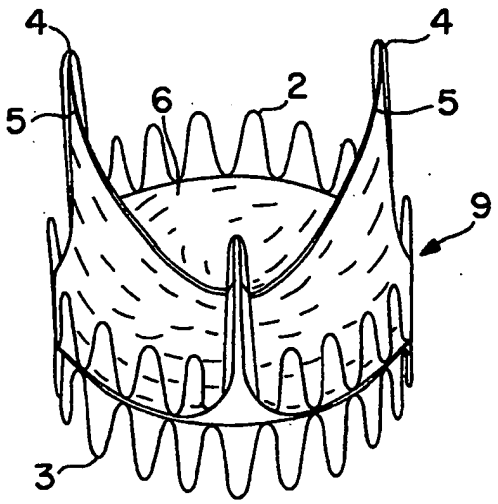
[57] **ABSTRACT**

A valve prosthesis (9) for implantation in the body by use of catheter (11) comprises a stent made from an expandable cylinder-shaped thread structure (2,3) comprising several spaced apices (4). The elastically collapsible valve (4) is mounted on the stent as the commissural points (5) of the valve (6) are secured to the projecting apices (4).

The valve prosthesis (9) can be compressed around the balloon means (13) of the balloon catheter (11) and be inserted in a channel, for instance in the aorta (10). When the valve prosthesis is placed correctly the balloon means (13) is inflated thereby expanding the stent and wedging it against the wall of aorta. The balloon means is provided with beads (14) to ensure a steady fastening of the valve prosthesis on the balloon means during insertion and expansion.

The valve prosthesis (9) and the balloon catheter (11) make it possible to insert a cardiac valve prosthesis without a surgical operation comprising opening the thoracic cavity.

8 Claims, 4 Drawing Sheets



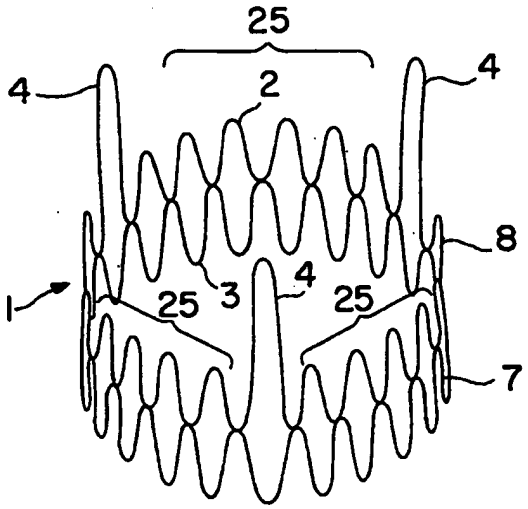


FIG. 1

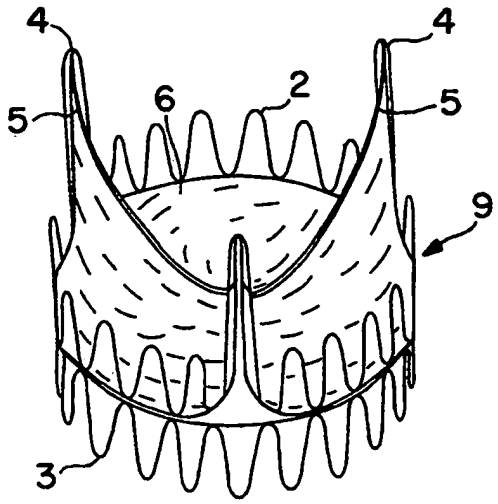


FIG. 2

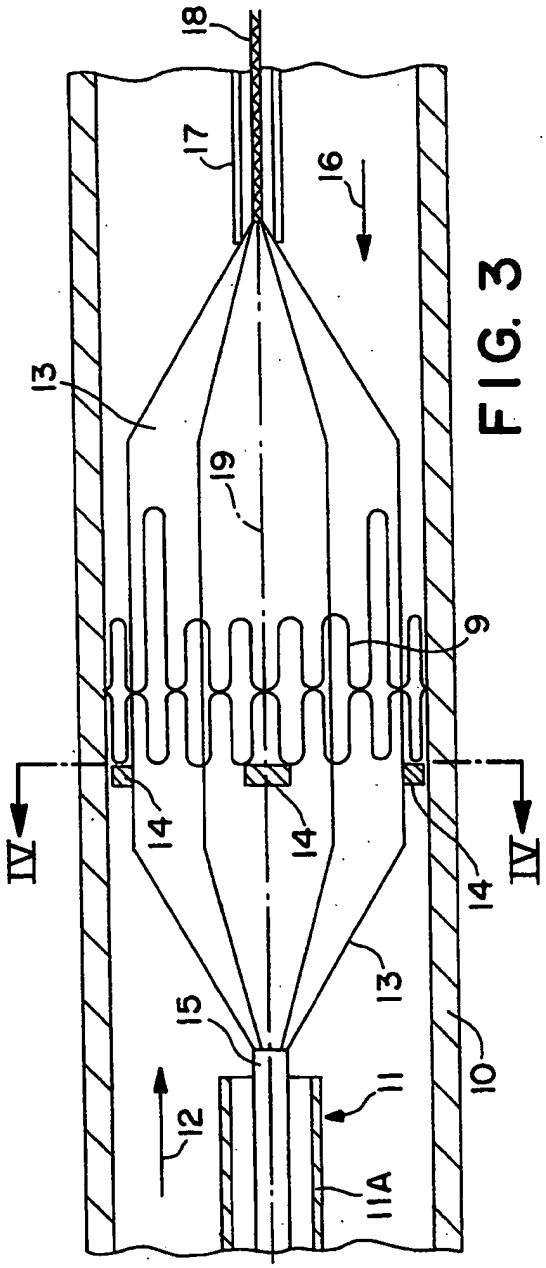


FIG. 3

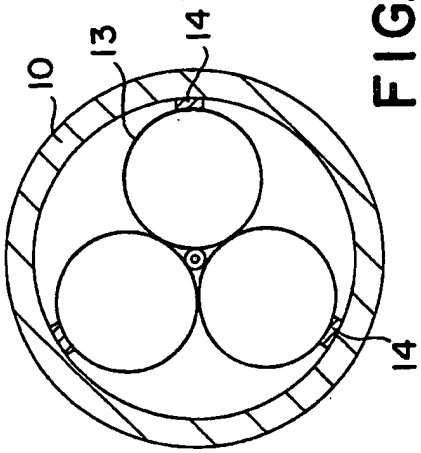


FIG. 4

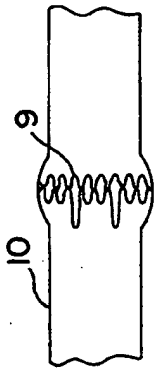


FIG. 7

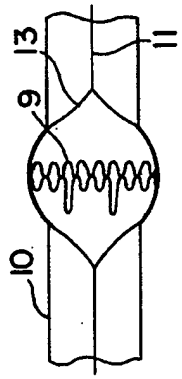


FIG. 6

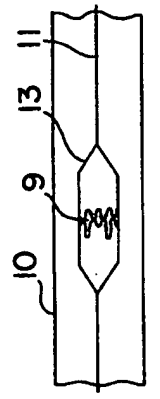


FIG. 5

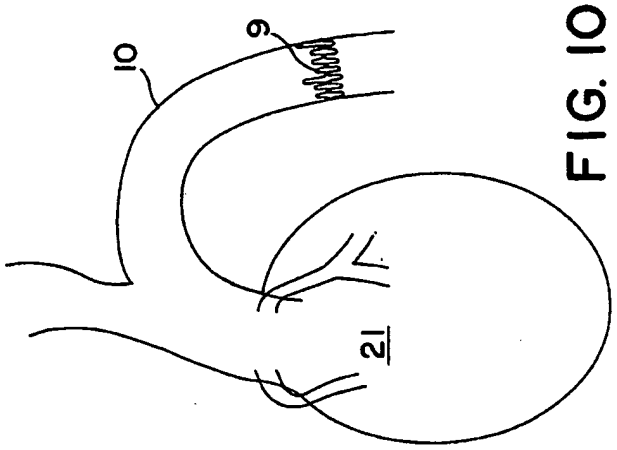


FIG. 10

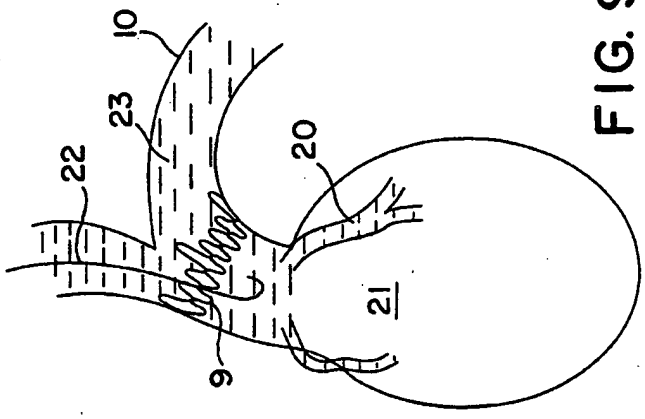


FIG. 9

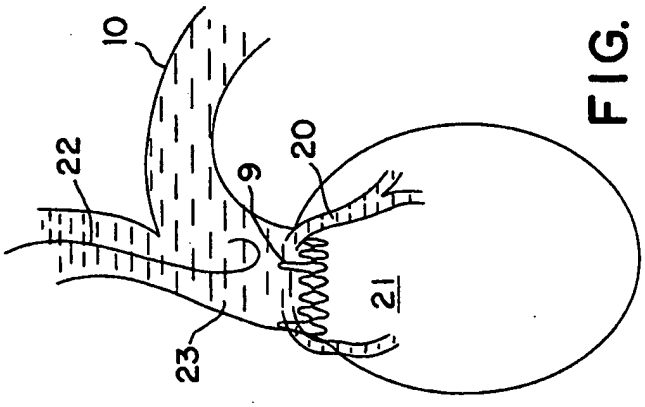


FIG. 8

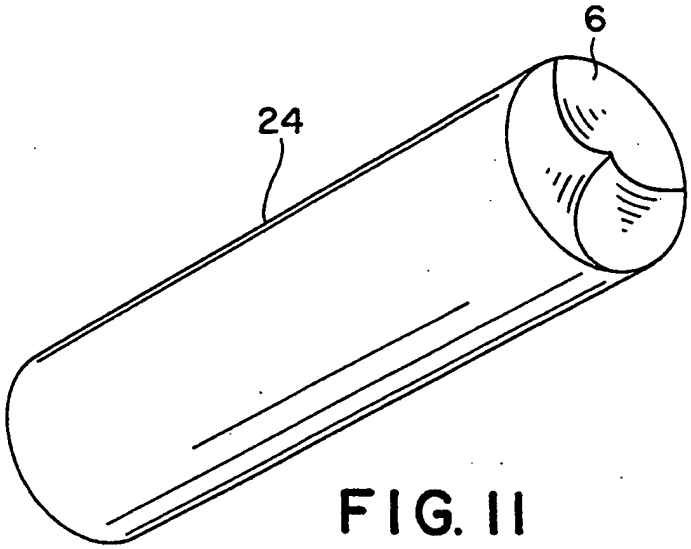


FIG. 11

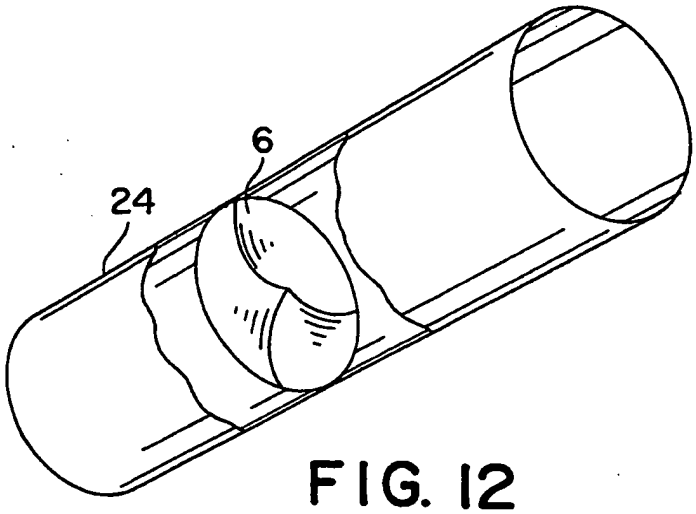


FIG. 12

VALVE PROTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROTHESIS

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation of application Ser. No. 961,891, filed Jan. 11, 1993, now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates to a valve prosthesis, preferably a cardiac valve prosthesis, for implantation in the body and comprising a collapsible elastical valve which is mounted on an elastical stent wherein the commissural points of the elastical collapsible valve are mounted on the cylinder surface of the elastical stent.

Valve prostheses of this type are usually implanted in one of the channels of the body to replace a natural valve. In the present description the invention will be explained in connection with an cardiac valve prosthesis for implantation in aorta. However, it will be possible to use a valve prosthesis according to the invention in connection with implantation in other channels in the body by using the same technique as the one used for implantation of cardiac valve prosthesis. Such an implantation may, e.g., comprise the implantation of:

1. a valve (for instance a cardiac valve) in the veins,
2. a valve in the oesophagus and at the stomach,
3. a valve in the ureter and/or the vesica,
4. a valve in the biliary passages,
5. a valve in the lymphatic system, and
6. a valve in the intestines.

An existing natural valve in the body is traditionally replaced with a valve prosthesis by a surgical implantation. However, a surgical implantation is often an exacting operation. Thus, today the implantation of cardiac valves are solely made by surgical technique where the thoracic cavity is opened. The operation calls for the use of a heart and lung machine for external circulation of the blood as the heart is stopped and opened during the surgical intervention and the artificial cardiac valves are subsequently sewed in.

Due to its exacting character, it is impossible to offer such operation to certain people. For instance, this is due to the fact that the person is physically weak because of age or illness. Moreover, the number of heart and lung machines available at a hospital will be a substantially limiting factor.

Cardiac valve prostheses that need no surgical intervention are known as there are used for implantation by means of a technique of catheterization. Examples of such valve prostheses are described in U.S. Pat. Nos. 3,671,979 and 4,056,854. However, both of these valve prostheses are connected to means which lead to the surface of the patient either for a subsequent activation of the valve or for a subsequent reposition or removal of the valve prosthesis. With these valve prostheses it is impossible to make an implantation which makes it possible for the patient to resume a substantially normal life in the same way as it is possible in connection with a surgical implantation of a cardiac valve.

From U.S. Pat. No. 3,755,823 an elastic stent for a cardiac valve prosthesis is known. However, this valve prosthesis is not designed for implantation in the body by catheterization. Even though this patent contains no detailed explanation, the description indicates that this valve prosthesis is designed for implantation and sewering on by a surgical intervention.

Moreover, from U.S. Pat. Nos. 4,856,516 and 4,733,665 different shapes of expandable stents are known. These stents are made to be expanded by impression of a radially outward force coming from a balloon catheter or the like. These stents are made to reinforce the wall when there is a risk that the channel is closed and/or compressed.

The nearest prior art may be that described in GB-A-2,056,023. This document discloses an elastic stent as described by way of introduction. Thus, the stent described comprises an elastic collapsible valve mounted on the cylinder surface of a cylindrical stent. However, the valve prosthesis including the stent is designated for mounting through a surgical intervention. Even though the stent is slightly collapsible, it will not be suited for implantation by a catheterization procedure.

SUMMARY OF THE INVENTION

It is the object of the present invention to provide a valve prosthesis of the type mentioned in the introductory part, which permits implantation without surgical intervention in the body and by using a catheter technique known per se and which makes it possible for the patient to resume a substantially normal life.

This is achieved according to the invention with a valve prosthesis of the type mentioned in the introductory part, which is characterized in that the stent is made from a radially collapsible and re-expandable cylindrical support means for folding and expanding together with the collapsible valve for implantation in the body by means of a technique of catheterization.

The collapsible elastic valve is mounted on the stent for instance by gluing, welding or by means of a number of suitable sutures.

If the support means are made from a thread structure, this can for instance be grate shaped, loop shaped or helical. This makes it possible to compress the stent and the collapsible valve mounted thereon for placing on the insertion catheter. The use of a non-self-expandable stent may, e.g., be effected by a compression of the stent around the expansion arrangement of the catheter which preferably consists of a balloon. When using a self-expandable stent, a catheter with an expansion arrangement is not used. In this case the stent is compressed and is inserted into an insertion or protection cap from which the stent is eliminated after implantation in order to obtain an expansion due to the stresses in the compressed support means, which for instance may be made from plastics or metal. After the compression the entire outer dimension is relatively small, which makes it possible to introduce the valve prosthesis through a channel in the body.

When the valve prosthesis is introduced and placed correctly, the stent is expanded by self-expansion or by means of the expansion arrangement until the stent is given an outer dimension which is slightly larger than the channel in which it is placed. As the stent is elastic, a contraction of the stent is prevented once it is expanded. The stiffness in the material of the support means contributes to maintain the expanded shape of the stent. After the expansion is made, the expansion arrangement of the catheter is contracted and the catheter can be removed from the channel. The inlet opening can subsequently be closed and the patient will then be able to resume a normal life.

The valve prosthesis according to the invention does not require an actual operation but merely a small intervention to optionally expose the body channel, e.g., a vein, through which the insertion takes place. Thus, patients for whom an operation would be associated with high risk can be offered implantation of, for instance, cardiac valves. After the implantation has taken place, the after-treatment will advantageously be shorter than normally, which means fewer hospital days for the patient. Moreover, it is assumed that it will be possible to implantate the valve prosthesis under local anaesthetic.

The valve prosthesis can be used to replace a natural valve or to establish a new valve function in one of the channels in the body which do not naturally contain a valve. For instance this goes for veins (arteries and veins) on a place without natural valves. The function of the valve prosthesis is then to ensure that the blood flows in one direction only. The valve is meant to be used in veins in the legs of persons suffering from varicose veins (varices).

In persons having varicose veins the blood flows in a wrong direction, viz. from the central veins in the centre of the leg towards the superficial veins. Among other things, this is due to the changed pressure in the legs, upright working position and other conditions. A valve prosthesis according to the invention may easily be placed in the veins and prevent the flow of the blood in a wrong direction.

Also, the valve prosthesis can be used in connection with diseases, for instance cancerous tumors, where too much humour is produced. If the humour is able to flow from the cancerous tumor through several channels, it is possible to drain the humour in one desired direction through the channels of the body by an appropriate placing of the valve prosthesis.

When the valve prosthesis is used as a cardiac valve prosthesis in the aorta, it is possible to mount it in three positions, viz., in the descending part of the aorta, in a position between the coronary arteries and the left ventricle of the heart, or in the aorta in a position immediately after the mouth of the coronary arteries.

The cardiac valve prosthesis can also be used in other places than in the aorta. Thus, the valve prosthesis can be used in the pulmonary artery and/or the right ventricle of the heart for replacing the pulmonary valves. Likewise, the cardiac valve prosthesis can be used in the passage between the right auricle of the heart and the right ventricle of the heart (tricuspidalostium) and the passage between the left auricle of the heart and the left ventricle of the heart (mistralostium) for replacing the tricuspidal valve and the mitral valve, respectively.

Even though the cardiac valve preferably is meant to be used for patients suffering from aorta insufficiency and who cannot be offered an open heart surgery, the valve prosthesis can also be used for patients in connection with treatment of aorta stenosis. Several of the patients with aorta stenosis are elderly people who cannot be offered a surgical cardiac operation. The patients are offered balloon dilatation of the aorta stenosis which may result in an aorta insufficiency as a side effect of the treatment.

As to these patients it is possible to insert a valve prosthesis in the descending or ascending part of the aorta thoracalis a few days or weeks before the balloon dilatation. As a result thereof, the left ventricle is protected against weight if the subsequent balloon dilatation of the stenosis results in aorta insufficiency. In certain cases the weight (reflux) on the left ventricle is reduced by up to approximately 75%.

Furthermore, the stent may be made with a relatively great height and with a cylinder surface which is closed by a suitable material. Thus, a vascular prosthesis known per se is formed wherein the valve is mounted. This may facilitate the implantation of the valve prosthesis, for instance in the arcus aorta. Moreover, the great surface which abuts the inner wall of the channel contributes to ensure the securing of the valve prosthesis in the channel. This embodiment is also suitable as valve prothesis which is inserted in veins. As veins have relatively thin and weaker walls than arteries, it is desirable that the valve prothesis has a greater surface to distribute the outward pressure which is necessary to secure the valve prosthesis.

Moreover, the invention relates to a balloon catheter for implantating a valve prosthesis according to the invention and comprising a channel for injection of a fluid for the inflation of the balloon means of the catheter and an insertion cap wherein the balloon means of the catheter and a collapsible valve prosthesis mounted thereon are located during the injection, characterized in that the balloon means are provided with a profiled surface which is made to ensure a steady fastening of the valve prosthesis during the withdrawal of the balloon means from the protection cap and the subsequent inflation for the expansion of the stent.

Different balloon catheters for implantating cores in the body are known. For instance, such balloon catheters are known from U.S. Pat. Nos. 4,856,516, 4,733,665 and 4,796,629 and from DE publication No. 2,246,526. However, the known balloon catheters have a smooth or a slightly wavy surface. The use of such balloon catheter is disadvantageous for mounting a valve prosthesis in a channel having a large flow as for instance the aorta. A large humour flow is able to displace the stent on the smooth surface of the balloon and makes an accurate positioning difficult. This drawback has been remedied with the balloon catheter according to the present invention as the profiled surface prevents a displacement of the valve prosthesis in relation to the balloon means during introduction and the subsequent inflation of the balloon means.

In connection with the implantation, any prior art technique may be used to supervise an accurate introduction and positioning of the valve prosthesis. Thus, guide wires for the catheter, X-ray supervision, injection of X-ray traceable liquids, ultrasonic measuring, etc., may be used.

DESCRIPTION OF THE DRAWINGS

The invention will now be explained in detail with reference to the accompanying schematical drawing, wherein

FIG. 1 shows a perspective view of a stent without a valve,

FIG. 2 is a perspective view of a valve prosthesis according to the invention made from the stent shown in FIG. 1 having a biological valve mounted thereon,

FIG. 3 is a partial view through the aorta illustrating a partially inflated balloon catheter,

FIG. 4 is a cross section through the embodiment shown in FIG. 9,

FIG. 5–7 are views illustrating the introduction and implantation of a valve prosthesis of the invention in the aorta,

FIG. 8–10 are views illustrating three possible positions of a cardiac valve prosthesis, and

FIG. 11–12 are perspective views illustrating two further embodiments of a valve prosthesis having a closed cylindrical wall.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 shows a stent 1 made by support means in the form of two 0.55 mm surgical stainless steel wires 2,3. The wires are folded in 15 loops. Three loops 4 are 14 mm in height and are intended to secure the commissural points 5 (see FIG. 2) from a biological cardiac valve 6 which is mounted in the stent 1. The remaining loops have a height of 8 mm. These loops form circumferentially expandable sections 25 between the commissural points 5 forming commissural supports. Each of the two folded wires 2,3 is bent to form rings 7,8 which are closed by welding the ends. The two rings are placed on top of each other as will appear from FIG. 1 and they are mutually secured by means of a number of sutures (not shown). The lower ring is circumferentially expandable at least along sections thereof which correspond to the circumferentially expandable sections 25. By using a substantially cylindrical thread structure with projecting apices, a reduction in weight is obtained as compared to a stent which is exclusively cylindrical with the same loop heights for all the loops.

The biological valve 6 was removed from a slaughtered pig of 100 kg. The valve was cleaned before mounting in the stent 1. The cleaned valve has an outer diameter of 25–27 mm and the height of the three commissural points 5 is 8 mm. The valve 6 is mounted in the stent by means of a suitable number of sutures to form the cardiac valve prosthesis 9 shown in FIG. 2. The valve prosthesis produced is used for performing tests in pigs by implantation of cardiac valve prosthesis. However, the cardiac valve prosthesis for use in human beings has a corresponding form.

FIG. 3 shows a partial view through the aorta 10. A balloon catheter 11 is introduced in the aorta according to the direction of an arrow 12. In the Figure shown the balloon means 13 of the balloon catheter is led out of the protection cap 11A and is partly inflated through a fluid channel 15, which is led to the surface of the patient. The balloon means 13 constitutes a tri-sectional balloon upon which the cardiac valve prosthesis is placed. In the form shown, the cardiac valve prosthesis is expanded exactly to be in contact with the aorta 10. The balloon means 13 is provided with three projecting beads 14 which are engaged with the one side of the cardiac valve prosthesis 9. The blood flowing through the aorta according to the direction of an arrow 16 will thus cause the cardiac valve prosthesis 9 to abut on the beads 14 and the valve cannot be displaced in relation to the balloon means 13. Moreover, the balloon catheter used comprises a central channel 17 to receive a guide wire 18 which is used in a way known per se for supervising the introduction of the catheter through fluoroscopi. In the shown embodiment beads 14 are only used at one side of the valve prosthesis, but, however, it will often be desirable to use the beads in pairs placed along lines parallel to the longitudinal axes 19 through the balloon means 13. In this case the spacing of the pair of beads 14 will correspond to the height of the loops of the stent. This makes it possible to make an effective fastening of a valve prosthesis on balloon means. Moreover, the fastening on the balloon means may be provided by using balloon means with an indentation in the surface (not shown).

FIG. 4 shows a cross section through the embodiment shown in FIG. 3 illustrating the placing of the beads 14 on the tri-sectional balloon means 13.

A balloon catheter of the above-described type which was used in tests of implantating the cardiac valve prosthesis 9 in pigs had the following dimensions. Each of the three balloons was 60 mm in length and 15 mm in diameter. The total diameter for the three inflated balloons was 31 mm and in the balloon catheter used two beads 14 having a height of 3 mm were mounted on each side of the three balloons. The beads had a spacing of 15 mm. The protection cap 11A of the balloon catheter had an outer diameter of 13.6 mm and an inner diameter of 12.5 mm and a length of 75 cm. The balloon catheter was provided with a standard guide wire having a diameter of 0.9 mm and a length of 300 cm.

FIGS. 5–7 show the valve prosthesis 9 at different steps in introducing and implantating in the aorta 10 by means of the catheter 11 having the inflatable balloon means 13. The cardiac valve prosthesis 9 is initially placed above the deflated balloon means 13 and compressed manually around the balloon means (FIG. 5), whereafter the outer diameter for the valve prosthesis is approximately 10 mm. After the introduction and positioning, the balloon means 13 is inflated (FIG. 6), thereby contributing an outer dimension of approximately 30 mm to the cardiac valve prosthesis. To obtain an effective fastening in the aorta, the outer dimension of the cardiac valve prosthesis is greater than the diameter of the aorta. This means that the prosthesis is tight against the inner wall of the aorta with a pressure which is sufficiently large to counteract a detachment due to the flow of the blood. The balloon catheter 11 may subsequently be removed from the aorta 10 (FIG. 7). Due to the stiffness of the metal the valve prosthesis will prevent a contraction. However, smaller contractions may occur (<10% diameter reduction) after the deflation and removal of the balloon catheter 13. When the valve prosthesis is mounted as shown in FIG. 7, the patient will be able to resume a substantially normal life after a few days.

FIGS. 8–10 show the positioning of the valve prosthesis 9 as cardiac valve prosthesis in the aorta 10 in three different positions, i.e., in a position between the coronary arteries 20 and the left ventricle of the heart 21 (FIG. 8), in a position immediately after the mouth of the coronary arteries in the ascending part of the aorta (FIG. 9), and in a position in the descending part of the aorta 10. The positioning of the valve prosthesis is chosen in accordance with the diagnosis of the illness of the patient. By placing the cardiac valve prosthesis as shown in FIG. 8, there is a risk of detachment and/or covering the mouth of the coronary arteries, and therefore it is preferred to use a higher stent which, for instance, comprises several rings 7,8 placed on top of each other. This allows a fixation of the prosthesis at a place after the mouth of coronary arteries even though the valve itself is in the position between the coronary arteries and the left ventricle. FIGS. 8 and 9 show how a contrast medium 23 is injected by means of a so-called pigtail catheter for registration of the tightness of the implantated valve prosthesis 9.

A specific embodiment for a valve prosthesis and a balloon catheter for implantating the valve prosthesis has been explained above. However, it is obvious that it

is possible to modify the valve prosthesis depending on the desired use, and moreover, it is possible to modify the catheter used in the implantation. Thus, the stent of the valve prosthesis may be made solely of one closed ring folded in a number of loops or with three or more mutually secured loop-shaped rings placed on top of each other. Moreover, it is possible to make the stent having a thread structure which instead of loops is grate shaped, helical or is formed otherwise if only it is ensured that the form of the stent permits the compression and expansion of the stent and fastening of the collapsible valve. Instead of a biological valve it might be possible to use other collapsible valves, such as valves made from synthetic materials, e.g., polyurethane. It is also possible to use valves with more or fewer flaps than three.

It is possible to make the valve prosthesis with a closed cylinder surface as illustrated in FIGS. **11** and **12**. In both Figures the support means of the valve prosthesis is made of an elongated tubular means **24** having a closed cylinder surface. This valve prosthesis is intended to expand by self-expansion or by means of a catheter according to the invention. This prosthesis is especially suitable for placing in veins and other channels where only a small pressure is exerted against he wall of the channel. In FIG. **11** the valve **6** is mounted at the end of the tubular means **24**. In FIG. **12** an embodiment is shown where the valve **6** is mounted in a central position in the tubular means **24**.

An explanation of a method of implantating a valve prosthesis according to the invention is given below:

- a valve prosthesis **9** made of a stent **1** and a collapsible valve **6**, as described above, is placed on a deflated balloon means and is manually compressed thereon,
- the balloon means **13** and the valve prosthesis are drawn into an insertion cover **11A**,
- a guide wire **18** is inserted into the left ventricle of the heart through the central opening **17** of the balloon catheter under continuous fluoroscopi,
- the insertion cover **11A** conveys the guide wire **18** to a point in the channel in the immediate vicinity of the desired position of the valve prosthesis,
- the balloon means **13** is pushed out of the protection cap **11A** and the valve prosthesis is positioned in the desired position if necessary by use of further registration means to ensure an accurate positioning,
- the balloon means **13** is inflated with a certain overstretching of the channel,
- the balloon means **13** is deflatated, and
- the balloon means **13**, the guide wire **18** and the protection cap **11A** are drawn out and the opening in the channel, if any, wherein the valve prosthesis is inserted can be closed.

We claim:

1. A valve prosthesis for implantation in a body channel, the valve prosthesis comprising a collapsible elastical valve which is mounted on an elastical stent, the elastical valve having a plurality of commissural points, wherein the stent comprises:

cylindrical support means which is radially collapsible for introduction within the body channel and which has a plurality of circumferentially-expandable sections such that the cylindrical support means is radially expandable for being secured within the body channel; and

a plurality of commissural supports projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof for supporting the commissural points of the collapsible valve, at least one circumferentially-expandable section of the cylindrical support means lying between each of the commissural supports, such that the collapsible valve may be collapsed and expanded together with the cylindrical support means for implantation in the body channel by means of a technique of catheterization.

2. A valve prosthesis according to claim **1**, wherein the cylindrical support means is made of a thread structure.

3. A valve prosthesis according to claim **2**, wherein the thread structure comprises several spaced apices projecting from the one side of the cylindrical structure and in a direction along the longitudinal axis of the cylinder and that the commissural points of the valve are attached to the projecting apices.

4. A valve prosthesis according to claim **3**, wherein the elastically collapsible valve is a biological trilobate valve.

5. A valve prosthesis to claim **4**, wherein the stent is made from a stainless steel wire folded in a number of loops and bent into a circle and welded to form a closed ring, wherein the stent comprises two or more such closed rings which are mutually connected end to end to form the cylindrical thread structure, and wherein three of the loops in a ring at an end of said stent are folded with a greater height than the remaining loops to form the apices to which the commissural points of the biological valve are attached.

6. A valve prosthesis according to claim **5**, wherein each of the rings of the stent is made from a wire having a diameter of 0.55 mm and a loop height of approximately 8 mm and approximately 14 mm for the three greater loops, and wherein the cylindrical thread structure produced and the collapsible valve mounted thereon in a folded state have an outer diameter of approximately 10 mm and in expanded state an outer diameter of approximately 30 mm.

7. A valve prosthesis according to claim **5**, wherein the stent is made to be fixed through the expansion at one point in the channel wherein the valve prosthesis is inserted, which point is different from the point where the valve is mounted in the stent.

8. A valve prosthesis according to claim **1**, wherein the cylinder surface of the support means is closed to form a tubular element.

* * * * *

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(12) EX PARTE REEXAMINATION CERTIFICATE (8463rd)

United States Patent

Anderson et al.

(10) Number: US 5,411,552 C1

(45) Certificate Issued: Aug. 16, 2011

(54) VALVE PROTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROTHESIS

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(52) **U.S. Cl.** **623/2.18**; 137/343; 137/844

(58) **Field of Classification Search** 623/2
See application file for complete search history.

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Primary Examiner—Cary E Wehner

(57) **ABSTRACT**

A valve prosthesis (9) for implantation in the body by use of catheter (11) comprises a stent made from an expandable cylinder-shaped threaded structure (2,3) comprising several spaced apices (4). The elastically collapsible valve (4) is mounted on the stent as the commissural points (5) of the valve (6) are secured to the projecting apices (4).

The valve prosthesis (9) can be compressed around the balloon means (13) of the balloon catheter (11) and be inserted in a channel, for instance in the aorta (10). When the valve prosthesis is placed correctly the balloon means (13) is inflated thereby expanding the stent and wedging it against the wall of aorta. The balloon means is provided with beads (14) to ensure a steady fastening of the valve prosthesis on the balloon means during insertion and expansion.

The valve prosthesis (9) and the balloon catheter (11) make it possible to insert a cardiac valve prosthesis without a surgical operation comprising opening the thoracic cavity.

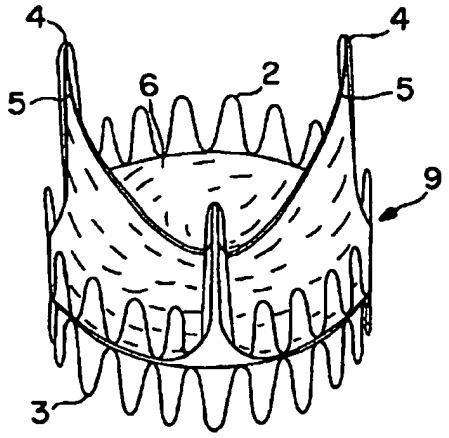

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Photo of the Andersen Prototype Device from the Aarhus University webpage submitted as Plaintiff Trial Exhibit 82 in C.A. No. 08-091-GMS in the District Court of Delaware.
Press Release re: CoreValve Establishes U.S. Operations, Hires Veteran Medical Device Management and Development Team, submitted as Plaintiff Trial Exhibit 109 in C.A. No. 08-091-GMS in the District Court of Delaware.

CoreValve, Inc.'s Objections and Re Designated Responses to Interrogatory Nos. 1–7 & 9–13 of Plaintiffs' First Set of Interrogatories and Supplemental Responses to Interrogatory Nos. 9 and 13 submitted as Plaintiff Trial Exhibit 151 in C.A. No. 08–091–GMS in the District Court of Delaware.

Knudsen et al., Catheter–Implanted Hasenkam Hasenkam Prosthetic Heart Valves—Transluminal Catheter Implantation of a New Expandable Artificial Heart Valve in the Descending Thoracic Aorta in Isolated Vessels and Closed Chest Pigs, The International Journal of Artificial Organs, vol. 16, No. 5, pp. 253–262 (1993), submitted as Plaintiff Trial Exhibit 156 in C.A. No. 08–091–GMS in the District Court of Delaware.

Grube et al., First Report on a Human Percutaneous Transluminal Implantation of a Self–Expanding Valve Prosthesis for Interventional Treatment ofAortic Valve Stenosis, Catherization and Cardiovascular Interventions, vol. 66, pp. 465–469 (2005) submitted as Plaintiff Trial Exhibit 158 in C.A. No. 08–091–GMS in the District Court of Delaware.

English Translation of French Patent 00 14028 submitted as Plaintiff Trial Exhibit 165 in C.A. No. 08–091–GMS in the District Court of Delaware.

Transcript of CoreValve analyst update conference call submitted as Plaintiff Trial Exhibit 168 in C.A. No. 08–091–GMS in the District Court of Delaware.

Photo of Edwards Sapien THV submitted as Plaintiff Trial Exhibit 285 in C.A. No. 08–091–GMS in the District Court of Delaware.

EC Design Examination Certificate Medical Device Directive submitted as Plaintiff Trial Exhibit 380 in C.A. No. 08–091–GMS in the District Court of Delaware.

First Witness Statement of Robrecht Michiels submitted as Plaintiff Trial Exhibit 401 in C.A. No. 08–091–GMS in the District Court of Delaware.

Andersen et al., Transluminal Hasenkam Hasenkam Implantation ofartificial heart valves. Description ofa new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs, European Heart Journal, vol. 13, pp. 704–708 (1992) submitted as Plaintiff Trial Exhibit 477 in C.A. No. 08–091–GMS in teh District Court of Delaware.

Letter from Henning Rud Andersen to D. L. Brutsaert enclosing manuscript submission for European Heart Journal submitted as Plaintiff Trial Exhibit 523 in C.A. No. 08–091–GMS in the District Court of Delaware.

Andersen et al., Transluminal catheter implantation ofa new expandable artificial cardiac valve in the aorta and the beating heart ofclosed chest pigs, European Heart Journal, vol. 11, pp. 224 (Aug. 1990) submitted as Plaintiff Trial Exhibit 531 in C.A. No. 08–091–GMS in the District Court of Delaware.

Andersen et al., Implantation of Artificial Heart Valves (Manuscript), submitted as Plaintiff Trial Exhibit 532 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Simon Dack of JACC to Henning Andersen enclosing referee comments of manuscript (No. JAC000331) submitted as Plaintiff Trial Exhibit 533 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Simon Dack of JACC to Henning Andersen enclosing referee comments of manuscript (No. JAC000333) submitted as Plaintiff Trial Exhibit 534 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Ruth R. Ohman of JACC to Henning Andersen acknowledging receipt of manuscript (No. JAC000331) submitted as Plaintiff Trial Exhibit 535 in C.A. No. 08–091–GMS in the District Court of Delaware.

Rejection of article titled "Implantation of Artificial Heart Valves" submitted as Plaintiff Trial Exhibit 536 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Knud Tange Rasmussen of DTI to Kenneth H. Levin of C.R. Bard submitted as Plaintiff Trial Exhibit 537 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from H. Anderson to S. Rowe re: developments of U.S. Patent No. 5,411,552 submitted as Plaintiff Trial Exhibit 544 in C.A. No. 08–091–GMS in the District Court of Delaware.

Fax from Anderson to S. Rowe attching letter re: meeting to discuss possibilities for Johnson & Johnson to negotiate license agreement of U.S. Patent No. 5,411,552 submitted as Plaintiff Trial Exhibit 545 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from H. Anderson to S. Rowe re: reimbursement of travel expenses submitted as Plaintiff Trial Exhibit 548 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from H. Anderson to W. Sterman re Sep. 12, 1995 announcement regarding corporation between Heartport and St. Jude submitted as Plaintiff Trial Exhibit 565 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from M. Garrison to H. Anderson re: renewed Heartport effort in endovascular valve replacement submitted as Plaintiff Trial Exhibit 566 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from H. Anderson to M. Garrison re: development of invention by Heartport submitted as Plaintiff Trial Exhibit 567 in C.A. No. 08–091–GMS in the District Court of Delaware.

Edwards Endovascular HVT—Patriot submitted as Plaintiff Trial Exhibit 589 in C.A. No. 08–091–GMS in the District Court of Delaware.

L.L. Knudsen, H.R. Andersen & J.M. Hasenkam, Transluminal Catheter Implantation ofa New Expandable Artificial Heart Valve in the Descending Thoracic Aorte in Isolated Vessels and Closed Chest Pigs (Abstract), submitted as Plaintiff Trial Exhibit 647 in C.A. No. 08–091–GMS in the District Court of Delaware.

H.R. Andersen et al., Abstract Submission Form for XII Congress of the European Society of Cardiology, Transluminal catheter implantation ofa new expandable artificial cardiac valve (the stent–valve) in the aorta and the beating heart of closed chest pigs submitted as Plaintiff Trial 683 in C.A. No. 08–091–GMS in the District Court of Delaware.

Excerpt from Abstracts from the 65th Scientific Sessions New Orleans Convention Center Nov. 16–19, 1992, Supplement to Circulation vol. 86, No. 4, 1–698 (Oct. 1992) submitted as Plaintiff Trial Exhibit 695 in C.A. No. 08–091–GMS in the District Court of Delaware.

Steven R. Bailey, Percutaneous Expandable Prosthetic Valves, Textbook of Interventional Cardiology, 2nd Edition, vol. 2, pp. 1268–1276 (1994) submitted as Plaintiff Trial Exhibit 700 in C.A. No. 08–091–GMS in the District Court of Delaware.

H. R. Andersen, Transluminal Catheter Implanted Prosthetic Heart Valves, Int'l J. of Angiology 7: 102–106 (1998) submitted as Plaintiff Trial Exhibit 708 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 1 submitted as Plaintiff Trial Exhibit 753 n C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 2 submitted as Plaintiff Trial Exhibit 755 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 2 (English Translation) submitted as Plaintiff Trial Exhibit 756 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 3 submitted as Plaintiff Trial Exhibit 757 in C.A. No. 08–091–GMS n the District Court of Delaware with Stent–Valve Pig No. 3 (English Translation) submitted as Plaintiff Trial Exhibit 7586 in C.A. No. 08–091–GMS in the District Court Delaware.

"Stent–Klappen" (Danish) GRIS NR. 4 submitted as Plaintiff Trial Exhibit 759 with Stent–Valve Pig No. 4 (English Translation) submitted as Plaintiff Trial Exhibit 760, "Stent–Klappen" (Danish) GRIS NR. 4 (with handwriting) submitted as Plantiff Trial Exhibit 761 and Stent–Valve Pig No. 4 (English Translation) with handwriting submitted s Paintiff Trial Exhibit 762 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 5 submitted as Plaintiff Trial Exhibit 763 with Stent–Valve Pig No. 5 (English Translation) submitted as Plaintiff Trial Exhibit 764, "Stent–Klappen" (Danish) GRS NR. 5 (with handwriting) submitted as Plantiff Trial and Stent–Valve Pig No. 5 (English Translation) with handwriting as Plaintiff Trial Exhibit 766 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 6 submitted as Plaintiff Trial Exhibit 767 with Stent–Valve Pig No. 6 (English Translation submitted as Plaintiff Trial Exhibit 768, "Stent–Klappen" (Danish) GRIS NR. 6 (with handwriting) submitted as Plantiff Trial Exhibit 769 and Stent–Valve Pig No. 6 (English Translation) with handwriting submitted as Plaintiff Trial Exhibit 770 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. No. 7 (English Translation) submitted as Plaintiff 772 in C.A. No. 08–091 GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 8 submitted as Plaintiff Trial Exhibit 773 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 8 (English Translation0 Subimitted as Plaintiff Trial Exhibit 774 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 9 submitted as Plaintiff Trial Exhibit 775 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 9 (English Translation) submitted as Plaintiff Trial Exhibit 776 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 10 submitted as Plaintiff Trial Exhibit 777 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 10 (English Translation) submitted as Plaintiff Trial Exhibit 778 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 11 submitted as Plaintiff Trial Exhibit 779 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 11 (English Translation) submitted as Plaintiff Trial Exhibit 780 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 12 submitted as Plaintiff Trial Exhibit 781 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 12 (English Translation) submitted as Plaintiff Trial Exhibit 782 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 13 submitted as Plaintiff Trial Exhibit 783 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 13 (English Translation) submitted as Plaintiff Trial Exhibit 784 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 14 submitted as Plaintiff Trial Exhibit 785 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 14 (English Translation) submitted as plaintiff Trial Exhibit 786 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 15 submitted as Plantiff Trial Exhibit 787 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 15 (English Translation) submitted as Plaintiff Trial Exhibit 788 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 16 submitted as Plaintiff Trial Exhibit 789 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 16 (English Translation) submitted as Plaintiff Trial Exhibit 790 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 17 submitted as Plaintiff Trial Exhibit 791 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 17 (English Translation) submitted as Plaintiff Trial Exhibit 792 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 18 submitted as Plaintiff Trial Exhibit 793 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 18 (English Translation) submitted as Plaintiff Trial Exhibit 794 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 19 submitted as Plaintiff Trial Exhibit 795 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 19 (English Translation) submitted as Plaintiff Trial Exhibit 796 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 20 submitted as Plaintiff Trial Exhibit 797 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 20 (English Translation) submitted as Plaintiff Trial Exhibit 798 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 21 submitted as Plaintiff Trial Exhibit 799 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 21 (English Translation) submitted as Plaintiff Trial Exhibit 800 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 22 submitted as Plaintiff Trial Exhibit 801 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 22 (English Translation) submitted as Plaintiff Trial Exhibit 802 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 23 submitted as Plaintiff Trial Exhibit 803 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 23 (English Translation) submitted as Plaintiff Trial Exhibit 804 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 24 submitted as Plaintiff Trial Exhibit 805 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 24 (English Translation) submitted as Plaintiff Trial Exhibit 806 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 25 submitted as Plaintiff Trial Exhibit 807 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 25 (English Translation) submitted as Plaintiff Trial Exhibit 808 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) undated GRIS NR. 26 submitted as Plaintiff Trial Exhibit 809 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 26 (English Translation) undated submitted as Plaintiff Trial Exhibit 810 in C.A. No. 08–091–GMS in the District Court of Delaware and "Stent–Klappen" (Danish) GRIS NR. 26 submitted as Plaintiff Trial Exhibit 811 in C.A. No. 08–091 GMS in the District Court of Delaware with Stent–Valve Pig No. 26 (English Translation) submitted as Plaintiff Trial Exhibit 812 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 27 submitted as Plaintiff Trial Exhibit 813 in C.A. No.08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 27 (English Translation) submitted as Plaintiff Trial Exhibit 814 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 28 submitted as Plaintiff Trial Exhibit 815 with Stent–Valve Pig No. 28 (English Translation) submitted as Plaintiff Trial Exhibit 816, "Stent–Klappen" (Danish) GRIS NR. 28 (with handwriting) submitted as Plantiff Trial Exhibit 817 and Stent–Valve Pig No. 28 (English Translation) with handwriting submitted as Plaintiff Trial Exhibit 818 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 29 submitted as Plaintiff Trial Exhibit 819 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 29 (English Translation) submitted as Plaintiff Trial Exhibit 820 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 30 submitted as Plaintiff Trial Exhibit 821 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 30 (English Translation) submitted as Plaintiff Trial Exhibit 822 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 30B submitted as Plaintiff Trial Exhibit 823 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 30B (English Translation) submitted as Plaintiff Trial Exhibit 824 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 31 submitted as Plaintiff Exhibit 825 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 31 (English Translation) submitted as Plaintiff Trial Exhibit 826 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 32 submitted as Plaintiff Trial Exhibit 827 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 32 (English Translation) submitted as Plaintiff Trial Exhibit 828 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 33 submitted as Plaintiff Exhibit 829 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 33 (English Translation) submitted as Trial Exhibit 830 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 34 submitted as Plaintiff Trial Exhibit 831 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–valve Pig No. 34 (English Translation) submitted as Plaintiff Trial Exhibit 832 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 35 submitted as Plaintiff Trial Exhibit 833 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 35 (English Translation) submitted as Plaintiff Trial Exhibit 834 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 36 submitted as Plaintiff Trial Exhibit 835 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 36 (English Translation) submitted as Plaintiff Trial Exhibit 836 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 37 submitted as Plaintiff Trial 837 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 37 (English Translation) submitted as Plaintiff Trial Exhibit 838 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 38 submitted as Plaintiff Trial Exhibit 839 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 38 (English Translation) submitted as Plaintiff Trial Exhibit 840 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 39 submitted as Plaintiff Trial Exhibit 841 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 39 (English Translation) submitted as Plaintiff Trial Exhibit 842 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 40 submitted as Plaintiff Trial Exhibit 843 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 40 (English Translation) submitted as Plaintiff Trial Exhibit 844 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 41 submitted as Plaintiff. Trial Exhibit 845 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 41 (English Translation) submitted as Plaintiff Trial Exhibit 846 in C.A. No. 08–091–GMS in the District Court of Delaware.

Collection of letters between P. Block, M. Chan, and H.R. Andersen submitted as Plaintiff Trial Exhibit 851 in C.A. No. 08–091–GMS in the District Court of Delaware.

Stent–Klappen (Danish) submitted as Plaintiff Trial Exhibit 852 in C.A. No. 08–091–GMS in the District Court of Delaware.

Stent–Klappen (Danish) submitted as Plaintiff Trial Exhibit 853 in C.A. No. 08–091–GMS in the District Court of Delaware with English translation to be agreed upon by the parties submitted as Plaintiff Trial Exhibit Exhibit 853A in C.A. No. 08–091–GMS in the District Court of Delaware.

"EN NY Kateterbaren Stent–Monterer Kunstig Hjerteklap Til Implantation Uden Aben Hjertekirurgi" (Danish) submitted as Plaintiff Trial Exhibit 860 in C.A. No. 08–091–GMS in the District Court of Delaware with English translation to be agreed upon by the parties submitted as Plaintiff Trial Exhibit 860A in C.A. No. 08–091–GMS in the District Court of Delaware.

Andersen et al., Implantation of Artifical Heart Valves (manuscript) submitted as Plaintiff Trial Exhibit 861 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Knud Tange Rasmussen of DTI (Danish) submitted as Plaintiff Trial Exhibit 863 in C.A. No. 08–091–GMS in the District Court of Delaware English with translation to be agreed upon by the parties submitted as Plaintiff Trial Exhibit 863A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Hans Rasmussen of DTI to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 865 in C.A. No. 08–091–GMS in the District Court of Delaware with English translation to be agreed upon by the parties submitted as Plaintiff Trial Exhibit 865A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Knud Tange Rasmussen of DTI (Danish) submitted as Plaintiff Trial Exhibit 866 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 866A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Knud Tange Rasmussen of DTI (Danish) submitted as Plaintiff Trial Exhibit 867 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 867A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Knud Tange Rasmussen of DTI (Danish) submitted as Plaintiff Trial 868 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 868A in C.A. No. 08–091–GMS in the District Court of Delaware.

Miscellaneous data sheets from Pig No. 17 (Danish) submitted as Plaintiff Trial Exhibit 869 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Dansk Cardiologisk Selskab's" (Danish) submitted as Plaintiff Trial Exhibit 870 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 870A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Per Holm of Vingmed A/S (Danish) submitted as Plaintiff Trial Exhibit 871 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 871A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Peter De Jong of Baxter submitted as Plaintiff Trial Exhibit 872 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Niels Christiansen of Pfizer (Danish) submitted as Plaintiff Trial Exhibit 873 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 873A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Hans Rasmussen of DTI to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 874 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 874A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Kaj Berlich of Baxter (Danish) submitted as Plaintiff Trial Exhibit 875 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 875A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Per Holm on Vingmed A/S to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 876 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Exhibit 876A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Niels Christiansen of Pfizer (Danish) submitted as Plaintiff Trial Exhibit 877 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 877A in C.A. No. 08–091–GMS in the District Court of Delaware.

Fax from Per Holm Vingmed A/S to Peter Chevalier of Medtronic, Inc. (Danish) submitted as Plaintiff Trial Exhibit 878 in C.A. No. 08–091–GMS in the District Court of Delaware with English Traslation submitted as Plaintiff Trial Exhibit 878A in C.A. No. 08–091–GMS in the District Court of Delaware.

Fax from Peter Chevalier of Medtronic, Inc. to Per Holm of Vingmed A/S submitted as Plaintiff Trial Exhibit 879 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Bent Holmegand of Meadox Surgimed A/S to Knud Tange Rasmussen of DTI (Danish) submitted as Plaintiff Trial Exhibit 881 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 881A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Knud Tange Rasmussen of DTI to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 882 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 882A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Kenneth H. Levin of C.R. Bard, Inc. to Hemming [sic] Andersen submitted as Plaintiff Trial Exhibit 883 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Knud Tange Rasmussen of DTI (Danish) submitted as Plaintiff Trial Exhibit 884 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 884A in C.A. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Kenneth Levin of C. R. Bard, Inc. submitted as Plaintiff Trial Exhibit 885 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Flemming Hoj Sorensen of DTI to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 886 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Exhibit 886A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Knud Tange Rasmussen of DTI (Danish) submitted as Plaintiff Trial Exhibit 867 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 867A in C.A. No. 08–091–GMS in the District Court of Delaware.

Miscellaneous date sheets from Pig No. 17 (Danish) sumbitted as Plaintiff Trial Exhibit 869 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Peter De Jong of Baxter sumbitted as Plaintiff Trial Exhibit 872 in C.A. No. 08–091–GMS in the District Court of Delaware.

Fax from Per Holm of Vingmed A/S to Peter Chevalier of Medtronic, Inc. (Danish) submitted as Plaintiff Trial Exhibit 878 in C.A. No. 08–091–GMS in the District Court of Delaware with English Traslation submitted as Plaintiff Trial Exhibit 878A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Bent Holmegaand of Meadox Surgimed A/S to Knud Tange Rasmussen of DTI (Danish) submitted as Plaintiff Trial Exhibit 881 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 881A in C.A. 08–091–GMS in the District Court of Delaware.

Fax from Kennth H. Levin of C.R. Bard, Inc. to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 887 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Flemming Hoj Sorensen of DTI (Danish) submitted as Plaintiff Trial Exhibit 888 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Exhibit 888A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Flemming Hoj Sorensen and Knud Tange Rasmussen of DTI (Danish) submitted as Plaintiff Trial Exhibit 890 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 890A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to MArcel van den Brand of Erasmus University Hospital submitted as Plaintiff Trial Exhibit 891 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Knud Tange Rasmussen of DTI to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 892 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 892A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Knud Tange Rasmussen of DTI to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 893 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 893A in C:A. 08–091–GMS in the District Court of Delaware.

Letter from Lars Lyhne Kndusen to Professor P. Sleight enclosing manuscripts for review by Cardiovascular Research submitted as Plaintiff Trial Exhibit 894 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Knud Tange Rasmussen of DTI to Kenneth H. Levin of C.R. Bard submitted as Plaintiff Trial Exhibit 895 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Knud Tange Rasmussen of DTI to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 896 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 896A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Marvin P. Loeb of Trimedyne to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 897 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Knud Tange Rasmussen of DTI to Erik Andersen of Boston Scientific (Danish) submitted as Plaintiff Trial Exhibit 898 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 898A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Marvin P. Loeb of Trimedyne, Inc. submitted as Plaintiff Trial Exhibit 899 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to SCIMED submitted as Plaintiff Trial Exhibit 900 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Anderson to Marvin P. Loeb of Trimedyne, Inc. submitted as Plaintiff Trial Exhibit 901 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Erik Andersen of Boston Scientific to Dansk Teknologisk Institut (Danish) submitted as Plaintiff Trial Exhibit 902 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 902A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Marvin P. Loeb of Trimedyne, Inc. to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 903 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Knud Tange Rasmussen of DTI submitted as Plaintiff Trial Exhibit 904 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Knud Tange Rasmussen of DTI to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 905 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Tamar J. Preminger of Children's Hospital (Boston) to Henning R. Andersen submitted as Plaintiff Trial Exhibit 906 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Ruder Andersen to Tamar J. Preminger of Children's Hospital submitted as Plaintiff Trial Exhibit 907 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Marvin P. Loeb of Trimedyne, Inc. to Rasmus Offersen of DTI submitted as Plaintiff Trial Exhibit 908 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Rasmus Offersen of DTI to Kurt Anker Jensen of Astra Meditek A/S (Danish) submitted as Plaintiff Trial Exhibit 909 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 909A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Rasmus Offersen of DTI to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 910 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 910A in C.A. No. 08–091–GMS in the District Court of Delaware.

Fax from Rasmus Offersen of DTI to Marvin P. Loeb of Trimedyne, Inc. submitted as Plaintiff Trial Exhibit 911 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Rasmus Offersen of DTI to Kurt Anker Jensen of Astra Meditek A/S (Danish) submitted as Plaintiff Trial Exhibit 912 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 912A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Rasmus Offersen of DTI to Peter Selley of Astra Tech AB (Danish) submitted as Plaintiff Trial Exhibit 915 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 915A in C.A. No. 08–091–GMS in the District Court of Delaware.

Fax from Rasmus Offersen of DTI to Peter Selley of Astra Tech AB (Danish) submitted as Plaintiff Trial Exhibit 916 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 916A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from American Heart Association to Henning Rud Andersen concerning poster presentation acceptance submitted as Plaintiff Trial Exhibit 917 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Rasmus Offersen of DTI (Danish) submitted as Plaintiff Trial Exhibit 918 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 918A in C.A. No. 08–091–GMS in the District Court of Delaware.

Fax from Rasmus Offersen of DTI to Wes Sterman of Stanford Surgical Technologies submitted as Plaintiff Trial Exhibit 919 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Rasmus Offersen of DTI to Wesley Sterman of Stanford Surgical Technologies, Inc. submitted as Plaintiff Trial Exhibit 920 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Lars Lyhne Kundsen to Eli A. Friedman of ASAIO Journal enclosing manuscript for review submitted as Plaintiff Trial Exhibit 922 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Rasmus Offersen of DTI to Marvin P. Loeb of Trimedyne, Inc.submitted as Plaintiff Trial Exhibit 923 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Diego Brancaccio of Int'l Journal of Artificial Organs to Lars L. Knudsen concerning publication of manuscript submitted as Plaintiff Trial Exhibit 924 in C.A. No. 08–091–GMS in the District Court of Delaware.

Fax from Rasmus Offersen of DTI to Wesley Sterman of Stanford Surgical Technologies enclosing executed licensing agreement submitted as Plaintiff Trial Exhibit 925 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Wesley D. Sterman of Stanford Surgical Technologies, Inc. submitted as Plaintiff Trial Exhibit 926 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Hanson Giffort of Stanford Surgical Technologies, Inc. submitted as Plaintiff Trial Exhibit 927 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Tamar J. Preminger of Children's Hospital (Boston) to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 929 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Ted Feldman of the University of Chicago to H. Rud Andersen submitted as Plaintiff Trial Exhibit 930 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Tamar J. Preminger of Children's Hospital (Boston) submitted as Plaintiff Trial Exhibit 931 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Robert F. Kuhling of Onset Ventures to Leif Nielsen of Lehman & Ree submitted as Plaintiff Trial Exhibit 932 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Robert F. Kuhling of Onset Ventures to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 933 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Robert F. Kuhling of Onset Ventures submitted as Plaintiff Trial Exhibit 934 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Wesley D. Sterman of Heartport, Inc. submitted as Plaintiff Trial Exhibit 935 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Peter C. Block of St. Vincent's Medical Center to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 936 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Peter C. Block of St. Vincent's Medical Center to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 937 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Peter C. Block of St. Vincent's Medical Center submitted as Plaintiff Trial Exhibit 938 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Peter C. Block of St. Vincent's Medical Center to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 939 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Peter C. Block of St. Vincent's Medical Center submitted as Plaintiff Trial Exhibit 940 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Rasmus Offersen of DTI (Danish) submitted as Plaintiff Trial Exhibit 941 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 941A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Peter C. Block of St. Vincent's Medical Center to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 942 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Dusan Pavenik to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 943 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letetr from HenninG Rud Andersen to George Teitelbaum submitted as Plaintiff Trial Exhibit 944 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Jan Peregrin submitted as Plaintiff Trial Exhibit 945 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Jeffry J. Grainger of Hearport, Inc. to Vibeke Walde of DTI submitted as Plaintiff Trial Exhibit 949 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Jeffry Grainger of Heartport, Inc. submitted as Plaintiff Trial Exhibit 951 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Jan Komtebedde to Andersen et al. re: update on license agreement submitted as Plaintiff Trial Exhibit 953 in C.A. No. 08–091–GMS in the District Court of Delaware.

Consent of Merger Agreement between Heartport, Inc. and Andersen et al. submitted as Plaintiff Trial Exhibit 954 in C.A. No. 08–091–GMS in the District Court of Delaware.

Email chain from Vibeke Wakle to Henning Rud Andersen re: VS: Andersen license (Danish in part) submitted as Plaintiff Trial Exhibit 956 in C.A. No. 08–091–GMS in the District Court of Delaware.

PVT Design Review—1st Design Iteration submitted as Plaintiff Trial Exhibit 1005 in C.A. No. 08–091–GMS in the District Court of Delaware.

Emails from Hanne Rask Hansen to Abi Zakai re: Collaboration submitted as Plaintiff Trial Exhibit 1013 in C.A. No. 08–091–GMS in the District Court of Delaware.

In vivo picture of CoreValve device, excerpted from CoreValve Slide Presentation of Two heart valve prostheses in patients at Albert Einstein Hospital in Sao Paulo, Brazil submitted as Plaintiff Trial Exhibit 1078 in C.A. No. 08-091-GMS in the District Court of Delaware.

French Catheter Scales submitted as Plaintiff Trial Exhibit 1083 in C.A. No. 08-091-GMS in the District Court of Delaware.

PVT, Inc. Series B Convertible Preferred Stock Purchase Agreement b/w PVT and Medtronic submitted as Plaintiff Trial Exhibit 1092 in C.A. No. 08-091-GMS in the District Court of Delaware.

Edwards Lifesciences AG v. *Cook Biotech, Inc.* (HC 08C00934)—UK trial transcripts—Days 1-5 submitted as Plaintiff Trial Exhibit 1178 in C.A. No. 08-091-GMS in the District Court of Delaware.

Heartport Consent to Merger with Johnson & Johnson and HP Merger Sub submitted as Plaintiff Trial Exhibit 1556 in C.A. No. 08-091-GMS in the District Court of Delaware.

Disclosure Statement between Edwards and PVT (Dec. 15, 2003) submitted as Plaintiff Trial Exhibit 1563 in C.A. 08-091-GMS in the District Court of Delaware.

Certificate of Merger between PVT and Edwards submitted as Plaintiff Trial Exhibit 1565 in C.A. No. 08-091-GMS in the District Court of Delaware.

PVT Amended and Restated Certificate of Incorporation (Oct. 8, 2004) submitted as Plaintiff Trial Exhibit 1567 in C.A. No. 08-091-GMS in the District Court of Delaware.

Certification of Stanton Rowe (Jun. 15, 2007) submitted as Plaintiff Trial Exhibit 1572 in C.A. No. 08-091-GMS in the District Court of Delaware.

California Statement by Domestic Stock Corporation (Stanford Surgical) submitted as Plaintiff Trial Exhibit 1573 in C.A. No. 08-091-GMS in the District Court of Delaware.

Certifcate of Filing Merger between Stanford Surgical and Hearport submitted as Plaintiff Trial Exhibit 1574 in C.A. No. 08-091-GMS in the District Court of Delaware.

Consent to Assignment between Stanford Surgical and Inventors submitted as Plaintiff Trial Exhibit 1575 in C.A. No. 08-091-GMS in the District Court of Delaware.

Edwards SAPIEN Transcatheter Heart Valve with RetroFlex 3 Transfermoral Kit submitted as Plaintiff Trial Exhibit 1630 in C.A. No. 08-091-GMS in the District Court of Delaware.

Presentation Business Review-Manufacturing submitted as Plaintiff Trial Exhibit 1635 in C.A. No. 08-091-GMS in the District Court of Delaware.

Printout of List of Centers and Country (Excel) submitted as Plaintiff Trial Exhibit 1654A in C.A. No. 08-091-GMS in the District Court of Delaware.

Report—Leading the way to the next frontier of the cardio vascular device industry submitted as Plaintiff Trial Exhibit 1712 in C.A. No. 08-091-GMS in the District Court of Delaware.

Report—Leading the way to the next frontier of the cardio vascular device industry: Percutaneous aortic heart valve replacement submitted as Plaintiff Trial Exhibit 1713 in C.A. No. 08-091-GMS in the District Court of Delaware.

Colin Stewart, How Rob Michiels and Corevalve got where they are today, The Orange County register, submitted as Plaintiff Trial Exhibit 1747 in C.A. No. 08-091-GMS in the District Court of Delaware.

Financial Frontier for the years ending Dec. 21, 2007-2012 submitted as Plaintiff Trial Exhibit 1748 in C.A. No. 08-091-GMS in the District Court of Delaware.

"Edwards Lifesciences: Speed Bumps Ahead for Sapien, Downgrading to Underweight," North America Equity Research submitted as Plaintiff Trial Exhibit 1807 in C.A. No. 08-091-GMS in the District Court of Delaware.

Print out- Corevalve reporting-Apr. 2005-Version 1 (Excel) submitted as Plaintiff Trial Exhibit 1900A in C.A. No. 08-091-GMS in the District Court of Delaware.

PVT Press Release—Hearport Announces Exclusive Licensing Agreement with Percutaneous Valve Technologies submitted as Plaintiff Trial 1968 in C.A. No. 08-091-GMS in the District Court of Delaware.

Medical Device Daily, vol. 10, No. 60 submitted as Plaintiff Trial Exhibit 20303 in C.A. No. 08-091-GMS in the District Court of Delaware.

Corelative press release: CoreValve Completes $24 Million Series B Round of Financing Led by Apax Partners submitted as Plaintiff Trial Exhibit 2031 in C.A. No. 08-091-GMS in the District Court of Delaware.

Corevalve press release: CoreValve Completes $33 Million Private Financing submitted as Plaintiff Trial Exhibit 2032 in C.A. No. 08-091-GMS in the District Court of Delaware.

In Strategy Shift, CoreValve to Manufacture Device in U.S. Facility, Dow Jone VentureWire submitted as Plaintiff Trial Exhibit 2033 in C.A. No. 08-091-GMS in the District Court of Delaware.

CoreValve, Inc. Financial Forecas submitted as Plaintiff Trial Exhibit 2034 in C.A. No. 08-091-GMS in the District Court of Delaware.

Edwards' CE Marking of Conformity Certificate submitted as Plaintiff Trial Exhibit 2059 in C.A. No. 08-091-GMS in the District Court of Delaware.

Edwards' EC-Design Examination Certificate submitted as Plaintiff Trial Exhibit 2060 in C.A. No. 08-091-GMS in the District Court of Delaware.

Patient Selection for the CoreValve ReValving System by Ganesh Manoharan et al. submitted as Plaintiff Trial Exhibit 2090 in C.A. No. 08-091-GMS in the District Court of Delaware.

Presentation—France Registry: French Aortic National Core Valve and Edwards Registry, Helene Eltchaninoff submitted as Plaintiff Trial Exhibit 2123 in C.A. No. 08-091-GMS in the District Court of Delaware.

CE Markings of Conformity issued to Edwards Lifesciences submitted as Plaintiff Trial Exhibit 2124 in C.A. No. 08-091-GMS in the District Court of Delaware.

Color Photographs of Andersen et al. stent valve and related materials submitted as Plaintiff Trial Exhibit 2129 in C.A. No. 08-091-GMS in the District Court of Delaware.

Color Photographs of Andersen et al. stent valve and related materials submitted as Plaintiff Trial Exhibit 2130 in C.A. No. 08-091-GMS in the District Court of Delaware.

Color Photographs of Andersen et al. stent valve and related materials submitted as Plaintiff Trial Exhibit 2131 in C.A. No. 08-091-GMS in the District Court of Delaware.

Color Photographs of Andersen et al. stent valve and related materials submitted as Plaintiff Trial Exhibit 2132 in C.A. No. 06-091-GMS in the District Court of Delaware.

Handwritten notes made by Dr. Buller on CoreValve device during his direct testimony (top view) submitted as Plaintiff Trial Exhibit 2135 in C.A. No. 08-091-GMS in the District Court of Delaware.

Handwritten notes made by Dr. Buller on CoreValve device during his direct testimony (side view) submitted as Plaintiff Trial Exhibit 2136 in C.A. No. 08–091–GMS in the District Court of Delaware.

Handwritten notes made by Dr. Buller on CoreValve device during his direct testimony (side view) submitted as Plaintiff Trial Exhibit 2137 in C.A. No. 08–091–GMS in the District Court of Delaware.

CoreValve's Timeline: Actual vs. *No Infringement* submitted as Plaintiff Trial exhibit 2141 in C.A. No. 08–091–GMS in the District Court of Delaware.

CoreValve's Timeline: Actual vs. *No Infringement* (Europe) submitted as Plaintiff Trial Exhibit 2142 in C.A. No. 08–091–GMS in the District Court of Delaware.

Edwards' *Damages—Lost Profits Units* vs. *Reasonable Royalty Units* (Europe) submitted as Plaintiff Trial Exhibit 2143 in C.A. No. 08–091–GMS in the District Court of Delaware.

Summary of Edwards' Damages in Europe submitted as Plaintiff Trial Exhibit 2144 in C.A. No. 08–091–GMS in the District Court of Delaware.

Summary of Edwards' Lost Profits Damages submitted as Plaintiff Trial Exhibit 2145 in C.A. 08–091–GMS in the District Court of Delaware.

Summary of Edwards' Total Damages submitted as Plaintiff Trial Exhibit 2146 in C.A. No. 08–091–GMS in the District Court of Delaware.

Reasonable Royalty if No Lost Profits submitted as Plaintiff Trial Exhibit 2147 in C.A. No. 08–091–GMS in the District Court of Delaware.

Translation of Letter from K. Rasmussen to H. Andersen re Novelty Search on Implantable Stent Valve. dated Oct. 25, 1989, submitted as Defendant Trial Exhibit 7 in C.A. No. 08–091–GMS in the District Court of Delaware.

Article: "Transluminal Implantation of Artificial Heart Valves. Description of a New Expandable Aortic Valve and Initial 1992 Results with Implantation by Catheter Technique in Closed Chest Pigs", European Heart Journal, vol. 13, pp. 704–708, by H, Andersen, L. Knudsen and J. Hasenkam, dated 1992 submitted as Defendant Trial Exhibit 14 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from D.L. Brutsaert to H. Andersen re Manuscript Entitled "Transluminal Implantation of Artificial Heart Valves" Accepted for Publication, dated Oct. 3, 1991 submitted as Defendant Trial Exhibit 17 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from J. Fabricius to Danish Institute ofTechnology re Opinion on "Stent Valve Project" dated Mar. 5, 1990 Letter from H. Andersen to K. Rasmussen re Comments on Written Opinion from J. Fabricius, dated May 15, 1990 submitted as Defendant Trial Exhibit 42 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from S. Dack to H. Andersen re Hasenkam Hasenkam Rejection of Manuscript Entitled "Implantation of Artificial Heart Valves" dated Jul. 26, 1990 submitted as Defendant Trial Exhibit 48 in C.A. No. 08–091–GMS in the District Court of Delaware.

Drawing by Witness of Stent Prototype submitted as Defendant Trial Exhibit 57 in C.A. No. 08–091–GMS in the District Court of Delaware.

Report: "Development, Manufacture, and In Vitro and In Vivo Evaluation of an Artificial Heart Valve for Implantation Using the Catheter Technique with a View to Future Intravasal Treatment of Heart Valve Disorders", by L. Knudsen, dated 1992 submitted as Defendant Trial Exhibit 60 in C.A. No. 08–091–GMS in the District Court of Delaware.

Article: "Catheter–Implanted Prosthetic Heart Valves–Transluminal Catheter Implantation of a New Expandable Artificial Heart Valve in the Descending Thoracic Aorta in Isolated Vessels and Closed Chest Pigs", The International Journal of Artificial Organs, vol. 16, pp. 253–262, by L. Knudsen, H. Andersen, & J. Hasenkam, dated 1993 submitted as Defendant Trial Exhibit 61 in C.A. No. 08–091–GMS in the District Court of Delaware.

Powerpoint Presentation: "Percutaneous Rowe–Rowe–Valve Technologies"by A. Cribier, M. Leon, S. Rabinovich & S. Rowe submitted as Defendant Trial Exhibit 76 in C.A. No. 08–091–GMS in the District Court of Delaware.

Document: "Percutaneous Valve Technologies, Inc. Business Plan," dated Feb. 2000 submitted as Defendant Trial–Exhibit 81 in C.A. No. 08–091–GMS in the District Court of Delaware.

Drawing of CAD Design for the Production of Two Stents, dated Jan. 2, 2000 submitted as Defendent Trial Exhibit 84 in C.A. No. 08–091–GMS in the District Court of Delaware.

Report: "Design Review—Concept Phase," dated May 15, 2000 submitted as Defendant Trial Exhibit 85 in C.A. No. 08–091–GMS in the District Court of Delaware.

Report: "R & D Monthly Report–Jun. 2000," dated Jun. 13, 2000 submitted as Defendant Trial Exhibit 87 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from H. Gifford to H. Andersen re Endovascular Valve Replacement Porcedure, dated Sep. 29, 1993 submitted as Defendant Trial Exhibit 97 in C.A. 08–091–GMS in the District Court of Delaware.

PowerPoint Slides of PHV Frame Evolution submitted as Defendant Trial Exhibit 102 in C.A. No. 08–091–GMS in the District Court of Delaware.

Exhibit "SR–7" referred to in the First Witness Statement of Stanton Rowe dated May 27, 2008 submitted as Defendant Trial Exhibit 103 in C.A. No. 08–091–GMS in the District Court of Delaware.

Document: "PVT Stent Follow–Up Table" submitted as Defendant Trial Exhibit 104 in C.A. No. 08–091–GMS in the District Court of Delaware.

Document: "Outlines of a Research Program for the Development of an Implantable Heart Valve (1HV)" submitted as Defendant Trial Exhibit 207 in C.A. No. 08–091–GMS in the District Court of Delaware.

Document: "Non–Surgical Cardiac Valve Implanation" submitted as Defendant Trial Exhibit 211 in C.A. No. 08–091–GMS in the District Court of Delaware.

Document: Conception Review–Prosthesis Design Conception, date May 5, 2004 submitted as Defendant Trial Exhibit 239 in C.A. No. 08–091–GMS in the District Court of Delaware.

U.S. Patent No. 7,018,406 B2, entitled "Prosthetic Valve for Transluminal Delivery" issued to Sequin et al on Mar. 28, 2006 with attached file history, submitted as Defendant Trial Exhibit 289 in C.A. No. 08–091–GMS in the District Court of Delaware.

Pig experiments of Drs. Andersen, Hasenkam, and Knudsen submitted as Defendant Trial Exhibit 294 in C.A. No. 08–091–GMS in the District Court of Delaware.

Color version of Test Report and signature page of #R-2006-006: Frame Deflection and Leaflet Angle-Core Valve Percutaneous Aortic Valve Generation 3, 26 mm (Previously produced black and white image COR674610-674633) submitted as Defendant Trial Exhibit 1313 in C.A. No. 08-091-GMS in the District Court of Delaware.

Color version or Report and signature page for Protocol #R-2006-010: Frame Deflection and Leaflet Angle-Core Valve Percutaneous Aortic Valve Generation 3, 29mm (Previously produced black and white image COR680225-680238) submitted as Defendant Trial Exhibit 1314 in C.A. No. 08-091-GMS in the District Court of Delaware.

Contact Sheet of photographs of CoreValve prototypes taken by Edwards' counsel on Jan. 25, 2010 submitted as Defendant Trial Exhibit 1459 in C.A. No. 08-091-GMS in the District Court of Delaware.

Picture of Physical Device submitted as Defendant Trial Exhibit 1460 in C.A. No. 08-091-GMS in the District Court of Delaware.

Picture of Physical Device submitted as Defendant Trial Exhibit 1462 in C.A. No. 08-091-GMS in the District Court of Delaware.

Picture of Physical Device submitted as Defendant Trial Exhibit 1466 in C.A. No. 08-091-GMS in the District Court of Delaware.

Picture of Physical Device submitted as Defendant Trial Exhibit 1467 in C.A. No. 08-091-GMS in the District Court of Delaware.

Picture of Generation 1 CoreValve device submitted as Defendant Trial Exhibit 1469 in C.A. No. 08-091-GMS in the District Court of Delaware.

Picture of Physical Device submitted as Defendant Trial Exhibit 1471 in C.A. No. 08-091-GMS in the District Court of Delaware.

Picture of Physical Device submitted as Defendant Trial Exhibit 1473 in C.A. No. 08-091-GMS in the District Court of Delaware.

Timeline re CoreValve would have made all its Sales overseas—Fall 2004 start date submitted as Defendant Trial Exhibit 1478 in C.A. No. 08-091-GMS in the District Court of Delaware.

Timeline re CoreValve would have made all its Sales overseas—Spring 2005 start date submitted as Defendant Trial Exhibit 1479 in C.A. No. 08-091-GMS in the District Court of Delaware.

Jeffery Kinrich demonstrative graphic submitted as Defendant Trial Exhibit 1483 in C.A. No. 08-091-GMS in the District Court of Delaware.

Jeffery Kinrich demonstrative graphic submitted as Defendant Trial Exhibit 1484 in C.A. No. 08-091-GMS in the District Court of Delaware.

Jeffery Kinrich demonstrative graphic submitted as Defendant Trial Exhibit 1485 in C.A. No. 08-091-GMS in the District Court of Delaware.

Jeffery Kinrich demonstrative graphic submitted as Defendant Trial Exhibit 1486 in C.A. No. 08-091-GMS in the District Court of Delaware.

Jeffery Kinrich demonstrative graphic submitted as Defendant Trial Exhibit 1487 in C.A. No. 08-091-GMS in the District Court of Delaware.

Final Jury Instructions, *Edwards Lifesciences AG and Edwards Lifesciences, LLC.* v. *Medtronic CoreValve LLC*, United States District Court for the District of Delaware, Civil Action No. 1:08-CV-00091-GMS, Apr. 1, 2010.

Trial Transcripts, *Edwards Lifesciences AG and Edwards Lifesciences, LLC.* v. *Medtronic CoreValve LLC*, United States District Court for the District of Delaware, Civil Action No. 1:08-CV-00091-GMS, Mar. 23, 2010-Apr. 1, 2010.

Affidavit of Michael Gadeberg, Jul. 8, 2010.

Slide Deck for Plaintiff's Opening Statement in *Edwards Lifesciences AG and Edwards Lifesciences, LLC.* v. *Medtronic CoreValve LLC*, United States District Court for the District of Delaware, Civil Action No. 1:08-CV-00091-GMS, Mar. 23, 2010.

Plaintiff's Trial Exhibitexhibit 2135, *Edwards Lifesciences AG and Edwards Lifesciences, LLC.* v. *Medtronic CoreValve LLC*, United States District Court for the District of Delaware, Civil Action No. 1:08-CV-00091-GMS, Mar. 26, 2010.

Slide Deck for Plaintiff's Closing Arguments in *Edwards Lifesciences AG and Edwards Lifesciences, LLC.* v. *Medtronic CoreValve LLC*, United States District Court for the District of Delaware, Civil Action No. 1:08-CV-00091-GMS, Apr. 1, 2010.

Revised Slides for Plaintiff's Closing Arguments in *Edwards Lifesciences AG and Edwards Lifesciences, LLC.* v. *Medtronic CoreValve LLC*, United States District Court for the District of Delaware, Civil Action No. 1:08-CV-00091-GMS, Apr. 1, 2010.

U.S. App. No. 95/001,615, filed May 4, 2011 Andersen et al.

U.S. App. No. 95/001,616, filed May 4, 2011 Andersen et al.

U.S. App. No. 90/009,791, filed Jul. 29, 2010 Andersen et al.

U.S. App. No. 90/009779, filed Jul. 9, 2010 Andersen et al.

Memorandum on post-trial motions and Order, dated Feb. 7, 2011, Edwards Lifesciences AG and Edwards Lifesciences LLC, v. Corevalve, Inc and Medtronic Corevalve, LLC U S District Court for the District of Delaware, CA No 08-91-GMS.

EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

NO AMENDMENTS HAVE BEEN MADE TO THE PATENT

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claim 1 is confirmed.

Claims 2-8 were not reexamined.

* * * * *

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MAINTENANCE FEE STATEMENT

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PATENT NUMBER	FEE AMT	SUR CHARGE	PYMT DATE	U.S. APPLICATION NUMBER	PATENT ISSUE DATE	APPL. FILING DATE	PAYMENT YEAR	SMALL ENTITY?	ATTY DKT NUMBER
5,411,552	**$525.00**	**$0.00**	**07/14/98**	**08/261,235**	**05/02/95**	**06/14/94**	**04**	**NO**	**PVI-5844CON**

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5,411,552	**$1,010.00**	**$0.00**	**10/22/02**	**08/261,235**	**05/02/95**	**06/14/94**	**08**	**NO**	**PVI-5844CON**

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Direct any questions about this statement to: Mail Stop M Correspondence, Director of the USPTO, P.O.Box 1450, Alexandria, VA 22313-1450.

PATENT NUMBER	FEE AMT	SUR CHARGE	PYMT DATE	U.S. APPLICATION NUMBER	PATENT ISSUE DATE	APPL. FILING DATE	PAYMENT YEAR	SMALL ENTITY?	ATTY DKT NUMBER
5,411,552	**$3,800.00**	**$130.00**	**12/20/06**	**08/261,235**	**05/02/95**	**06/14/94**	**12**	**NO**	**PVI-5844CON**

D

UHealth | MILLER SCHOOL OF MEDICINE
UNIVERSITY OF MIAMI HEALTH SYSTEM | UNIVERSITY OF MIAMI

William O'Neill, MD
Executive Dean for Clinical Affairs
Chief Medical Officer, University of Miami Health System

December 15th, 2011

Edwards Lifesciences AG
Route de L'etraz 70
Nyon Switzerland 1260

Re: Application for Extension of Patent term
For U.S. Patent No., 5,411,552

To Whom It May Concern:

I was the marketing applicant before the Food and Drug Administration in regard to investigational device exemption (IDE) applications G030069 (relating to SAPIEN – bioprosthetic valve technology for transfemoral implantation) from the time of institution until Edwards Lifesciences, LLC, became marketing applicant in regard to IDE G030069 in 2004. I authorize Edwards Lifesciences AG ("Edwards"), to rely on my activities as marketing applicant in regard to IDE G030069 in connection with Edwards' application for extension of the term of U.S. Patent No. 5,411,552.

With best regards.

Sincerely,

William W. O'Neill

William W. O'Neill, M.D., FACC
Executive Dean for Clinical Affairs
And Chief Medical Officer, University of Miami
Health System

WWO/gms

1600 NW 10th Avenue, RMSB 1122A | Miami, FL 33136
Phone: (305) 243-9483 | Fax: (305) 243-1758
WONeill@med.miami.edu

E

Edwards

December 7, 2011

Ms. Mary Till
Office of Patent Legal Administration
U.S. Patent and Trademark Office
Room MDW 7D55
600 Dulany Street (Madison Building)
Alexandria, VA 22314

Re: Application for Extension of Patent Term
For U.S. Patent No. 5,411,552

Dear Ms. Till:

I am an authorized representative of Edwards Lifesciences, LLC. Edwards Lifesciences, LLC, became the marketing applicant in regard to investigational device exemption (IDE) application G030069 (relating to SAPIEN – bioprosthetic valve technology for transfemoral implantation) in 2004, and has remained the marketing applicant before the Food and Drug Administration from the time of becoming marketing applicant in regard to IDE G030069 through approval of premarket approval (PMA) application P100041. Edwards Lifesciences, LLC, authorizes Edwards Lifesciences AG ("Edwards"), to rely on the activities of Edwards Lifesciences, LLC, as marketing applicant before the Food and Drug Administration in regard to IDE G030069 and PMA P100041 in connection with Edwards' application for extension of the term of U.S. Patent No. 5,411,552.

Very truly yours,

Denise Botticelli
VP, Associate General Counsel and Secretary

Edwards Lifesciences LLC
One Edwards Way · Irvine, CA USA 92614
Phone: 949.250.2500 · Fax: 949.250.2525 · www.edwards.com

DOCKET NO: 372336US0-SD **MAIL STOP HATCH-WAXMAN PTE**

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF	:
HENNING R. ANDERSEN, ET AL.	: GROUP ART UNIT: 3308
SERIAL NO: 08/261,235	: EXAMINER: WILLSE, DAVID H.
FILED: JUNE 14, 1994	: PATENT NO.: 5,411,552
FOR: VALVE PROTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROTHESIS	: ISSUED: MAY 2, 1995

DISCLOSURE PURSUANT TO 35 U.S.C. § 156(d)(4) AND 37 C.F.R. § 1.765

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Edwards Lifesciences AG ("Edwards") has applied herewith for extension of patent term under 35 U.S.C. § 156 and 37 C.F.R. §§ 1.710, et seq., for U.S. Patent No. 5,411,552 ("the '552 patent"). In compliance with Edwards' duty of disclosure pursuant to 35 U.S.C. § 156(d)(4) and 37 C.F.R. § 1.765, Edwards provides the following information.

The '552 patent has been the subject of reexamination proceedings. A request for reexamination filed on June 12, 2009 (control no. 90/009,484) was denied on August 7, 2009. A request for reexamination filed on May 5, 2010 (control no. 90/009,745) was denied on June 9, 2010. A request for reexamination filed on July 9, 2010 (control no. 90/009,779) was granted on September 10, 2010, and reexamination proceedings ensued. As a result of such reexamination

proceedings, reexamination certificate (No. 8463) issued in the '552 patent on August 16, 2011. In the reexamination certificate, the patentability of claim 1 of the '552 patent is confirmed. During reexamination, claim 1 of the '552 patent was not amended. Claims 2-8 of the '552 patent were not reexamined. A copy of the reexamination certificate is attached hereto as Exhibit A.

The '552 patent has been and continues to be the subject of litigation.

Edwards and its exclusive licensee, Edwards Lifesciences, LLC, sued CoreValve, Inc., and its successor in interest, Medtronic CoreValve, LLC, for infringement of the '552 patent in the U.S. District Court for the District of Delaware (No. 08-091-GMS). At the conclusion of a jury trial, CoreValve, Inc., and Medtronic CoreValve, LLC, were found to willfully infringe the '552 patent, and the '552 patent was not found invalid. The May 4, 2010 Judgment, attaching the Jury's April 1, 2010 Verdict Form, is attached hereto as Exhibit B. The Court's February 7, 2011 Memorandum and Order concluding the case is attached hereto as Exhibit C.

During the course of the suit before the U.S. District Court for the District of Delaware, the Court construed certain terms of claim 1 of the '552 patent. The Court's May 27, 2009 Order and February 16, 2010 Amended Order construing such terms are attached hereto as Exhibits D and E, respectively. The portion of the Court's Final Jury Instructions dated April 1, 2010, setting forth the Court's claim construction is attached hereto as Exhibit F.

Following conclusion of the case before the U.S. District Court for the District of Delaware, the parties appealed to the U.S. Court of Appeals for the Federal Circuit (Nos. 2011-1215 and 2011-1257). The Federal Circuit has not yet rendered a decision on the appeal. The issues on appeal are set forth in the briefing identified below.

May 18, 2011 Opening Brief of Defendants-Appellants (Non-Confidential Version without Exhibits) (attached hereto as Exhibit G)

June 27, 2011 Plaintiffs - Cross Appellants' Opposition Brief and Cross-Appeal Brief (Non-Confidential Version without Exhibits) (attached hereto as Exhibit H)

August 8, 2011 Reply Brief of Defendants-Appellants (Non-Confidential Version without Exhibits) (attached hereto as Exhibit I)

August 22, 2011 Plaintiffs-Cross-Appellants' Reply Brief (Non-Confidential Version without Exhibits) (attached hereto as Exhibit J)

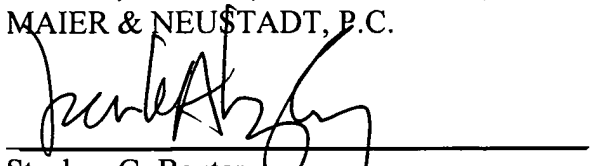
Oral argument on the appeal has been scheduled for January 11, 2012.

* * * *

Should the foregoing information raise any questions or should any supplemental information be required, please contact the undersigned.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Stephen G. Baxter
Registration No. 32,884

Jacob A. Doughty
Registration No. 46,671

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 08/07)

Attachment:
Exhibits A to J

US005411552C1

Exhibit A

(12) EX PARTE REEXAMINATION CERTIFICATE (8463rd)

United States Patent

Anderson et al.

(10) Number: US 5,411,552 C1

(45) Certificate Issued: Aug. 16, 2011

(54) **VALVE PROTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROTHESIS**

(75) Inventors: **Henning R. Anderson**, Hoejbjerg (DK); **John M. Hasenkam**, Aarhus V (DK); **Lars L. Knudsen**, Aarhus C (DK)

(73) Assignee: **Edwards Lifesciences AG**, St.-Prex (CH)

Reexamination Request:
No. 90/009,779, Jul. 9, 2010

Reexamination Certificate for:

Patent No.:	**5,411,552**
Issued:	**May 2, 1995**
Appl. No.:	**08/261,235**
Filed:	**Jun. 14, 1994**

Related U.S. Application Data

(63) Continuation of application No. 07/961,891, filed on Jan. 11, 1993, now abandoned.

(51) **Int. Cl.**
A61F 2/24 (2006.01)

(52) **U.S. Cl.** **623/2.18**; 137/343; 137/844

(58) **Field of Classification Search** 623/2
See application file for complete search history.

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First Expert Report of Professor John R. Pepper in German High Court of Justice Chancery Division Patents Court, HC07 CO1243 signed Apr. 28, 2008.

(Continued)

Primary Examiner—Cary E Wehner

(57) **ABSTRACT**

A valve prosthesis (9) for implantation in the body by use of catheter (11) comprises a stent made from an expandable cylinder-shaped threaded structure (2,3) comprising several spaced apices (4). The elastically collapsible valve (4) is mounted on the stent as the commissural points (5) of the valve (6) are secured to the projecting apices (4).

The valve prosthesis (9) can be compressed around the balloon means (13) of the balloon catheter (11) and be inserted in a channel, for instance in the aorta (10). When the valve prosthesis is placed correctly the balloon means (13) is inflated thereby expanding the stent and wedging it against the wall of aorta. The balloon means is provided with beads (14) to ensure a steady fastening of the valve prosthesis on the balloon means during insertion and expansion.

The valve prosthesis (9) and the balloon catheter (11) make it possible to insert a cardiac valve prosthesis without a surgical operation comprising opening the thoracic cavity.

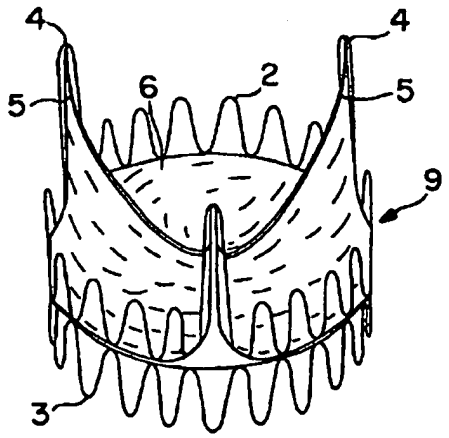

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Exhibit JRP–3 referred to in the First Expert report of Professor John R. Pepper in German High Court of Justice Chancery Division Patents Court, HC07 CO1243 dated Apr. 28, 2008.

Exhibit JRP–4 referred to in the First Expert report of Professor John R. Pepper in German High Court of Justice Chancery Division Patents Court, HC07 CO1243 dated Apr. 28, 2008.

Exhibit JRP–5 referred to in the First Expert report of Professor John R. Pepper in German High Court of Justice Chancery Division Patents Court, HC07 CO1243 dated Apr. 28, 2008.

Exhibit JRP–6 referred to in the First Expert report of Professor John R. Pepper in German High Court of Justice Chancery Division Patents Court, HC07 CO1243 dated Apr. 28, 2008.

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Letter from Simon Dack of JACC to Henning Andersen enclosing referee comments of manuscript (No. JAC000331) submitted as Plaintiff Trial Exhibit 533 in C.A. No. 08–091–GMS in the District Court of Delaware.

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Letter from Ruth R. Ohman of JACC to Henning Andersen acknowledging receipt of manuscript (No. JAC000331) submitted as Plaintiff Trial Exhibit 535 in C.A. No. 08–091–GMS in the District Court of Delaware.

Rejection of article titled "Implantation of Artificial Heart Valves" submitted as Plaintiff Trial Exhibit 536 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Knud Tange Rasmussen of DTI to Kenneth H. Levin of C.R. Bard submitted as Plaintiff Trial Exhibit 537 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from H. Anderson to S. Rowe re: developments of U.S. Patent No. 5,411,552 submitted as Plaintiff Trial Exhibit 544 in C.A. No. 08–091–GMS in the District Court of Delaware.

Fax from Anderson to S. Rowe attching letter re: meeting to discuss possibilities for Johnson & Johnson to negotiate license agreement of U.S. Patent No. 5,411,552 submitted as Plaintiff Trial Exhibit 545 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from H. Anderson to S. Rowe re: reimbursement of travel expenses submitted as Plaintiff Trial Exhibit 548 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from H. Anderson to W. Sterman re Sep. 12, 1995 announcement regarding corporation between Heartport and St. Jude submitted as Plaintiff Trial Exhibit 565 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from M. Garrison to H. Anderson re: renewed Heartport effort in endovascular valve replacement submitted as Plaintiff Trial Exhibit 566 in C.A. No. 08–091–GMS in the District Court of Delaware.

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"Stent–Klappen" (Danish) GRIS NR. 1 submitted as Plaintiff Trial Exhibit 753 n C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 2 submitted as Plaintiff Trial Exhibit 755 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 2 (English Translation) submitted as Plaintiff Trial Exhibit 756 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 3 submitted as Plaintiff Trial Exhibit 757 in C.A. No. 08–091–GMS n the District Court of Delaware with Stent–Valve Pig No. 3 (English Translation) submitted as Plaintiff Trial Exhibit 7586 in C.A. No. 08–091–GMS in the District Court Delaware.

"Stent–Klappen" (Danish) GRIS NR. 4 submitted as Plaintiff Trial Exhibit 759 with Stent–Valve Pig No. 4 (English Translation) submitted as Plaintiff Trial Exhibit 760, "Stent–Klappen" (Danish) GRIS NR. 4 (with handwriting) submitted as Plantiff Trial Exhibit 761 and Stent–Valve Pig No. 4 (English Translation) with handwriting submitted s Paintiff Trial Exhibit 762 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 5 submitted as Plaintiff Trial Exhibit 763 with Stent–Valve Pig No. 5 (English Translation) submitted as Plaintiff Trial Exhibit 764, "Stent–Klappen" (Danish) GRS NR. 5 (with handwriting) submitted as Plantiff Trial and Stent–Valve Pig No. 5 (English Translation) with handwriting as Plaintiff Trial Exhibit 766 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 6 submitted as Plaintiff Trial Exhibit 767 with Stent–Valve Pig No. 6 (English Translation submitted as Plaintiff Trial Exhibit 768, "Stent–Klappen" (Danish) GRIS NR. 6 (with handwriting) submitted as Plantiff Trial Exhibit 769 and Stent–Valve Pig No. 6 (English Translation) with handwriting submitted as Plaintiff Trial Exhibit 770 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. No. 7 (English Translation) submitted as Plaintiff 772 in C.A. No. 08–091 GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 8 submitted as Plaintiff Trial Exhibit 773 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 8 (English Translation0 Subimitted as Plaintiff Trial Exhibit 774 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 9 submitted as Plaintiff Trial Exhibit 775 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 9 (English Translation) submitted as Plaintiff Trial Exhibit 776 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 10 submitted as Plaintiff Trial Exhibit 777 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 10 (English Translation) submitted as Plaintiff Trial Exhibit 778 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 11 submitted as Plaintiff Trial Exhibit 779 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 11 (English Translation) submitted as Plaintiff Trial Exhibit 780 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 12 submitted as Plaintiff Trial Exhibit 781 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 12 (English Translation) submitted as Plaintiff Trial Exhibit 782 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 13 submitted as Plaintiff Trial Exhibit 783 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 13 (English Translation) submitted as Plaintiff Trial Exhibit 784 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 14 submitted as Plaintiff Trial Exhibit 785 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 14 (English Translation) submitted as plaintiff Trial Exhibit 786 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 15 submitted as Plantiff Trial Exhibit 787 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 15 (English Translation) submitted as Plaintiff Trial Exhibit 788 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 16 submitted as Plaintiff Trial Exhibit 789 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 16 (English Translation) submitted as Plaintiff Trial Exhibit 790 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 17 submitted as Plaintiff Trial Exhibit 791 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 17 (English Translation) submitted as Plaintiff Trial Exhibit 792 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 18 submitted as Plaintiff Trial Exhibit 793 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 18 (English Translation) submitted as Plaintiff Trial Exhibit 794 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 19 submitted as Plaintiff Trial Exhibit 795 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 19 (English Translation) submitted as Plaintiff Trial Exhibit 796 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 20 submitted as Plaintiff Trial Exhibit 797 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 20 (English Translation) submitted as Plaintiff Trial Exhibit 798 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 21 submitted as Plaintiff Trial Exhibit 799 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 21 (English Translation) submitted as Plaintiff Trial Exhibit 800 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 22 submitted as Plaintiff Trial Exhibit 801 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 22 (English Translation) submitted as Plaintiff Trial Exhibit 802 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 23 submitted as Plaintiff Trial Exhibit 803 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 23 (English Translation) submitted as Plaintiff Trial Exhibit 804 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 24 submitted as Plaintiff Trial Exhibit 805 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 24 (English Translation) submitted as Plaintiff Trial Exhibit 806 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 25 submitted as Plaintiff Trial Exhibit 807 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 25 (English Translation) submitted as Plaintiff Trial Exhibit 808 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) undated GRIS NR. 26 submitted as Plaintiff Trial Exhibit 809 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 26 (English Translation) undated submitted as Plaintiff Trial Exhibit 810 in C.A. No. 08–091–GMS in the District Court of Delaware and "Stent–Klappen" (Danish) GRIS NR. 26 submitted as Plaintiff Trial Exhibit 811 in C.A. No. 08–091 GMS in the District Court of Delaware with Stent–Valve Pig No. 26 (English Translation) submitted as Plaintiff Trial Exhibit 812 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 27 submitted as Plaintiff Trial Exhibit 813 in C.A. No.08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 27 (English Translation) submitted as Plaintiff Trial Exhibit 814 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 28 submitted as Plaintiff Trial Exhibit 815 with Stent–Valve Pig No. 28 (English Translation) submitted as Plaintiff Trial Exhibit 816, "Stent–Klappen" (Danish) GRIS NR. 28 (with handwriting) submitted as Plantiff Trial Exhibit 817 and Stent–Valve Pig No. 28 (English Translation) with handwriting submitted as Plaintiff Trial Exhibit 818 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 29 submitted as Plaintiff Trial Exhibit 819 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 29 (English Translation) submitted as Plaintiff Trial Exhibit 820 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 30 submitted as Plaintiff Trial Exhibit 821 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 30 (English Translation) submitted as Plaintiff Trial Exhibit 822 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 30B submitted as Plaintiff Trial Exhibit 823 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 30B (English Translation) submitted as Plaintiff Trial Exhibit 824 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 31 submitted as Plaintiff Exhibit 825 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 31 (English Translation) submitted as Plaintiff Trial Exhibit 826 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 32 submitted as Plaintiff Trial Exhibit 827 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 32 (English Translation) submitted as Plaintiff Trial Exhibit 828 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 33 submitted as Plaintiff Exhibit 829 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 33 (English Translation) submitted as Trial Exhibit 830 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 34 submitted as Plaintiff Trial Exhibit 831 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–valve Pig No. 34 (English Translation) submitted as Plaintiff Trial Exhibit 832 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 35 submitted as Plaintiff Trial Exhibit 833 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 35 (English Translation) submitted as Plaintiff Trial Exhibit 834 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 36 submitted as Plaintiff Trial Exhibit 835 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 36 (English Translation) submitted as Plaintiff Trial Exhibit 836 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 37 submitted as Plaintiff Trial 837 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 37 (English Translation) submitted as Plaintiff Trial Exhibit 838 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 38 submitted as Plaintiff Trial Exhibit 839 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 38 (English Translation) submitted as Plaintiff Trial Exhibit 840 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 39 submitted as Plaintiff Trial Exhibit 841 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 39 (English Translation) submitted as Plaintiff Trial Exhibit 842 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 40 submitted as Plaintiff Trial Exhibit 843 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 40 (English Translation) submitted as Plaintiff Trial Exhibit 844 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Stent–Klappen" (Danish) GRIS NR. 41 submitted as Plaintiff. Trial Exhibit 845 in C.A. No. 08–091–GMS in the District Court of Delaware with Stent–Valve Pig No. 41 (English Translation) submitted as Plaintiff Trial Exhibit 846 in C.A. No. 08–091–GMS in the District Court of Delaware.

Collection of letters between P. Block, M. Chan, and H.R. Andersen submitted as Plaintiff Trial Exhibit 851 in C.A. No. 08–091–GMS in the District Court of Delaware.

Stent–Klappen (Danish) submitted as Plaintiff Trial Exhibit 852 in C.A. No. 08–091–GMS in the District Court of Delaware.

Stent–Klappen (Danish) submitted as Plaintiff Trial Exhibit 853 in C.A. No. 08–091–GMS in the District Court of Delaware with English translation to be agreed upon by the parties submitted as Plaintiff Trial Exhibit Exhibit 853A in C.A. No. 08–091–GMS in the District Court of Delaware.

"EN NY Kateterbaren Stent–Monterer Kunstig Hjerteklap Til Implantation Uden Aben Hjertekirurgi" (Danish) submitted as Plaintiff Trial Exhibit 860 in C.A. No. 08–091–GMS in the District Court of Delaware with English translation to be agreed upon by the parties submitted as Plaintiff Trial Exhibit 860A in C.A. No. 08–091–GMS in the District Court of Delaware.

Andersen et al., Implantation of Artifical Heart Valves (manuscript) submitted as Plaintiff Trial Exhibit 861 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Knud Tange Rasmussen of DTI (Danish) submitted as Plaintiff Trial Exhibit 863 in C.A. No. 08–091–GMS in the District Court of Delaware English with translation to be agreed upon by the parties submitted as Plaintiff Trial Exhibit 863A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Hans Rasmussen of DTI to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 865 in C.A. No. 08–091–GMS in the District Court of Delaware with English translation to be agreed upon by the parties submitted as Plaintiff Trial Exhibit 865A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Knud Tange Rasmussen of DTI (Danish) submitted as Plaintiff Trial Exhibit 866 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 866A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Knud Tange Rasmussen of DTI (Danish) submitted as Plaintiff Trial Exhibit 867 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 867A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Knud Tange Rasmussen of DTI (Danish) submitted as Plaintiff Trial 868 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 868A in C.A. No. 08–091–GMS in the District Court of Delaware.

Miscellaneous data sheets from Pig No. 17 (Danish) submitted as Plaintiff Trial Exhibit 869 in C.A. No. 08–091–GMS in the District Court of Delaware.

"Dansk Cardiologisk Selskab's" (Danish) submitted as Plaintiff Trial Exhibit 870 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 870A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Per Holm of Vingmed A/S (Danish) submitted as Plaintiff Trial Exhibit 871 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 871A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Peter De Jong of Baxter submitted as Plaintiff Trial Exhibit 872 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Niels Christiansen of Pfizer (Danish) submitted as Plaintiff Trial Exhibit 873 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 873A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Hans Rasmussen of DTI to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 874 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 874A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Kaj Berlich of Baxter (Danish) submitted as Plaintiff Trial Exhibit 875 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 875A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Per Holm on Vingmed A/S to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 876 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Exhibit 876A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Niels Christiansen of Pfizer (Danish) submitted as Plaintiff Trial Exhibit 877 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 877A in C.A. No. 08–091–GMS in the District Court of Delaware.

Fax from Per Holm Vingmed A/S to Peter Chevalier of Medtronic, Inc. (Danish) submitted as Plaintiff Trial Exhibit 878 in C.A. No. 08–091–GMS in the District Court of Delaware with English Traslation submitted as Plaintiff Trial Exhibit 878A in C.A. No. 08–091–GMS in the District Court of Delaware.

Fax from Peter Chevalier of Medtronic, Inc. to Per Holm of Vingmed A/S submitted as Plaintiff Trial Exhibit 879 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Bent Holmegand of Meadox Surgimed A/S to Knud Tange Rasmussen of DTI (Danish) submitted as Plaintiff Trial Exhibit 881 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 881A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Knud Tange Rasmussen of DTI to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 882 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 882A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Kenneth H. Levin of C.R. Bard, Inc. to Hemming [sic] Andersen submitted as Plaintiff Trial Exhibit 883 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Knud Tange Rasmussen of DTI (Danish) submitted as Plaintiff Trial Exhibit 884 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 884A in C.A. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Kenneth Levin of C. R. Bard, Inc. submitted as Plaintiff Trial Exhibit 885 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Flemming Hoj Sorensen of DTI to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 886 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Exhibit 886A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Knud Tange Rasmussen of DTI (Danish) submitted as Plaintiff Trial Exhibit 867 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 867A in C.A. No. 08–091–GMS in the District Court of Delaware.

Miscellaneous date sheets from Pig No. 17 (Danish) sumbitted as Plaintiff Trial Exhibit 869 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Peter De Jong of Baxter sumbitted as Plaintiff Trial Exhibit 872 in C.A. No. 08–091–GMS in the District Court of Delaware.

Fax from Per Holm of Vingmed A/S to Peter Chevalier of Medtronic, Inc. (Danish) submitted as Plaintiff Trial Exhibit 878 in C.A. No. 08–091–GMS in the District Court of Delaware with English Traslation submitted as Plaintiff Trial Exhibit 878A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Bent Holmegaand of Meadox Surgimed A/S to Knud Tange Rasmussen of DTI (Danish) submitted as Plaintiff Trial Exhibit 881 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 881A in C.A. 08–091–GMS in the District Court of Delaware.

Fax from Kennth H. Levin of C.R. Bard, Inc. to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 887 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Flemming Hoj Sorensen of DTI (Danish) submitted as Plaintiff Trial Exhibit 888 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Exhibit 888A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Flemming Hoj Sorensen and Knud Tange Rasmussen of DTI (Danish) submitted as Plaintiff Trial Exhibit 890 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 890A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to MArcel van den Brand of Erasmus University Hospital submitted as Plaintiff Trial Exhibit 891 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Knud Tange Rasmussen of DTI to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 892 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 892A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Knud Tange Rasmussen of DTI to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 893 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 893A in C:A. 08–091–GMS in the District Court of Delaware.

Letter from Lars Lyhne Kndusen to Professor P. Sleight enclosing manuscripts for review by Cardiovascular Research submitted as Plaintiff Trial Exhibit 894 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Knud Tange Rasmussen of DTI to Kenneth H. Levin of C.R. Bard submitted as Plaintiff Trial Exhibit 895 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Knud Tange Rasmussen of DTI to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 896 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 896A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Marvin P. Loeb of Trimedyne to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 897 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Knud Tange Rasmussen of DTI to Erik Andersen of Boston Scientific (Danish) submitted as Plaintiff Trial Exhibit 898 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 898A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Marvin P. Loeb of Trimedyne, Inc. submitted as Plaintiff Trial Exhibit 899 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to SCIMED submitted as Plaintiff Trial Exhibit 900 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Anderson to Marvin P. Loeb of Trimedyne, Inc. submitted as Plaintiff Trial Exhibit 901 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Erik Andersen of Boston Scientific to Dansk Teknologisk Institut (Danish) submitted as Plaintiff Trial Exhibit 902 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 902A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Marvin P. Loeb of Trimedyne, Inc. to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 903 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Knud Tange Rasmussen of DTI submitted as Plaintiff Trial Exhibit 904 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Knud Tange Rasmussen of DTI to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 905 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Tamar J. Preminger of Children's Hospital (Boston) to Henning R. Andersen submitted as Plaintiff Trial Exhibit 906 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Ruder Andersen to Tamar J. Preminger of Children's Hospital submitted as Plaintiff Trial Exhibit 907 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Marvin P. Loeb of Trimedyne, Inc. to Rasmus Offersen of DTI submitted as Plaintiff Trial Exhibit 908 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Rasmus Offersen of DTI to Kurt Anker Jensen of Astra Meditek A/S (Danish) submitted as Plaintiff Trial Exhibit 909 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 909A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Rasmus Offersen of DTI to Henning Rud Andersen (Danish) submitted as Plaintiff Trial Exhibit 910 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 910A in C.A. No. 08–091–GMS in the District Court of Delaware.

Fax from Rasmus Offersen of DTI to Marvin P. Loeb of Trimedyne, Inc. submitted as Plaintiff Trial Exhibit 911 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Rasmus Offersen of DTI to Kurt Anker Jensen of Astra Meditek A/S (Danish) submitted as Plaintiff Trial Exhibit 912 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 912A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Rasmus Offersen of DTI to Peter Selley of Astra Tech AB (Danish) submitted as Plaintiff Trial Exhibit 915 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 915A in C.A. No. 08–091–GMS in the District Court of Delaware.

Fax from Rasmus Offersen of DTI to Peter Selley of Astra Tech AB (Danish) submitted as Plaintiff Trial Exhibit 916 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 916A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from American Heart Association to Henning Rud Andersen concerning poster presentation acceptance submitted as Plaintiff Trial Exhibit 917 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Rasmus Offersen of DTI (Danish) submitted as Plaintiff Trial Exhibit 918 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 918A in C.A. No. 08–091–GMS in the District Court of Delaware.

Fax from Rasmus Offersen of DTI to Wes Sterman of Stanford Surgical Technologies submitted as Plaintiff Trial Exhibit 919 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Rasmus Offersen of DTI to Wesley Sterman of Stanford Surgical Technologies, Inc. submitted as Plaintiff Trial Exhibit 920 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Lars Lyhne Kundsen to Eli A. Friedman of ASAIO Journal enclosing manuscript for review submitted as Plaintiff Trial Exhibit 922 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Rasmus Offersen of DTI to Marvin P. Loeb of Trimedyne, Inc.submitted as Plaintiff Trial Exhibit 923 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Diego Brancaccio of Int'l Journal of Artificial Organs to Lars L. Knudsen concerning publication of manuscript submitted as Plaintiff Trial Exhibit 924 in C.A. No. 08–091–GMS in the District Court of Delaware.

Fax from Rasmus Offersen of DTI to Wesley Sterman of Stanford Surgical Technologies enclosing executed licensing agreement submitted as Plaintiff Trial Exhibit 925 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Wesley D. Sterman of Stanford Surgical Technologies, Inc. submitted as Plaintiff Trial Exhibit 926 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Hanson Giffort of Stanford Surgical Technologies, Inc. submitted as Plaintiff Trial Exhibit 927 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Tamar J. Preminger of Children's Hospital (Boston) to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 929 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Ted Feldman of the University of Chicago to H. Rud Andersen submitted as Plaintiff Trial Exhibit 930 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Tamar J. Preminger of Children's Hospital (Boston) submitted as Plaintiff Trial Exhibit 931 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Robert F. Kuhling of Onset Ventures to Leif Nielsen of Lehman & Ree submitted as Plaintiff Trial Exhibit 932 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Robert F. Kuhling of Onset Ventures to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 933 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Robert F. Kuhling of Onset Ventures submitted as Plaintiff Trial Exhibit 934 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Wesley D. Sterman of Heartport, Inc. submitted as Plaintiff Trial Exhibit 935 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Peter C. Block of St. Vincent's Medical Center to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 936 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Peter C. Block of St. Vincent's Medical Center to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 937 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Peter C. Block of St. Vincent's Medical Center submitted as Plaintiff Trial Exhibit 938 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Peter C. Block of St. Vincent's Medical Center to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 939 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Peter C. Block of St. Vincent's Medical Center submitted as Plaintiff Trial Exhibit 940 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Rasmus Offersen of DTI (Danish) submitted as Plaintiff Trial Exhibit 941 in C.A. No. 08–091–GMS in the District Court of Delaware with English Translation submitted as Plaintiff Trial Exhibit 941A in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Peter C. Block of St. Vincent's Medical Center to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 942 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Dusan Pavenik to Henning Rud Andersen submitted as Plaintiff Trial Exhibit 943 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letetr from HenninG Rud Andersen to George Teitelbaum submitted as Plaintiff Trial Exhibit 944 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Jan Peregrin submitted as Plaintiff Trial Exhibit 945 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Jeffry J. Grainger of Hearport, Inc. to Vibeke Walde of DTI submitted as Plaintiff Trial Exhibit 949 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Henning Rud Andersen to Jeffry Grainger of Heartport, Inc. submitted as Plaintiff Trial Exhibit 951 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from Jan Komtebedde to Andersen et al. re: update on license agreement submitted as Plaintiff Trial Exhibit 953 in C.A. No. 08–091–GMS in the District Court of Delaware.

Consent of Merger Agreement between Heartport, Inc. and Andersen et al. submitted as Plaintiff Trial Exhibit 954 in C.A. No. 08–091–GMS in the District Court of Delaware.

Email chain from Vibeke Wakle to Henning Rud Andersen re: VS: Andersen license (Danish in part) submitted as Plaintiff Trial Exhibit 956 in C.A. No. 08–091–GMS in the District Court of Delaware.

PVT Design Review—1st Design Iteration submitted as Plaintiff Trial Exhibit 1005 in C.A. No. 08–091–GMS in the District Court of Delaware.

Emails from Hanne Rask Hansen to Abi Zakai re: Collaboration submitted as Plaintiff Trial Exhibit 1013 in C.A. No. 08–091–GMS in the District Court of Delaware.

In vivo picture of CoreValve device, excerpted from CoreValve Slide Presentation of Two heart valve prostheses in patients at Albert Einstein Hospital in Sao Paulo, Brazil submitted as Plaintiff Trial Exhibit 1078 in C.A. No. 08-091-GMS in the District Court of Delaware.

French Catheter Scales submitted as Plaintiff Trial Exhibit 1083 in C.A. No. 08-091-GMS in the District Court of Delaware.

PVT, Inc. Series B Convertible Preferred Stock Purchase Agreement b/w PVT and Medtronic submitted as Plaintiff Trial Exhibit 1092 in C.A. No. 08-091-GMS in the District Court of Delaware.

Edwards Lifesciences AG v. *Cook Biotech, Inc.* (HC 08C00934)—UK trial transcripts—Days 1-5 submitted as Plaintiff Trial Exhibit 1178 in C.A. No. 08-091-GMS in the District Court of Delaware.

Heartport Consent to Merger with Johnson & Johnson and HP Merger Sub submitted as Plaintiff Trial Exhibit 1556 in C.A. No. 08-091-GMS in the District Court of Delaware.

Disclosure Statement between Edwards and PVT (Dec. 15, 2003) submitted as Plaintiff Trial Exhibit 1563 in C.A. 08-091-GMS in the District Court of Delaware.

Certificate of Merger between PVT and Edwards submitted as Plaintiff Trial Exhibit 1565 in C.A. No. 08-091-GMS in the District Court of Delaware.

PVT Amended and Restated Certificate of Incorporation (Oct. 8, 2004) submitted as Plaintiff Trial Exhibit 1567 in C.A. No. 08-091-GMS in the District Court of Delaware.

Certification of Stanton Rowe (Jun. 15, 2007) submitted as Plaintiff Trial Exhibit 1572 in C.A. No. 08-091-GMS in the District Court of Delaware.

California Statement by Domestic Stock Corporation (Stanford Surgical) submitted as Plaintiff Trial Exhibit 1573 in C.A. No. 08-091-GMS in the District Court of Delaware.

Certifcate of Filing Merger between Stanford Surgical and Hearport submitted as Plaintiff Trial Exhibit 1574 in C.A. No. 08-091-GMS in the District Court of Delaware.

Consent to Assignment between Stanford Surgical and Inventors submitted as Plaintiff Trial Exhibit 1575 in C.A. No. 08-091-GMS in the District Court of Delaware.

Edwards SAPIEN Transcatheter Heart Valve with RetroFlex 3 Transfermoral Kit submitted as Plaintiff Trial Exhibit 1630 in C.A. No. 08-091-GMS in the District Court of Delaware.

Presentation Business Review-Manufacturing submitted as Plaintiff Trial Exhibit 1635 in C.A. No. 08-091-GMS in the District Court of Delaware.

Printout of List of Centers and Country (Excel) submitted as Plaintiff Trial Exhibit 1654A in C.A. No. 08-091-GMS in the District Court of Delaware.

Report—Leading the way to the next frontier of the cardio vascular device industry submitted as Plaintiff Trial Exhibit 1712 in C.A. No. 08-091-GMS in the District Court of Delaware.

Report—Leading the way to the next frontier of the cardio vascular device industry: Percutaneous aortic heart valve replacement submitted as Plaintiff Trial Exhibit 1713 in C.A. No. 08-091-GMS in the District Court of Delaware.

Colin Stewart, How Rob Michiels and Corevalve got where they are today, The Orange County register, submitted as Plaintiff Trial Exhibit 1747 in C.A. No. 08-091-GMS in the District Court of Delaware.

Financial Frontier for the years ending Dec. 21, 2007-2012 submitted as Plaintiff Trial Exhibit 1748 in C.A. No. 08-091-GMS in the District Court of Delaware.

"Edwards Lifesciences: Speed Bumps Ahead for Sapien, Downgrading to Underweight," North America Equity Research submitted as Plaintiff Trial Exhibit 1807 in C.A. No. 08-091-GMS in the District Court of Delaware.

Print out- Corevalve reporting-Apr. 2005-Version 1 (Excel) submitted as Plaintiff Trial Exhibit 1900A in C.A. No. 08-091-GMS in the District Court of Delaware.

PVT Press Release—Hearport Announces Exclusive Licensing Agreement with Percutaneous Valve Technologies submitted as Plaintiff Trial 1968 in C.A. No. 08-091-GMS in the District Court of Delaware.

Medical Device Daily, vol. 10, No. 60 submitted as Plaintiff Trial Exhibit 20303 in C.A. No. 08-091-GMS in the District Court of Delaware.

Corelative press release: CoreValve Completes $24 Million Series B Round of Financing Led by Apax Partners submitted as Plaintiff Trial Exhibit 2031 in C.A. No. 08-091-GMS in the District Court of Delaware.

Corevalve press release: CoreValve Completes $33 Million Private Financing submitted as Plaintiff Trial Exhibit 2032 in C.A. No. 08-091-GMS in the District Court of Delaware.

In Strategy Shift, CoreValve to Manufacture Device in U.S. Facility, Dow Jone VentureWire submitted as Plaintiff Trial Exhibit 2033 in C.A. No. 08-091-GMS in the District Court of Delaware.

CoreValve, Inc. Financial Forecas submitted as Plaintiff Trial Exhibit 2034 in C.A. No. 08-091-GMS in the District Court of Delaware.

Edwards' CE Marking of Conformity Certificate submitted as Plaintiff Trial Exhibit 2059 in C.A. No. 08-091-GMS in the District Court of Delaware.

Edwards' EC-Design Examination Certificate submitted as Plaintiff Trial Exhibit 2060 in C.A. No. 08-091-GMS in the District Court of Delaware.

Patient Selection for the CoreValve ReValving System by Ganesh Manoharan et al. submitted as Plaintiff Trial Exhibit 2090 in C.A. No. 08-091-GMS in the District Court of Delaware.

Presentation—France Registry: French Aortic National Core Valve and Edwards Registry, Helene Eltchaninoff submitted as Plaintiff Trial Exhibit 2123 in C.A. No. 08-091-GMS in the District Court of Delaware.

CE Markings of Conformity issued to Edwards Lifesciences submitted as Plaintiff Trial Exhibit 2124 in C.A. No. 08-091-GMS in the District Court of Delaware.

Color Photographs of Andersen et al. stent valve and related materials submitted as Plaintiff Trial Exhibit 2129 in C.A. No. 08-091-GMS in the District Court of Delaware.

Color Photographs of Andersen et al. stent valve and related materials submitted as Plaintiff Trial Exhibit 2130 in C.A. No. 08-091-GMS in the District Court of Delaware.

Color Photographs of Andersen et al. stent valve and related materials submitted as Plaintiff Trial Exhibit 2131 in C.A. No. 08-091-GMS in the District Court of Delaware.

Color Photographs of Andersen et al. stent valve and related materials submitted as Plaintiff Trial Exhibit 2132 in C.A. No. 06-091-GMS in the District Court of Delaware.

Handwritten notes made by Dr. Buller on CoreValve device during his direct testimony (top view) submitted as Plaintiff Trial Exhibit 2135 in C.A. No. 08-091-GMS in the District Court of Delaware.

Handwritten notes made by Dr. Buller on CoreValve device during his direct testimony (side view) submitted as Plaintiff Trial Exhibit 2136 in C.A. No. 08–091–GMS in the District Court of Delaware.

Handwritten notes made by Dr. Buller on CoreValve device during his direct testimony (side view) submitted as Plaintiff Trial Exhibit 2137 in C.A. No. 08–091–GMS in the District Court of Delaware.

CoreValve's Timeline: Actual vs. *No Infringement* submitted as Plaintiff Trial exhibit 2141 in C.A. No. 08–091–GMS in the District Court of Delaware.

CoreValve's Timeline: Actual vs. *No Infringement* (Europe) submitted as Plaintiff Trial Exhibit 2142 in C.A. No. 08–091–GMS in the District Court of Delaware.

Edwards' *Damages—Lost Profits Units* vs. *Reasonable Royalty Units* (Europe) submitted as Plaintiff Trial Exhibit 2143 in C.A. No. 08–091–GMS in the District Court of Delaware.

Summary of Edwards' Damages in Europe submitted as Plaintiff Trial Exhibit 2144 in C.A. No. 08–091–GMS in the District Court of Delaware.

Summary of Edwards' Lost Profits Damages submitted as Plaintiff Trial Exhibit 2145 in C.A. 08–091–GMS in the District Court of Delaware.

Summary of Edwards' Total Damages submitted as Plaintiff Trial Exhibit 2146 in C.A. No. 08–091–GMS in the District Court of Delaware.

Reasonable Royalty if No Lost Profits submitted as Plaintiff Trial Exhibit 2147 in C.A. No. 08–091–GMS in the District Court of Delaware.

Translation of Letter from K. Rasmussen to H. Andersen re Novelty Search on Implantable Stent Valve. dated Oct. 25, 1989, submitted as Defendant Trial Exhibit 7 in C.A. No. 08–091–GMS in the District Court of Delaware.

Article: "Transluminal Implantation of Artificial Heart Valves. Description of a New Expandable Aortic Valve and Initial 1992 Results with Implantation by Catheter Technique in Closed Chest Pigs", European Heart Journal, vol. 13, pp. 704–708, by H, Andersen, L. Knudsen and J. Hasenkam, dated 1992 submitted as Defendant Trial Exhibit 14 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from D.L. Brutsaert to H. Andersen re Manuscript Entitled "Transluminal Implantation of Artificial Heart Valves" Accepted for Publication, dated Oct. 3, 1991 submitted as Defendant Trial Exhibit 17 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from J. Fabricius to Danish Institute ofTechnology re Opinion on "Stent Valve Project" dated Mar. 5, 1990 Letter from H. Andersen to K. Rasmussen re Comments on Written Opinion from J. Fabricius, dated May 15, 1990 submitted as Defendant Trial Exhibit 42 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from S. Dack to H. Andersen re Hasenkam Hasenkam Rejection of Manuscript Entitled "Implantation of Artificial Heart Valves" dated Jul. 26, 1990 submitted as Defendant Trial Exhibit 48 in C.A. No. 08–091–GMS in the District Court of Delaware.

Drawing by Witness of Stent Prototype submitted as Defendant Trial Exhibit 57 in C.A. No. 08–091–GMS in the District Court of Delaware.

Report: "Development, Manufacture, and In Vitro and In Vivo Evaluation of an Artificial Heart Valve for Implantation Using the Catheter Technique with a View to Future Intravasal Treatment of Heart Valve Disorders", by L. Knudsen, dated 1992 submitted as Defendant Trial Exhibit 60 in C.A. No. 08–091–GMS in the District Court of Delaware.

Article: "Catheter–Implanted Prosthetic Heart Valves–Transluminal Catheter Implantation of a New Expandable Artificial Heart Valve in the Descending Thoracic Aorta in Isolated Vessels and Closed Chest Pigs", The International Journal of Artificial Organs, vol. 16, pp. 253–262, by L. Knudsen, H. Andersen, & J. Hasenkam, dated 1993 submitted as Defendant Trial Exhibit 61 in C.A. No. 08–091–GMS in the District Court of Delaware.

Powerpoint Presentation: "Percutaneous Rowe–Rowe–Valve Technologies"by A. Cribier, M. Leon, S. Rabinovich & S. Rowe submitted as Defendant Trial Exhibit 76 in C.A. No. 08–091–GMS in the District Court of Delaware.

Document: "Percutaneous Valve Technologies, Inc. Business Plan," dated Feb. 2000 submitted as Defendant Trial–Exhibit 81 in C.A. No. 08–091–GMS in the District Court of Delaware.

Drawing of CAD Design for the Production of Two Stents, dated Jan. 2, 2000 submitted as Defendent Trial Exhibit 84 in C.A. No. 08–091–GMS in the District Court of Delaware.

Report: "Design Review—Concept Phase," dated May 15, 2000 submitted as Defendant Trial Exhibit 85 in C.A. No. 08–091–GMS in the District Court of Delaware.

Report: "R & D Monthly Report–Jun. 2000," dated Jun. 13, 2000 submitted as Defendant Trial Exhibit 87 in C.A. No. 08–091–GMS in the District Court of Delaware.

Letter from H. Gifford to H. Andersen re Endovascular Valve Replacement Porcedure, dated Sep. 29, 1993 submitted as Defendant Trial Exhibit 97 in C.A. 08–091–GMS in the District Court of Delaware.

PowerPoint Slides of PHV Frame Evolution submitted as Defendant Trial Exhibit 102 in C.A. No. 08–091–GMS in the District Court of Delaware.

Exhibit "SR–7" referred to in the First Witness Statement of Stanton Rowe dated May 27, 2008 submitted as Defendant Trial Exhibit 103 in C.A. No. 08–091–GMS in the District Court of Delaware.

Document: "PVT Stent Follow–Up Table" submitted as Defendant Trial Exhibit 104 in C.A. No. 08–091–GMS in the District Court of Delaware.

Document: "Outlines of a Research Program for the Development of an Implantable Heart Valve (1HV)" submitted as Defendant Trial Exhibit 207 in C.A. No. 08–091–GMS in the District Court of Delaware.

Document: "Non–Surgical Cardiac Valve Implanation" submitted as Defendant Trial Exhibit 211 in C.A. No. 08–091–GMS in the District Court of Delaware.

Document: Conception Review–Prosthesis Design Conception, date May 5, 2004 submitted as Defendant Trial Exhibit 239 in C.A. No. 08–091–GMS in the District Court of Delaware.

U.S. Patent No. 7,018,406 B2, entitled "Prosthetic Valve for Transluminal Delivery" issued to Sequin et al on Mar. 28, 2006 with attached file history, submitted as Defendant Trial Exhibit 289 in C.A. No. 08–091–GMS in the District Court of Delaware.

Pig experiments of Drs. Andersen, Hasenkam, and Knudsen submitted as Defendant Trial Exhibit 294 in C.A. No. 08–091–GMS in the District Court of Delaware.

Color version of Test Report and signature page of #R-2006-006: Frame Deflection and Leaflet Angle-Core Valve Percutaneous Aortic Valve Generation 3, 26 mm (Previously produced black and white image COR674610-674633) submitted as Defendant Trial Exhibit 1313 in C.A. No. 08-091-GMS in the District Court of Delaware.

Color version or Report and signature page for Protocol #R-2006-010: Frame Deflection and Leaflet Angle-Core Valve Percutaneous Aortic Valve Generation 3, 29mm (Previously produced black and white image COR680225-680238) submitted as Defendant Trial Exhibit 1314 in C.A. No. 08-091-GMS in the District Court of Delaware.

Contact Sheet of photographs of CoreValve prototypes taken by Edwards' counsel on Jan. 25, 2010 submitted as Defendant Trial Exhibit 1459 in C.A. No. 08-091-GMS in the District Court of Delaware.

Picture of Physical Device submitted as Defendant Trial Exhibit 1460 in C.A. No. 08-091-GMS in the District Court of Delaware.

Picture of Physical Device submitted as Defendant Trial Exhibit 1462 in C.A. No. 08-091-GMS in the District Court of Delaware.

Picture of Physical Device submitted as Defendant Trial Exhibit 1466 in C.A. No. 08-091-GMS in the District Court of Delaware.

Picture of Physical Device submitted as Defendant Trial Exhibit 1467 in C.A. No. 08-091-GMS in the District Court of Delaware.

Picture of Generation 1 CoreValve device submitted as Defendant Trial Exhibit 1469 in C.A. No. 08-091-GMS in the District Court of Delaware.

Picture of Physical Device submitted as Defendant Trial Exhibit 1471 in C.A. No. 08-091-GMS in the District Court of Delaware.

Picture of Physical Device submitted as Defendant Trial Exhibit 1473 in C.A. No. 08-091-GMS in the District Court of Delaware.

Timeline re CoreValve would have made all its Sales overseas—Fall 2004 start date submitted as Defendant Trial Exhibit 1478 in C.A. No. 08-091-GMS in the District Court of Delaware.

Timeline re CoreValve would have made all its Sales overseas—Spring 2005 start date submitted as Defendant Trial Exhibit 1479 in C.A. No. 08-091-GMS in the District Court of Delaware.

Jeffery Kinrich demonstrative graphic submitted as Defendant Trial Exhibit 1483 in C.A. No. 08-091-GMS in the District Court of Delaware.

Jeffery Kinrich demonstrative graphic submitted as Defendant Trial Exhibit 1484 in C.A. No. 08-091-GMS in the District Court of Delaware.

Jeffery Kinrich demonstrative graphic submitted as Defendant Trial Exhibit 1485 in C.A. No. 08-091-GMS in the District Court of Delaware.

Jeffery Kinrich demonstrative graphic submitted as Defendant Trial Exhibit 1486 in C.A. No. 08-091-GMS in the District Court of Delaware.

Jeffery Kinrich demonstrative graphic submitted as Defendant Trial Exhibit 1487 in C.A. No. 08-091-GMS in the District Court of Delaware.

Final Jury Instructions, *Edwards Lifesciences AG and Edwards Lifesciences, LLC.* v. *Medtronic CoreValve LLC*, United States District Court for the District of Delaware, Civil Action No. 1:08-CV-00091-GMS, Apr. 1, 2010.

Trial Transcripts, *Edwards Lifesciences AG and Edwards Lifesciences, LLC.* v. *Medtronic CoreValve LLC*, United States District Court for the District of Delaware, Civil Action No. 1:08-CV-00091-GMS, Mar. 23, 2010-Apr. 1, 2010.

Affidavit of Michael Gadeberg, Jul. 8, 2010.

Slide Deck for Plaintiff's Opening Statement in *Edwards Lifesciences AG and Edwards Lifesciences, LLC.* v. *Medtronic CoreValve LLC*, United States District Court for the District of Delaware, Civil Action No. 1:08-CV-00091-GMS, Mar. 23, 2010.

Plaintiff's Trial Exhibitexhibit 2135, *Edwards Lifesciences AG and Edwards Lifesciences, LLC.* v. *Medtronic CoreValve LLC*, United States District Court for the District of Delaware, Civil Action No. 1:08-CV-00091-GMS, Mar. 26, 2010.

Slide Deck for Plaintiff's Closing Arguments in *Edwards Lifesciences AG and Edwards Lifesciences, LLC.* v. *Medtronic CoreValve LLC*, United States District Court for the District of Delaware, Civil Action No. 1:08-CV-00091-GMS, Apr. 1, 2010.

Revised Slides for Plaintiff's Closing Arguments in *Edwards Lifesciences AG and Edwards Lifesciences, LLC.* v. *Medtronic CoreValve LLC*, United States District Court for the District of Delaware, Civil Action No. 1:08-CV-00091-GMS, Apr. 1, 2010.

U.S. App. No. 95/001,615, filed May 4, 2011 Andersen et al.

U.S. App. No. 95/001,616, filed May 4, 2011 Andersen et al.

U.S. App. No. 90/009,791, filed Jul. 29, 2010 Andersen et al.

U.S. App. No. 90/009779, filed Jul. 9, 2010 Andersen et al.

Memorandum on post-trial motions and Order, dated Feb. 7, 2011, Edwards Lifesciences AG and Edwards Lifesciences LLC, v. Corevalve, Inc and Medtronic Corevalve, LLC U S District Court for the District of Delaware, CA No 08-91-GMS.

EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

NO AMENDMENTS HAVE BEEN MADE TO THE PATENT

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claim 1 is confirmed.

Claims **2-8** were not reexamined.

* * * * *

B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 08-91-GMS
COREVALVE, INC. and, MEDTRONIC COREVALVE, LLC	)	
Defendant.	)	

JUDGMENT

This action came before the Court for a trial by jury. The issues have been tried and the jury rendered its verdict on April 1, 2010. The verdict was accompanied by a verdict form (D.I. 313), a copy of which is attached hereto. Therefore,

IT IS HEREBY ORDERED AND ADJUDGED that judgment be and is hereby entered in favor of the plaintiffs, EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC, AND against the defendants, COREVALVE, INC. and MEDTRONIC COREVALVE, LLC, in the amount of SEVENTY TWO MILLION SIX HUNDRED FORTY FIVE THOUSAND FIVE HUNDRED FIFTY FIVE DOLLARS ($72,645,555.00) in lost profits for infringement of the U.S. Patent No. 5,411,552; AND in the amount of ONE MILLION TWO HUNDRED EIGHTY FOUR THOUSAND EIGHT HUNDRED SIXTY ONE DOLLARS ($1,284,861.00) for reasonable royalty.

Dated: May 4, 2010

UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC, Plaintiffs, v. COREVALVE, INC. and MEDTRONIC COREVALVE, LLC Defendants.	C.A. No. 08-091-GMS

VERDICT FORM

We, the jury, having duly deliberated on the evidence presented by the parties, answer the interrogatories posed by the Court as follows:

I. PATENT INFRINGEMENT

QUESTION 1:

Has Edwards proven by a preponderance of the evidence that the CoreValve Generation 3 ReValving System literally infringes Claim 1 of the '552 Patent?

YES ___√___ (for Edwards) NO _____ (for CoreValve)

If you answered "yes" to Question 1, go to Question 3.

If you answered "no" to Question 1, go to Question 2.

QUESTION 2:

Has Edwards proven by a preponderance of the evidence that the CoreValve Generation 3 ReValving System infringes Claim 1 of the '552 Patent under the Doctrine of Equivalents?

YES _____ (for Edwards) NO _____ (for CoreValve)

If you answered "yes" to Question 2, go to Question 3.

If you answered "no" to both Questions 1 and 2, go to Question 4.

II. WILLFUL PATENT INFRINGEMENT

QUESTION 3:

Has Edwards proven by clear and convincing evidence that CoreValve's infringement of Claim 1 of the '552 Patent was willful?

YES ___√___ (for Edwards) NO _____ (for CoreValve)

Please go to Question 4.

III. PATENT VALIDITY

QUESTION 4:

Has CoreValve proven by clear and convincing evidence that Claim 1 of the '552 Patent is invalid because it is not enabled?

YES _____ (for CoreValve) NO ___✓___ (for Edwards)

Please go to Question 5.

IV. EDWARDS' DAMAGES

If you found that CoreValve has infringed Claim 1 of the '552 Patent (either literally or under the Doctrine of Equivalents), and that CoreValve did not prove that Claim 1 of the '552 Patent is invalid, you must decide the amount of damages adequate to compensate Edwards for CoreValve's infringement.

QUESTION 5:

If you believe that Edwards has proven by a preponderance of the evidence that it is entitled to lost profits for a portion of CoreValve's infringing sales, please enter the amount of lost profits:

Answer: $ 72,645,555.00

QUESTION 6:

For those CoreValve infringing sales for which you did not award Edwards lost profits, what is the amount of reasonable royalty to which Edwards is entitled?

Answer: $ 1,284,861.00

Dated: April 1, 2010

Foreperson

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 08-91-GMS
COREVALVE, INC. and, MEDTRONIC COREVALVE, LLC	)	
Defendants.	)	

MEMORANDUM

I. INTRODUCTION

In this patent infringement action, plaintiffs Edwards Lifesciences AG and Edwards Lifesciences LLC (collectively, "Edwards" or "the plaintiffs") allege that a medical device manufactured by defendants CoreValve, Inc. and Medtronic CoreValve, LLC ("CoreValve") infringe the asserted claim of the patent-in-suit. (D.I. 1.) The court held an eight-day jury trial in this matter on March 23 through April 1, 2010. (D.I. 326-333.) At trial, CoreValve properly moved for judgment as a matter of law ("JMOL") on a number of grounds pursuant to Rule 50(a) of the Federal Rules of Civil Procedure (see D.I. 303-304, 308, and 310), and the court denied CoreValve's motions. (See Tr. 1264-70.)

On April 1, 2010, the jury returned a unanimous verdict in favor of Edwards on all claims. The jury found that CoreValve's Generation 3 ReValving System (the "Gen 3" device) directly infringed claim 1 of United States Patent No. 5,411,552 ("the '552 Patent"), the only asserted claim in this case. (D.I. 313.) The jury further found that CoreValve's infringement was willful, and rejected CoreValve's claim of non-enablement with respect to the asserted

claim. (Id.) The jury awarded Edwards $72,645,555 in lost profits and $1,284,861 in reasonable royalties. (Id.) The court entered judgment on the verdict on May 4, 2010. (D.I. 324.) Presently before the court are the parties' post-trial motions.[1] Having considered the entire record in this case, the substantial evidence in the record, the parties' post-trial submissions, and the applicable law, the court will deny all the parties' post-trial motions with the exception of: Edwards' motion for pre-judgment and post-judgment interest (D.I. 344), which the court will grant; and Edwards' motion for permanent injunction and accounting (D.I. 356), which it will grant in part and deny in part. The court's reasoning follows.

II. BACKGROUND OF THE TECHNOLOGY

The patent-in-suit relates to medical device technology. Specifically, the '552 Patent relates to a "valve prosthesis, preferably a cardiac valve prosthesis, for implantation in the body . . ." ('552 Patent, col. 1, ll.13-15.) The object of the invention, and the key innovation upon which the parties focused at trial, is to provide a valve prosthesis that can be implanted in the body without the need for surgical intervention, but rather through use of a catheter. With respect to cardiac valves, the invention thus permits a valve to be implanted without the need for open heart surgery and the risks that come with such surgery. The claimed prosthesis comprises: "A collapsible elastical valve which is mounted on an elastic stent, the elastical valve having a plurality of commissural points" where the valve is attached to the stent. ('552 Patent, claim 1.) Relevant to the pending motions, the asserted claim requires that the stent include "cylindrical

[1] These motions are: CoreValve's Renewed Motion for Judgment as a Matter of Law (D.I. 318), CoreValve's Motion for a New Trial or Alternatively to Amend Judgment (D.I. 320), Edwards' Motion for Attorney Fees (D.I. 339), Edwards' Motion for Enhanced Damages Pursuant To 35 U.S.C. § 284 (D.I. 341), Edwards' Motion for Prejudgment and Postjudgment Interest (D.I. 344), CoreValve's Motion to Stay Judgment Pending Post-Trial Motions (D.I. 348), Edwards' Motion for Permanent Injunction, Accounting and Related Relief (D.I. 356), CoreValve's Local Rule 7.1.3(c)(2) Motion to Strike (D.I. 391), and CoreValve's Motion to Supplement Court Record (D.I. 417).

support means" and "a plurality of commissural supports projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof." (Id.)

III. DISCUSSION

A. Renewed JMOL Motions

To prevail on a renewed motion for judgment as a matter of law following a jury trial and verdict, the moving party "'must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings.'" *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998) (quoting *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984)). "Substantial evidence" is defined as "such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." *Perkin-Elmer Corp.*, 732 F.2d at 893.

The court should only grant the motion "if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993) (citing *Wittekamp v. Gulf Western Inc.*, 991 F.2d 1137, 1141 (3d Cir. 1993)). "In determining whether the evidence is sufficient to sustain liability, the court may not weigh the evidence, determine the credibility of witnesses, or substitute its version of the facts for the jury's version." *Lightning Lube*, 4 F.3d at 1166 (citing *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 190 (3d Cir. 1992)). Rather, the court must resolve all conflicts of evidence in favor of the non-movant. *Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1348 (3d Cir. 1991); *Perkin-Elmer Corp.*, 732 F.2d at 893.

"The question is not whether there is literally no evidence supporting the party against whom the motion is directed but whether there is evidence upon which the jury could properly find a verdict for that party." *Lightning Lube*, 4 F.3d at 1166 (quoting *Patzig v. O'Neil*, 577 F.2d 841, 846 (3d Cir. 1978)). In conducting such an analysis, "the court may not determine the credibility of the witnesses nor 'substitute its choice for that of the jury between conflicting elements of the evidence.'" *Syngenta Seeds, Inc. v. Monsanto Co.*, 409 F. Supp. 2d 536, 539 (D. Del. 2005) (quoting *Perkin-Elmer Corp.*, 732 F.2d at 893).

1. "Projecting"

CoreValve asserts that it is entited to judgment as a matter of law ("JMOL") because its accused device does not meet the limitation of the asserted claim "projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof." Here, a brief review of the discussions surrounding this phrase during the claim construction process illustrates that CoreValve's renewed JMOL motion on this issue is actually an effort to reopen claim construction and grant CoreValve summary judgment based on a construction that the court never adopted. Initially the parties offered these proposed constructions for the phrase:

Edwards: The commissural supports *project* from *one side* of the cylindrical support means in a direction generally parallel to the longitudinal axis of the cylindrical support means, namely, the commissural supports may not necessarily be parallel to that longitudinal axis in a strict geometric sense	**CoreValve**: *Extending away* from *one end* of the cylindrical support means in a direction generally parallel to the longitudinal axis of the cylindrical support means

(D.I. 45 at 12 (emphasis added).) The parties' proposed constructions differed in at least two respects. First, Edwards' construction included language (specifically, everything after "namely") reminiscent of the language they proposed in their construction of the term

"cylindrical." Second, whereas Edwards' proposed construction left unaltered the "project[ing] from one side" claim language, CoreValve proposed a construction that replaced "projecting" with "extending away" and "one side" with "one end."

With respect to the latter difference, CoreValve's claim construction answering brief stated that its proposed construction "is important to specify that the supports do not extend from a ***side*** of the cylindrical support means, but rather from its end." (D.I. 64 at 16 (emphasis in original).) Edwards took issue with CoreValve's proposed "extending away from one end" construction in its answering brief. Edwards argued that "'[e]xtending away' is inaccurate because a portion of the commissural supports in the preferred embodiment shown in Figure 2 overlap and thus do not extend away from one end of the cylindrical support means." (D.I. 62 at 14.) At the *Markman* hearing, Edwards stated that the dispute regarding the "extending away from one side" limitation was over "a very minor detail" (id. at 30-31), and CoreValve agreed that their positions on the meaning of this phrase were "very close." (D.I. 100 at 74.) Edwards did repeat its opposition to the "extending away" limitation as "an unnecessary limitation which isn't there." (Id. at 30.) CoreValve's sole statement regarding its "extending away" proposal at the hearing was:

> Now, [Edwards' counsel] didn't like the fact that we said extending away. We were trying to give another word for projecting. If the parties want to use projecting, that's probably fine with us as well. We didn't intend to change anything by "projecting."

(Id. at 74.) No mention was made between the distinction between "one end" and "one side," nor did CoreValve press the court further to adopt its "extending away construction," despite the fact that Edwards had specifically repeated its opposition to CoreValve's proposal.

Given the parties' indication that they did not view the differences between their

proposals as substantial, the court adopted a construction of the term that left the claim language intact and gave the term its plain and ordinary meaning. (D.I. 271 at 3.) The court noted that the parties' proposed constructions were "quite similar." (Id.) Neither CoreValve nor Edwards filed a motion for reconsideration or clarification regarding the court's construction of this term. CoreValve filed no motions in limine asking the court to clarify or further limit the meaning of this term. The term was not mentioned at all in the pretrial conference. (See D.I. 276.) CoreValve did not file any pre-trial objections with the court asserting that the infringement analysis for this term in Dr. Nigel Buller's expert report violated the court's claim construction order, nor does CoreValve argue now that Dr. Buller's testimony regarding the limitation at trial differed from the analysis in his report.[2]

CoreValve is now, in effect, asking the court to read its proposal into the court's construction of the disputed term, and test the jury's verdict against that far more limiting construction. In support of its argument as to the unreasonableness of the jury's verdict, CoreValve cites dictionary definitions of "projecting" in an effort to establish the term's plain and ordinary meaning, and then notes that there is nothing projecting from the top *end* of CoreValve's device. These arguments are, in effect, an attempt to reopen claim construction for the disputed term. At this stage in the proceedings, CoreValve's claim construction arguments are untimely, and the court rejects its renewed JMOL motion on that basis alone.[3] Edwards

[2] To the best of the court's knowledge, the only time that CoreValve raised this claim term before trial was its letter request to file a motion for summary judgment (D.I. 129), in which CoreValve also attempted to relitigate the court's constructions of "cylindrical" and "cylindrical support means" (see section III.A.4, *infra*). The court denied that letter request and a related subsequent "Motion for Clarification" (see D.I. 156) as untimely efforts to revisit claim construction. (*See* D.I. 149; D.I. 191.)

[3] Moreover, even if the court were to open claim construction for this term, the definitions CoreValve provided divorce the word "projecting" from the context in which it appears in the claims, and CoreValve's arguments gloss over the fact that the claim requires commissural supports projecting from one *side* rather than from one *end* of the support means.

specifically objected to CoreValve's "extending away" and "one end" limitations and noted that Figure 2 showed overlapping supports. Despite this, CoreValve indicated at the *Markman* hearing that it did not view its proposal as substantially different from Edwards'. If CoreValve wished for the court to further clarify the plain and ordinary meaning of the term with respect to their "extending away" and "one end" proposals, they could have insisted that the court rule on their proposed construction instead of stating that their proposed construction would not change the meaning of the term. Failing that, CoreValve could have filed a timely motion seeking clarification of the court's construction as to this term.

The test is not how CoreValve or even the court would interpret the plain and ordinary meaning of "projecting." Rather, the test is whether there is sufficient evidence to support the jury's implicit finding that the commissural supports on CoreValve's device "project[] from *one side* of the cylindrical support means," given the plain and ordinary meaning of that phrase in the context of the disputed claim. At trial, Dr. Buller gave testimony that provided a reasonable basis for the jury to conclude that CoreValve's device meets the requirements of the disputed claim term.[4] CoreValve's effort to create a more specific and limiting meaning of this term and test the jury's verdict against that meaning is untimely and unavailing.

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[4] Specifically, Dr. Buller used a photograph of CoreValve's device that was often used during trial to illustrate for the jury the location of the commissural points, commissural supports, and cylindrical support means. (*See* D.I. 337 at A894-96 (PTX 2135-2137.) Dr. Buller testified that the "top" portion of CoreValve's device as shown in PTX 2136-37 contained the commissural supports (Tr. 768:21-771:2; PTX 2137) while the "bottom" portion contained the cylindrical support means. (Tr. 769:24-25; PTX 2136.) He then explained, using the court's construction of the claim, how the commissural supports project from one side of the cylindrical support means, and how the commissural supports run generally parallel to the cylindrical support means. (Tr. 771:5-773:23.) It is true that these supports overlap with the cylindrical support means but, as Edwards notes, this is consistent with the specification and drawings of the '552 Patent. (*See* '552 Patent, Fig. 2 & col. 5:9-28.) In any case, and as discussed above, CoreValve's proposal to further limit the meaning of the "projecting from one side" limitation is untimely.

Moreover, CoreValve's effort to dismiss Dr. Buller's illustrations of CoreValve's device as "litigation-inspired" are unavailing. CoreValve did not object when Edwards moved to have those drawings moved into evidence. (Tr. 1003:14-20.) Furthermore, and as Edwards notes, experts routinely highlight and explain the components of an accused device in light of the asserted claim limitations. Indeed, the court is puzzled as to how infringement could ever be shown if experts were not permitted to refer to the accused device.

For similar reasons, the court rejects CoreValve's assertion that no reasonable jury could find that CoreValve's commissural support project "in a direction *generally parallel* to the longitudinal axis." CoreValve's argument depends on adopting a more limiting construction of the claim term than was included in the court's *Markman* order. Specifically, it requires that the "commissural supports" be limited so that the cells above the tabs that constitute the commissural points are excluded. The court's claim construction order, however, contains no such requirement. Indeed, both parties agreed that the proper construction of "commissural supports" is simply "portions of the stent that support the commissural supports of the valve." (D.I. 271 at 3.) CoreValve did not seek and the court did not impose a limitation excluding cells above the tab from being part of the "commissural supports." As with the "projecting from one side" portion of this limitation, Dr. Buller gave testimony that provided a reasonable basis for the jury to conclude that CoreValve's device meets the requirements of the disputed claim term.[5] Consequently, the court denies CoreValve's renewed JMOL motion with respect to this limitation.[6]

2. Willful Infringement

CoreValve next argues that the evidence presented at trial was not sufficient to support the jury's finding of willfulness. Under the rubric established by *In re Seagate Tech., LLC*,

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[5] *See* footnote 4, *supra*. Dr. Buller testified that the "portions of the stent that support the commissural points of the valve" (the court's construction of "commissural points") consists of "the structure . . . that rises up from the cylinder support means to the top of the device." (Tr. 770:2-5.) Given the honeycomb-like structure of CoreValve's device, this structure runs along most of the length of the stent; as CoreValve's own witness stated: "The CoreValve stent has the commissural supports, supported in a honeycomb structure." (Tr. 1465:2-8.) Dr. Buller then testified that supporting structure, as a whole, runs in a direction generally parallel to the longitudinal axis even though there are curves within the structure. (*See* Tr. 771:22-773:23.) The jury could reasonably have accepted Dr. Buller's testimony.

[6] CoreValve also argues that Edwards cannot resort to the doctrine of equivalents ("DOE") to prove infringement of the "commissural supports" claim term due to prosecution history estoppels. (See D.I. 335 at 9.) Since the jury found literal infringement of this claim, however, it did not (and did need to) determine DOE infringement. (See D.I. 313 at 2.) Consequently, the court finds that the DOE issue is moot.

willful infringement requires first that the patentee show that the infringer acted despite an objectively high likelihood that its actions constituted infringement. 497 F.3d 1360, 1371 (Fed. Cir. 2007). The existence of this risk is "determined by the record developed in the infringement proceeding." *Id.* If the objective risk prong is satisfied, the patentee must then show that the infringer either knew or should have known of this objective risk. *Id.* By its nature, the issue of willfulness in patent infringement hinges both on the fact finder's assessments of the credibility of witnesses and on the fact finder drawing inferences from the evidence presented to it. "The drawing of inferences, particularly in respect of an intent-implicating question such as willfulness, is peculiarly within the province of the fact finder that observed the witnesses." *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1225 (Fed. Cir. 2006). Since this case was tried before a jury, the court will not lightly disturb the jury's finding of willfulness.

In support of its arguments for a JMOL of non-willfulness, CoreValve cites the testimony of fact witnesses who testified as to the development of the Gen 3 device and their belief that the device did not infringe. (See D.I. 335 at 11.) The jury was under no obligation, however, to accept the testimony of CoreValve's witnesses. For instance, the jury was free to reject – and apparently did reject – Mr. Bortlein's assertion that he designed the Gen 3 device so that it contained no projecting commissural supports. (See D.I. 335 at 11 (citing Tr. 1035:4-1038:2).) Assessments of such testimony fall squarely within the province of the jury. CoreValve also cites the PTO's decision to grant CoreValve patents covering the Gen 3 device. While CoreValve correctly notes that evidence of such patents is potentially relevant to the issue of willfulness, it is not for the court to decide how much weight the jury should have given to CoreValve's patents in this case. Moreover, as Edwards notes in its answering brief, the record

contains considerable evidence from which a jury could have inferred willfulness. (See D.I. 369 at 10.) For these reasons, the court will deny CoreValve's renewed motion for JMOL on the issue of willfulness.

3. Non-Enablement

CoreValve next argues that no reasonable jury could have rejected CoreValve's non-enablement defense to claim 1. Non-enablement is an invalidity defense that must be established by clear and convincing evidence. *E.g.*, *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1375 (Fed. Cir. 2001). To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without "undue experimentation." *E.g.*, *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997).

CoreValve's motion confuses the standard under which enablement is determined by discussing enablement in terms of attributes that must be enabled "to cover the CoreValve device" rather than in terms of the language and scope of the actual claims. Specifically, CoreValve argues:

> [T]o cover *the CoreValve device*, claim 1 must encompass a device with "commissural supports projecting from one side . . . in a direction generally parallel" that is also (1) self-expanding, (2) suitable for use in humans, (3) suitable for delivery via minimally invasive techniques such as through the transfemoral artery, and (4) securable in the aortic annulus, like CoreValve's Gen 3.

(D.I. 335 at 12-13 (emphasis added).) CoreValve then proceeded to argue that each of the numbered attributes was not enabled by the '552 Patent.[7]

[7] Notably, CoreValve made no effort to argue that the '552 Patent did not enable "commissural supports projecting from one side . . . in a direction generally parallel," which was the only language from the actual claims that appeared in this section of CoreValve's motion. CoreValve only argued that there was nothing "projecting" in

CoreValve's recitation of what "claim 1 must encompass" in order "to cover the CoreValve device" is a misleading characterization of what must be enabled under § 112. It is the asserted claims rather than the accused device which must be "enabled" by the patent-in-suit. *See, e.g., Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1306 (Fed. Cir. 2001). In this case, the court did not construe the asserted claims to cover the four attributes of the accused device that CoreValve raises in its non-enablement argument, and CoreValve does not appear to make any effort to tie those attributes back to the actual claim language or to argue that actual limitations appearing in the asserted claim are not enabled. While it is true that the specification must enable the full scope of the asserted claim, there is no requirement that the claims must cover all features of the accused device. As the Federal Circuit has explained:

> The dispositive question of enablement does not turn on whether the accused product is enabled. Rather, "[t]o be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation."

Durel, 256 F.3d at 1306 (internal citation omitted).[8]

By that standard, since the court cannot discern from CoreValve's motion which limitations of the asserted claims are purportedly not enabled, CoreValve's motion does not even raise a colorable non-enablement defense against which the court can test the jury's verdict.

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the '552 Patent's only example of a "self-expandable" device. Self-expansion is not, however, required by or mentioned in the asserted claim.

[8] In *Invitrogen Corp. v. Clontech Laboratories, Inc.*, the Federal Circuit explained the reasoning underlying this approach to enablement:

> Enablement does not require the inventor to foresee every means of implementing an invention at pains of losing his patent franchise. Were it otherwise, claimed inventions would not include improved modes of practicing those inventions. Such narrow patent rights would rapidly become worthless as new modes of practicing the invention developed, and the inventor would lose the benefit of the patent bargain.

429 F.3d 1052, 1071 (Fed. Cir. 2005).

Certainly, considering the clear and convincing standard that non-enablement defenses must meet, CoreValve has failed to show that no reasonable jury could conclude that claim 1 of the '552 Patent is enabled.

4. "Cylindrical support means"

The next ground upon which CoreValve moves for JMOL relates to the court's construction of "cylindrical support means." CoreValve asked the court to revisit its construction of this term repeatedly throughout the pre-trial process and during the trial itself. CoreValve's repeated efforts to revisit claim construction led the court to warn CoreValve's counsel at trial to "stop pushing the issue." (Tr. 1649:11-18.) CoreValve chose to ignore the court's warning, and has once again raised the issue in their renewed JMOL motion. The court will deny the motion as (another) untimely effort to reopen claim construction and test the jury's verdict against a construction that did not appear in the court's *Markman* order.

The court will not comment further on the substance of the motion. Since attempts to relitigate claim construction have become increasingly prevalent, however, the court feels it necessary to lay out the history behind CoreValve's efforts to revisit claim construction on this issue. The court's claim construction order specifically rejected CoreValve's proposed constructions of "cylindrical support means" and "cylindrical," and specifically noted that the court rejected CoreValve's suggestion that "cylindrical" as that word is used in the disputed terms requires that the diameter be "constant along the longitudinal axis" as in the case of perfect geometric cylinders. (See D.I. 109 at 2 & 4; D.I. 271 at 2 & 4.) CoreValve did not file a motion for reargument during the ten day time frame imposed under Local Rule 7.1.5.[9] Once that period

[9] Local Rule 7.1.5 has since been amended to provide a fourteen day period for filing motions for reargument.

passed, the claim construction phase of the pre-trial process was complete.

Just a few weeks later, however, CoreValve attempted to revisit the constructions of "cylindrical" and "cylindrical support means" in its letter request to file a motion for summary judgment. (D.I. 129.) Despite the court's specific instruction that cylindrical did not mean "constant along the longitudinal axis" in the context of the disputed claims, CoreValve's letter argued that the court's claim construction was "grounded" in the geometric definition of a perfect cylinder with "straight parallel sides." (Id. at 2.) The court denied the letter request in an order that concluded by stating that "the court agrees with the plaintiffs, and will deny, as untimely, the defendant's request for reconsideration of the court's May 27, 2009 *Markman* order." (See D.I. 149.)

Undeterred, CoreValve filed a "Motion for Clarification" (D.I. 156) that contained a jumble of arguments stemming from CoreValve's insistence that "cylindrical" should be construed as referring to its "ordinary meaning" of cylinder (id. at 3) as "a shape with straight parallel sides." (Id. at 2.) CoreValve warned that if the court failed to "resolve" this issue, "the parties would inevitably litigate claim construction issues before the jury." The motion concluded with the following request:

> If the Court's use of the word "cylinder" in its claim construction was intended to refer to shapes that did not have the properties of a cylinder, as reflected by its ordinary meaning, then CoreValve respectfully requests clarification of the Court's view of the meaning of that term pursuant to *O2 Micro*, as a matter of law. If, on the other hand, the Court intends the parties to litigate before the jury whether the accused device has a shape "of or relating to a cylinder" under the ordinary meaning of the word "cylinder" as set forth in CoreValve's letter brief (D.I. 129), then CoreValve respectfully requests that the Court delete the last sentence from its [aforementioned order denying CoreValve's letter request to file a summary judgment motion].

(Id. at 3.)

The court denied this motion in an order dated January 7, 2010:

> Arguments concerning claim construction should have been presented at the *Markman* hearing or in the briefs filed with the court in connection with the *Markman* hearing. The defendant did not file a motion for re-argument within the ten-day period after the *Markman* order was issued, as is required under Local Rule 7.1.5, and the court will not permit the parties to argue or re-argue matters of claim construction at this stage.

(D.I. 191.) Upon further consideration, however, the court recognized that without further intervention, CoreValve's prediction that the parties might litigate claim construction issues before the jury might prove to be a self-fulfilling prophesy. Consequently, the court announced at the pretrial conference that it would make a minor amendment to footnote 13 in order to specify how it was rejecting CoreValve's argument. The court then issued an order formalizing this amendment, which changed the last sentence of footnote 13 of the court's *Markman* order so that it read "the court rejects the defendant's proposed construction that requires 'a diameter that is constant along the longitudinal axis'" instead of simply "[t]he court rejects the defendant's proposed construction." (*Compare* D.I. 271 at 4, note 13, *with* D.I. 109 at 4, note 13.)

The court fervently hoped that this amendment would deter CoreValve from raising this claim construction issue again at trial. Unfortunately, it did not take long for CoreValve to dash those hopes. At trial, CoreValve witness Dr. Martin Rothman testified as follows when asked whether CoreValve's device had a shape "of or related to a cylinder" as required by the court's construction:

> Well, to my mind, again, the "related to," we're not taught related by how much. And I take the cylinder to have parallel sides or virtually parallel sides and that is my definition, general definition of a cylinder.

(Tr. 1636:23-1637:3.) Shortly thereafter, CoreValve's counsel asked the court at sidebar

whether they could make a proffer of "evidence concerning the cylindrical rotation that would be pursuant to [CoreValve's] proposed claim construction." (Tr. 1649:11-13.) The court denied the request and warned CoreValve to "stop pushing the issue." (Tr. 1649:14-18.) On cross examination, Dr. Rothman again testified, in response to a question as to the meaning of "cylinder" in the context of the claims, that he took "cylinder" to mean an object whose "diameter . . . remain[s] constant" between the sides. (Tr. 1693:12-16.) Dr. Rothman insisted that he applied the court's claim construction, but his testimony clearly conflicted with the court's clear statement in its claim construction order that "cylindrical" within the meaning of the claims does not require "a diameter that is constant along the longitudinal axis."

With hope springing eternal, the court believed that the end of the jury trial, combined with the court's explicit warning at sidebar, would finally lead CoreValve to recognize that it would accomplish nothing by continuing to harass the court with belated claim construction arguments. Once again, the court apparently hoped for too much. In its post-trial motions, CoreValve once again is urging the court to adopt their proposed constructions of "cylindrical" and "cylindrical support means" and test the jury's verdict against those constructions. (See D.I. 335 at 16-19.) It has raised this argument both in its renewed JMOL motion and in its motion for a new trial (see *infra*, section III.B).

When parties repeatedly attempt to revisit claim construction months after the court issues its *Markman* order, it wastes the court's time and undermines the court's ability to resolve legal issues in an efficient and timely manner. Moreover, such efforts are bound to fail, since counsel on both sides are well aware that this court simply will not permit the sort of wholesale relitigation of a disputed claim term that CoreValve has sought (and sought and sought again).

The problem is even more serious where, as here, the party presents a witness who testifies and provides an interpretation of claim term that is plainly at odds with the court's claim construction order. In addition to violating the Federal Circuit's repeated directives that claim construction issues not be brought up at trial, presenting such testimony creates the potential for jury confusion. Such conduct is simply unacceptable in light of trial counsels' duties as officers of the court.

If a party disagrees with one or more of the court's claim constructions, the appropriate course is for the party to make its record during the *Markman* phase and pursue that issue on appeal. If appropriate, the party may also file a motion for reargument under Local Rule 7.1.5, bearing in mind that such motions are only "sparingly granted." *See* Local Rule 7.1.5(a). If the party fails to file such a motion, they cannot later reopen the issue by repeatedly harassing the court with untimely motions, requests, and proffers of evidence relating to their rejected claim construction. Such actions serve no constructive purpose.[10] In the future, parties who engage in such conduct may face sanctions.

5. Damages

The court also rejects CoreValve's renewed JMOL motion with respect to damages. For the reasons stated below in Part III.B, the court concludes that a reasonable jury could have concluded that the first date of infringement was January 2006 and that Edwards would have been able to meet demand and make the necessary sales. A reasonable jury could likewise have rejected CoreValve's contention that it would not have been able to move its manufacturing operations abroad (thus allowing CoreValve to avoid infringement) before January 2006.

[10] The court notes that a party's ability to appeal from the court's *Markman* order to the Federal Circuit after the trial is complete is not, to its knowledge, enhanced in any way by repeated efforts to revisit the issue at later stages in the trial process.

Edwards cites evidence presented at trial that the expense of moving operations from Irvine, California to an overseas location would have been expensive and disruptive, and would have deprived CoreValve of key design experts. (E.g., Tr. 917:17-918:4; 925:3-927:8; 944:3-947:18.) For these reasons, the court will deny CoreValve's motion.

B. New Trial Motion

CoreValve also moves the court to grant a new trial on a number of bases. First, CoreValve argues that the verdict was contrary to the weight of the evidence for the reasons spelled out in its renewed JMOL motion. The court rejects these arguments for the reasons laid out in sections III.A.1-3, *supra.*[11]

CoreValve also requests a new trial because, it argues, the court's instruction as to "comprising" claims (see Jury Instruction 3.4) allowed the jury to read "projecting" out of the asserted claims. Jury Instruction 3.4 provides as follows:

> The preamble to Claim 1 of the '552 patent uses the phrase "the stent comprises." This claim is open-ended. The word "comprising" means "including" or "containing." As such, the claim is not limited to only what is in the claim.
>
> If you find that the CoreValve GEN 3 ReValving system includes all of the elements of Claim 1 of the '552 patent, the fact that the CoreValve GEN 3 ReValving system also may include features or components not required by the claims is irrelevant. The presence of additional features or components in the GEN 3 ReValving system would not avoid infringement of claim 1.

(D.I. 311, Final Jury Instructions at 19.) CoreValve does not argue that any portion of this instruction is legally incorrect. Nor could it – the meaning of "comprising" as an open-ended transition in patent claims is well-established and understood, supported by decades of Federal Circuit case law. *E.g.*, *CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir.

[11] CoreValve's arguments concerning "projecting" and "cylindrical support means" were yet another example of their efforts to reopen claim construction.

2007) ("In the patent claim context the term 'comprising' is well understood to mean 'including but not limited to.'").

Instead, CoreValve argues that the court erred in refusing to add the phrase "unless those additional features cause the accused device to lack a claim limitation" to the end of the instruction. The court is, frankly, at a loss to see how such an addendum is necessary in light of the fact that the instruction specifically begins with the words: "*If* you find that the CoreValve GEN 3 ReValving system *includes all of the elements* of Claim 1 of the '552 patent." (D.I. 311, Final Jury Instructions at 19 (emphasis added).) Moreover, the very next instruction reiterated that the jury could only find literal infringement of the asserted claim "if CoreValve's GEN 3 product includes each and every element in the asserted claim. . . . If CoreValve's GEN 3 product does not contain one or more elements recited in Claim 1, then CoreValve does not literally infringe that claim." (Id. at 20.) The court's instruction on the open-ended nature of "comprising" was accurate and straightforward. Including CoreValve's proposed addition would have been unnecessarily duplicative at best. At worst, it would have been misleading and confusing, since an instruction including the word "unless" might be construed as presenting a (non-existent) exception to the rule that additional features beyond those satisfying the limitations of a "comprising" claim are irrelevant. CoreValve's motion for a new trial based on this instruction is therefore denied.

For similar reasons, the court rejects CoreValve's motion for a new trial based on the instruction regarding the term "cylindrical." CoreValve specifically requested before trial that the instruction state: "On the other hand, an object described as cylindrical must function as a cylinder." The court denied this request. CoreValve now moves for a new trial because the final

construction relating to this term "emphasized the breadth of the claim term . . . by highlighting what the limitation does *not* require (a 'diameter constant along its length' or 'the presence of a perfect geometric cylinder')" without including "any explanation of what the claim limitation *does* require." (D.I. 336 at 10 (emphasis in original).) This portion of CoreValve's motion boils down to yet another effort to reopen claim construction on the terms "cylindrical" and "cylindrical support means." CoreValve's objection ignores the fact that the court's claim construction order specifically addresses the issue of whether a "cylindrical" object within the meaning of the claim must be a perfect geometric cylinder with a diameter that is constant along its length, but makes no reference to whether the object must "function as a cylinder." There is no requirement that the court "counterbalance" the construction adopted in its claim construction order with language proposed by the party whose construction it rejected.

CoreValve also moves for a new trial "to correct the exclusions of evidence about the conclusions of foreign courts concerning similarly-worded claims." (See D.I. 336 at 8-9.) However, as the "similarly-worded" characterization of the claims in question suggests, the claims for which CoreValve sought to introduce evidence are not the same as the claim asserted in this case. Indeed, as Edwards points out in its answering brief, the European claims at issue in the British and German cases differed in material ways from the '552 Patent, which was not and apparently could not be asserted in the European cases. Moreover, the parties do not appear to dispute that foreign courts have procedures, legal standards, and substantive laws that often differ substantially from those of American courts in patent infringement cases. In the court's judgment, these differences created a risk of unfair prejudice and jury confusion far outweighing the evidence's probative value. CoreValve's motion is, therefore, denied.

Lastly, CoreValve asks the court to either limit the jury's damages award to no more than $1.2 million, or grant a new trial on the issue of damages. (D.I. 336 at 12.) CoreValve contends that the jury based its damages award on a date of first infringement that was unsupported by the evidence presented at trial. (Id. at 13.) Moreover, CoreValve presented evidence that Edwards did not have the capacity to fulfill most of CoreValve's infringing sales. (Id. at 14.) According to CoreValve, the evidence presented at trial also shows that many of CoreValve's customers would have refused to use an Edwards device, indicating that Edwards did not lose potential customers to CoreValve. (Id. at 15-16.)

In response, Edwards contends that the jury was entitled to reject CoreValve's proposed date of first infringement, which was calculated based on the manufacture of a device that was not accused of infringement at trial. (D.I. 370 at 15-16.) Edwards contends that the jury also properly rejected CoreValve's noninfringing alternative of moving abroad because Edwards demonstrated that CoreValve had limited capital and could not design a marketable product abroad. (Id. at 16-17.) Moreover, Edwards contends that Edwards and CoreValve were in direct competition to train the same highly rated heart centers in the use of their products, resulting in lost profits to Edwards. (Id. at 18.) According to Edwards, the jury's verdict on lost profits is reasonable because it reflects damages only for the patients treated by CoreValve's infringing device which Edwards had the capacity to treat. (Id. at 18-19.)

The court concludes that the weight of the evidence in support of the damages award is not so lacking that, without remittitur or a new trial, a miscarriage of justice would result. The jury was entitled to reject CoreValve's proffered first date of infringement and accept Edwards' calculation based on the date that the infringing device was first manufactured. (Tr. 1521:12-

1522:23, 1549:6-24.) Moreover, Edwards presented sufficient evidence for the jury to reasonably conclude that Edwards lost customers to CoreValve, despite CoreValve's contention that Edwards was unable to meet existing demand. (Tr. 521:9-522:22; D.I. 329 at 964:6-967:16.) The jury's lost profits calculation, based on the number of patients treated with CoreValve's device who could have been treated by Edwards at the time, was also reasonable in light of the evidence presented at trial. (Tr. 958:1-961:12.) Furthermore, the jury was entitled to discredit CoreValve's contention that doctors would refuse to use Edwards' device, particularly since Edwards presented medical evidence showing that a patient in need of a transcatheter heart valve device would suffer a short, poor quality of life without one. (Tr. 909:9-911:11.) Thus, the court will uphold the jury verdict as it applies to the award of damages.

C. Motion for Enhanced Damages

Edwards seeks enhanced treble damages for CoreValve's willful infringement of the patent-in-suit. Pursuant to 35 U.S.C. § 384, a court may "increase the damages up to three times the amount found or assessed." An increased damages award requires a showing of willfulness. *Seagate*, 497 F.3d at 1368. A finding of willfulness, however, does not mandate enhanced damages, much less treble damages. *See Cybor Corp. v. FAS Techs, Inc.*, 138 F.3d 1448, 1461 (Fed. Cir. 1998) (citing *Modine Mfg. Co. v. The Allen Group, Inc.*, 917 F.2d 538, 543 (Fed. Cir. 1990); *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826 (Fed. Cir. 1992). "Rather, '[t]he paramount determination [for enhanced damages] . . . is the egregiousness of the defendant's conduct based on all the facts and circumstances.'" *Electro Scientific Indus., Inc. v. General Scanning, Inc.*, 247 F.3d 1341, 1353 (Fed. Cir. 2001) (citation omitted). Thus, enhancement of damages is within the discretion of the district court and is informed by the totality of the circumstances.

See State Indus., Inc. v. Mor-Flo Indus., Inc., 948 F.2d 1573, 1576 (Fed. Cir. 1991).

Factors the court may take into consideration when determining whether, and to what extent, to exercise its discretion include: (1) whether the infringer deliberately copied the ideas or design of another; (2) whether the infringer, when he knew of the other's patent protection, investigated the scope of the patent and formed a good-faith belief that it was invalid or that it was not infringed; (3) the infringer's behavior as a party to the litigation; (4) the infringer's size and financial condition; (5) the closeness of the case; (6) the duration of the infringer's misconduct; (7) any remedial action by the infringer; (8) the infringer's motivation for harm; and (9) whether the infringer attempted to conceal its misconduct. *Read Corp.*, 970 F.2d at 826. The ultimate question remains, however, "whether the infringer, acting in good faith and upon due inquiry, had sound reason to believe that it had the right to act in the manner that was found to be infringing." *SRI Intern., Inc. v. Advanced Technology Labs., Inc.*, 127 F.3d 1462, 1464-65 (Fed. Cir. 1997).

Upon consideration of the parties' submissions and the *Read* factors, the court finds that enhanced damages are not warranted in this case under 35 U.S.C. § 284. Although the jury found that CoreValve's infringement of the asserted claim was willful, the court finds that the issue was sufficiently close that enhanced damages are not warranted. CoreValve mounted a substantial challenge to Edwards' infringement contentions and presented considerable evidence in support of their assertions of non-infringement. *See Delta-X v. Baker Hughes Prod. Tools*, 984 F.2d 410, 413 (Fed. Cir. 1993) ("[A]n infringer may generally avoid enhanced damages with a meritorious good faith defense and a substantial challenge to infringement.") CoreValve's defenses, although ultimately unsuccessful, were not frivolous and – their repeated efforts to

reopen claim construction notwithstanding – were litigated in apparent good faith. Moreover, the court cannot discern any evidence that CoreValve copied Edwards' invention or attempted to conceal their infringement. Therefore, the court finds that enhancement of damages is inappropriate in this case.

D. Motion for Attorney's Fees

Because the court does not find this case to be exceptional by clear and convincing evidence as required by 35 U.S.C. § 285, the court will not award attorneys' fees and costs. In deciding whether to award attorney's fees, the court must undertake a two-step inquiry. *Interspiro USA, Inc. v. Figgie Intern. Inc.*, 18 F.3d 927, 933 (Fed. Cir. 1994). First, the court "must determine whether there is clear and convincing evidence that the case is 'exceptional.'" *Id.* (quotation omitted). Second, the court must determine whether "an award of attorney fees to the prevailing party is warranted." *Id.* Exceptional cases include: "inequitable conduct before the PTO; litigation misconduct; vexatious, unjustified, and otherwise bad faith litigation; a frivolous suit or willful infringement." *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1034 (Fed. Cir. 2002) (citation omitted).

An award of attorney fees under § 285 is not intended to be an "ordinary thing in patent cases," and should be limited to circumstances in which it is necessary to prevent "a gross injustice" or bad faith litigation. *Forest Labs., Inc. v. Abbott Labs.*, 339 F.3d 1324, 1329 (Fed. Cir. 2003); *see also Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1375 (Fed. Cir. 2001) (affirming an award of attorney fees under § 285 for the "extreme litigation misconduct" of falsifying evidence); *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547 (Fed. Cir. 1989) (affirming an award under § 285 following repeated violations of a permanent

injunction and a district court finding of a "strategy of vexatious activity").

The defendants' conduct in this case does not rise to a level of bad faith or vexatious litigation that warrants an award of attorneys' fees and costs. The court was, admittedly, dismayed at CoreValve's repeated efforts to reargue claim construction issues well after the *Markman* phase was complete, and this conduct weighs in favor of an award of attorney's fees. For the most part, however, the record demonstrates that both sides defended their respective positions throughout this litigation in apparent good faith. *See Forest Labs., Inc. v. Ivax Pharms., Inc.*, No. 03-891-JJF, 2008 U.S. Dist. LEXIS 14623, at *6-7 (D. Del. Feb. 26, 2008) (noting that "hard-fought" litigation does not necessarily constitute "vexatious or bad faith litigation" for purposes of awarding attorney fees under § 285). The court therefore finds that none of the parties are entitled to an award for attorneys' fees and costs in this case.

E. Prejudgment and Postjudgment Interest

The court will grant Edwards' motion for prejudgment and postjudgment interest (D.I. 344) and set the interest rate at the Prime Rate, compounded quarterly. "'The Federal Circuit has given district courts great discretion' when determining the applicable interest rate for an award of prejudgment interest." *IPPV Enterprises, LLC v. EchoStar Comm'n Corp.*, No. Civ. A. 99-577-KAJ, 2003 WL 723260, at *3 (D. Del. Feb. 27, 2003) (citation omitted). "Courts have recognized that the prime rate best compensate[s] a patentee for lost revenues during the period of infringement because the prime rate represents the cost of borrowing money, which is 'a better measure of the harm suffered as a result of the loss of the use of money over time.'" *IMX, Inc. v. LendingTree, LLC*, 469 F.Supp.2d 203, 227 (D. Del. 2007) (citing *Mars, Inc. v. Conlux USA Corp.*, 818 F.Supp. 707, 720-21 (D. Del. 1993), *aff'd*, 16 F.3d 421 (Fed. Cir. 1993)).

CoreValve's arguments to the contrary notwithstanding, the court concludes that the prime rate is a reasonable approximation of Edwards' cost of borrowing money during the relevant period. Accordingly, the court will order CoreValve to pay prejudgment and postjudgment interest at the prime rate, compounded quarterly.[12]

F. Permanent Injunction and Accounting

Edwards' final motion requests that the court issue a permanent injunction and order an accounting with respect to infringing sales made after March 15, 2010. The court will grant Edwards' motion in part and deny it in part. Specifically, the court will deny Edwards' request for a permanent injunction but will grant its request for an accounting.

A district court "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283. "According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction. *Id.* "Courts awarding permanent injunctions typically do so under circumstances where [the] plaintiff practices its invention and is a direct market competitor." *Advanced Cardiovascular Sys. v. Medtronic Vascular, Inc.*, 579 F. Supp. 2d 554, 558 (D. Del. 2008).

[12] Since the court is denying Edwards' motions for enhanced damages and attorney's fees, the court denies the motion as moot to the extent that it requests interest on those items.

While the *eBay* standard makes clear that past harm is relevant to the irreparable harm analysis, an injunction is by definition a prospective remedy. *See, e.g., i4i Ltd. Partnership v. Microsoft Corp.*, 598 F.3d 831, 861-62 (Fed. Cir. 2010) ("Although injunctions are tools for prospective relief designed to alleviate future harm, by its terms the first *eBay* factor looks, *in part*, at what has already occurred" (emphasis added)). In this case, the irreparable harm factor weighs against granting a permanent injunction for several closely-related reasons. First, the "irreparable" component of the injury that Edwards alleges stems from CoreValve's past conduct, and would continue even if a permanent injunction were issued. Edwards makes no allegations of *prospective* lost customers or harms that are truly irreparable unless the court issues a permanent injunction. On the contrary, the court concludes that with respect to the irreparable harms that Edwards alleges, Edwards would not benefit substantially from an injunction being issued at this stage, several years after CoreValve's accused product entered the market.

Tellingly, the heading of the irreparable harm section of Edwards' opening brief states: "Irreparable Harm is Shown by How CoreValve Caused Edwards to Lose First-Mover Advantage and Market Share." (D.I. 357 at 6.) As the past-tense phrasing of the heading indicates, the injury that Edwards identifies as irreparable stems from events that occurred well before trial. At its core, the irreparable injury that Edwards asserts stems from the fact that CoreValve was the first to enter the market for the technology in question. (See id. at 8.) As a result, Edwards argues:

> Edwards lost a substantial share of the market because of CoreValve's willful infringement, and Edwards lost the opportunity to establish relationships and train medical centers that it otherwise could have had CoreValve not been on the market. Moreover, Edwards' reputation as a global leader in the science of heart

> valves has been compromised by CoreValve's early unauthorized entry into the market and continued willful infringement.

(Id. at 8-9.)

A permanent injunction would not change the fact that CoreValve was the first to bring its technology to market, nor would it reverse the reputational damage done to Edwards as a result of CoreValve getting its product to market before Edwards. Edwards does not explain how the alleged competitive market advantage that CoreValve established before the trial would be remedied by a permanent injunction stretching into the future. Consequently, the court cannot conclude that Edwards' alleged irreparable injuries are redressable by injunction.

Second, Edwards' allegations of irreparable harm are undercut because CoreValve's infringement stems not from sales of the accused product, all of which occurred outside the United States, but rather from the manufacturing of the accused product in the United States.[13] Thus, Edwards must establish that CoreValve's *manufacturing* operations *in the United States* are continuing and will continue to cause irreparable harm if not enjoined. Edwards, however, does not appear to dispute that CoreValve would be able to move its remaining manufacturing operations to Mexico almost immediately if the court enjoined it from continuing to manufacture its products in the United States.[14] (See, e.g., D.I. 402 at 1 ("Even now, CoreValve admits that it has been moving off shore to Mexico since January 2010 and could immediately ramp up

[13] Edwards requests that the court issue a far wider injunction covering "all modes of infringement," apparently including infringement under § 271(f), even though the jury only decided the issue of infringement under § 271(a). Indeed, the court specifically ruled that Edwards could not raise § 271(f) infringement at trial in this case due to lack of notice. (See D.I. 280.) Moreover, infringement of the '552 Patent, including § 271(f) infringement, as a result of MedTronic's activities in Mexico is currently the subject of a separate infringement suit between the same parties in this court, *Edwards Lifesciences AG v. Medtronic, Inc.*, 09-873-GMS. The court will not issue an injunction covering potential modes of infringement that it has not yet adjudicated, and that have not yet had an opportunity for a full hearing.

[14] While the jury's verdict carried with it an implicit finding that CoreValve would not have been able to move its manufacturing operations abroad by January 2006, it carried no such implicit finding with respect to whether CoreValve could do so today.

manufacturing there."); id. at 7-8; D.I. 357 at 15.) Thus, CoreValve would remain in the market with little or no interruption even if the court were to enjoin its infringing manufacturing operations in the United States, and an injunction thus would not affect the alleged harm.

As to the second *eBay* factor, any harm that Edwards does continue to suffer as a result of CoreValve continuing its United States manufacturing operations can be redressed by a monetary remedy. As with the other *eBay* factors, the burden for establishing the inadequacy of legal remedies falls on the plaintiff. *E.g.*, *eBay*, 547 U.S. at 391 (stating that the plaintiff must satisfy the four-factor test and demonstrate the presence of each factor). In its brief with respect to this factor, Edwards argues that since CoreValve is the only competitor in the market, monetary damages are insufficient. (See D.I. 357 at 10.) Edwards cites no evidence or testimony in the record, however, in support of its assertion that monetary damages would be inadequate to compensate Edwards if CoreValve were permitted to continue its United States manufacturing operations. (See id. at 10-11.) Instead, its section addressing this factor is "nothing more than attorney argument." *See Telcordia Techs., Inc. v. Cisco Systems, Inc.*, 592 F. Supp. 2d 727, 748 (D. Del. 2009). As it did in this case, Edwards can bring suit against CoreValve and seek damages if CoreValve continues its infringing manufacturing operations in spite of the judgment of infringement. Moreover, Edwards has licensed the '552 Patent to a competitor, 3F Therapeutics, for a field of use that overlaps significantly with that of Edwards' Sapien product. (See A116.) While not determinative, such licensing activity is further evidence that monetary damages would be adequate to compensate Edwards for any future infringing manufacturing operations by CoreValve.[15] *See, e.g.*, *Telcordia*, 592 F. Supp. 2d at 748 n. 10.

[15] Since the court is denying Edwards' request for a permanent injunction, the parties may, of course negotiate a license regarding the patent-in-suit. As the Federal Circuit has stated:

The remaining two *eBay* factors do not alter the court's analysis, since the only practical effect of a permanent injunction would be that CoreValve would be forced to move its United States manufacturing operations for the accused product to Mexico. Consequently, Edwards' market position and the parties' ability to sell their products would remain substantially the same regardless of whether an injunction is issued. The court fails to see what hardship Edwards would suffer if CoreValve were permitted to continue manufacturing its product in the United States, as opposed to in Mexico, that could not be compensated through remedies at law. The public interest would not be substantially advanced or harmed by the issuance of an injunction, since CoreValve would be able to continue manufacturing accused product abroad without seriously affecting the supply of the product available to the public. Consequently, the court will deny Edwards' motion for a permanent injunction.

The court will grant, however, Edwards' request for an accounting of the number of CoreValve Revalving System devices made, used, sold, offered for sale, imported or supplied in or from the United States and corresponding revenue from March 16, 2010 through the date of the order accompanying this memorandum.[16]

G. Other Post-Trial Motions

In addition to renewed JMOL and new trial motions discussed above, there are also three

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> In most cases, where the district court determines that a permanent injunction is not warranted, the district court may wish to allow the parties to negotiate a license amongst themselves regarding future use of a patented invention before imposing an ongoing royalty. Should the parties fail to come to an agreement, the district court could step in to assess a reasonable royalty in light of the ongoing infringement.

Paice LLC v. Toyota Motor Corp., 504 F.3d 1293, 1315 (Fed. Cir. 2007).

[16] It does not appear that CoreValve opposes Edwards' accounting request. (*See* D.I. 392.) The court's order with respect to accounting is made with the understanding that CoreValve remains liable only for the type of infringement that was the subject of the jury's verdict. That is to say, Edwards' damages are limited to lost profits and reasonable royalties, plus pre-judgment and post-judgment interest at the Prime Rate, resulting from CoreValve's manufacturing of infringing devices in the United States. *See* note 13, *supra*.

other post-trial motions currently pending: CoreValve's Motion to Stay Judgment Pending Post-Trial Motions (D.I. 348), CoreValve's Local Rule 7.1.3(c)(2) Motion to Strike (D.I. 391),[17] and CoreValve's Motion to Supplement Court Record (D.I. 417). The court will deny each of these motions without comment.

IV. CONCLUSION

For the reasons stated above, the court will grant Edwards' motion for pre-judgment and post-judgment interest (D.I. 344), grant-in-part and deny-in-part Edwards' motion for permanent injunction, accounting and related relief (D.I. 356), and deny the remaining pending motions.

Dated: February 7, 2011

CHIEF, UNITED STATES DISTRICT JUDGE

[17] The motion is styled "Motion to Strike Under Local Rule 7.1.3(c)(2) Portions of Edwards' Reply Briefs in Support of Its Motions for Enhanced Damages and Attorneys' Fees." (D.I. 391.)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC, Plaintiffs, v. COREVALVE, INC. and, MEDTRONIC COREVALVE, LLC Defendants.	)	C.A. No. 08-91-GMS

ORDER

For the reasons set forth in the court's Memorandum of this same date, IT IS HEREBY ORDERED that:

1. CoreValve's Renewed Motion for Judgment as a Matter of Law (D.I. 318) is DENIED in all respects.
2. CoreValve's Motion for a New Trial or Alternatively to Amend Judgment (D.I. 320) is DENIED in all respects.
3. Edwards' Motion for Attorney Fees (D.I. 339) is DENIED.
4. Edwards' Motion for Enhanced Damages Pursuant To 35 U.S.C. § 284 (D.I. 341) is DENIED.
5. Edwards' Motion for Prejudgment and Postjudgment Interest (D.I. 344) is GRANTED. The court awards Edwards prejudgment and postjudgment interest, based on the prevailing prime rate, compounded quarterly.
6. CoreValve's Motion to Stay Judgment Pending Post-Trial Motions (D.I. 348) is DENIED.

7. Edwards' Motion for Permanent Injunction, Accounting and Related Relief (D.I. 356) is GRANTED IN PART AND DENIED IN PART. Specifically, the court denies Edwards' request for a permanent injunction, but grants its request for an accounting with respect to the number of CoreValve Revalving System devices made, used, sold, offered for sale, imported or supplied in or from the United States and corresponding revenue from March 16, 2010 through the date of the order.[1]

8. CoreValve's Local Rule 7.1.3(c)(2) Motion to Strike (D.I. 391) is DENIED.

9. CoreValve's Motion to Supplement Court Record (D.I. 417) is DENIED.

Dated: February 7, 2011

CHIEF, UNITED STATES DISTRICT JUDGE

[1] Within ten (10) days from the date of this order, CoreValve shall provide Edwards with an accounting of the number of CoreValve Generation 3 THV devices made, used, sold, offered for sale, imported or supplied in or from the United States and corresponding revenue from March 16, 2010 through the date of the order, in a format acceptable to Edwards, from which Edwards can calculate its monetary damages not accounted for in the April 1, 2010 jury verdict or other post-judgment orders by the court. Within forty (40) days from the date of this order, the parties shall file a joint statement stating the amount of pre- and post-judgment monetary damages and interest attributable to this accounting. In accordance with the memorandum and order of this date, interest shall be set at the prime rate compounded quarterly, and the order for accounting is made with the understanding that CoreValve remains liable in this case only for the type of infringement that was the subject of the jury's verdict. *See* Memorandum at 29, note 16.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 08-91-GMS
COREVALVE, INC.,	)	
Defendant.	)	

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 5,411,552; 6,168,614; AND 6,582,462

After having considered the submissions of the parties and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent Nos. 5,411,552 (the "'552 patent"), 6,582,462 (the "'462 patent"), and 6,168,614 (the "'614 patent"):

A. The '552 Patent

1. The term "elastical" in claim 1 of the '552 patent is construed to mean "capable of returning to an original shape when forces are removed."[1]

2. The term "stent" in claim 1 of the '552 patent is construed to mean "a medical device that is inserted into an anatomical vessel or passageway to provide support."[2]

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[1] The parties agree on the construction of this term.

[2] The court adopts a construction that is consistent with the "ordinary and customary meaning" of the term. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). The court rejects the defendant's proposed construction. The defendant's proposed construction is not supported by the patent specification or the prosecution history. Specifically, the terms "meshed" and "tube" are not found in the specification and, if accepted, would exclude certain

3. The term "commissural points" in claim 1 of the '552 patent is construed to mean "points or locations where the leaflets of the valve are joined."[3]

4. The term "cylindrical support means" in claim 1 of the '552 patent is construed to mean "a portion of the stent supporting the valve that has a shape of or relating to a cylinder."[4]

5. The term "radially collapsible" in claim 1 of the '552 patent is construed to mean "capable of reducing or of being reduced in diameter along a cross section of the cylindrical support means."[5]

6. The term "circumferentially-expandable section" in claim 1 of the '552 patent is construed to mean "a section of the cylindrical support means that is capable of

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embodiments of the invention. *See SanDisk Corp. v. Memorex Products, Inc.*, 415 F.3d 1278, 1285 (Fed. Cir. 2005) ("A claim construction that excludes a preferred embodiment . . . 'is rarely, if ever, correct.'") (citations omitted).

[3] The court adopts a construction that is consistent with the ordinary and customary meaning of the term and that gives effect to each term of the claim. *See In re Gabapentin Patent Lit.*, 503 F.3d 1254, 1263 (Fed. Cir.2007) (noting that "claims are interpreted with an eye towards giving effect to all terms in a claim").

[4] The court rejects the defendant's proposed construction because it imports claim limitations that are not supported by the patent specification or the prosecution history. *See CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005) ("[I]t is improper to 'import limitations from the specification into the claims.'") (citations omitted). Specifically, the term "mesh" and the limitation that the diameter be "constant along the longitudinal axis" are not found in the specification.

[5] The court adopts a construction that is consistent with the "ordinary and customary meaning" of the term. *Phillips*, 415 F.3d at 1312. The court rejects the defendant's proposed construction. Specifically, the limitation that the reduction in diameter be "along the longitudinal axis" is not supported in the specification. *See CollegeNet, Inc.*, 418 F.3d at 1231; *see also* '552 Patent, Col. 2, ll. 28-34, 56-60; Col. 6, ll. 20-30.

increasing or of being increased in diameter."[6]

7. The term "radially-expandable" in claim 1 of the '552 patent is construed to mean "capable of increasing or of being increased in diameter along a cross section of the cylindrical support means."[7]

8. The term "commissural supports" in claim 1 of the '552 patent is construed to mean "portions of the stent that support the commissural points of the valve."[8]

9. The term "projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof" in claim 1 of the '552 patent is construed to mean "projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis of the cylindrical support means."[9]

10. The term "by means of a technique of catheterization" in claim 1 of the '552 patent is construed to mean "use of a catheter to deliver the valve prosthesis."[10]

11. The term "thread structure" in claim 2 of the '552 patent is construed to mean "a portion of the stent comprising one or more segments, such as a grate, loop or helical

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[6] *See* footnote 3.

[7] *Cf.* footnote 5.

[8] The parties agree on the construction of this term.

[9] *See* footnote 3. The court notes that the parties' proposed constructions for this term are quite similar.

[10] The court adopts a construction that is consistent with the "ordinary and customary meaning" of the term. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). The court rejects the defendant's proposed construction. The defendant's proposed construction is not supported by the patent specification or the prosecution history.

shaped portion."[11]

B. The '462 Patent

1. The term "radially collapsible and expandable" in claim 1 of the '462 patent is construed to mean "capable of reducing or being reduced in diameter, and capable of increasing or of being increased in diameter, along a cross section of the stent."[12]

2. The term "cylindrical" in claim 1 of the '462 patent is construed to mean "having a shape of or relating to a cylinder."[13]

3. The term "cylindrical support means having a cylinder surface" in claim 1 of the '462 patent is construed to mean "a portion of the stent supporting the valve that has a shape of or relating to a cylinder, and that has a cylinder-shaped surface."[14]

4. The term "stent" in claim 1 of the '462 patent is construed to mean "a medical device

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[11] The court adopts a construction that is consistent with the patent specification. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367, 1371 (Fed. Cir. 2003) ("A fundamental rule of claim construction is that terms in a patent document are construed with the meaning with which they are presented in the patent document. Thus, claims must be construed so as to be consistent with the specification, of which they are a part."); *see also* '552 Patent, Col. 2, ll. 35-42.

[12] *Cf.* footnote 5.

[13] The court adopts a construction that is consistent with the "ordinary and customary meaning" of the term. *Phillips*, 415 F.3d at 1312. The court rejects the defendant's proposed construction.

[14] The court concludes that this is not a means-plus-function claim under 35 U.S.C. § 112(6) because claim 1 imparts sufficient structure so as to remove this element from the purview of § 112(6). *See Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1302 (Fed. Cir. 1999) ("Where a claim recites a function, but then goes on to elaborate sufficient structure . . . the claim is not in means-plus-function format."). In addition, the court adopts a construction that is consistent with the ordinary and customary meaning of the term and that gives effect to each term of the claim. *See In re Gabapentin Patent Lit.*, 503 F.3d at 263.

that is inserted into an anatomical vessel or passageway to provide support."[15]

5. The term "commissural points" in claim 1 of the '462 patent is construed to mean "points or locations where the leaflets of the valve are joined."[16]

6. The term "by way of catheterization" in claim 1 of the '462 patent is construed to mean "use of a catheter to deliver the valve prosthesis."[17]

7. The term "thread structure" in claim 2 of the '462 patent is construed to mean "a portion of the stent comprising one or more segments, such as a grate, loop or helical shaped portion."[18]

C. <u>The '614 Patent</u>

1. The term "movable from a collapsed shape to an expanded shape" in claim 1 of the '614 patent is construed to mean "capable of moving from a smaller shape to a larger shape."[19]

Dated: May 27, 2009

CHIEF, UNITED STATES DISTRICT JUDGE

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[15] *See* footnote 2.

[16] *See* footnote 3.

[17] *See* footnote 10.

[18] *See* footnote 11.

[19] *See* footnote 13.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 08-91-GMS
COREVALVE, INC.,	)	
Defendant.	)	

AMENDED ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 5,411,552; 6,168,614; AND 6,582,462

After having considered the submissions of the parties and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent Nos. 5,411,552 (the "'552 patent"), 6,582,462 (the "'462 patent"), and 6,168,614 (the "'614 patent"):

A. The '552 Patent

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[1] The parties agree on the construction of this term.

[2] The court adopts a construction that is consistent with the "ordinary and customary meaning" of the term. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). The court rejects the defendant's proposed construction. The defendant's proposed construction is not supported by the patent specification or the prosecution history. Specifically, the terms "meshed" and "tube" are not found in the specification and, if accepted, would exclude certain

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4. The term "cylindrical support means" in claim 1 of the '552 patent is construed to mean "a portion of the stent supporting the valve that has a shape of or relating to a cylinder."[4]

5. The term "radially collapsible" in claim 1 of the '552 patent is construed to mean "capable of reducing or of being reduced in diameter along a cross section of the cylindrical support means."[5]

6. The term "circumferentially-expandable section" in claim 1 of the '552 patent is construed to mean "a section of the cylindrical support means that is capable of

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embodiments of the invention. *See SanDisk Corp. v. Memorex Products, Inc.*, 415 F.3d 1278, 1285 (Fed. Cir. 2005) ("A claim construction that excludes a preferred embodiment . . . 'is rarely, if ever, correct.'") (citations omitted).

[3] The court adopts a construction that is consistent with the ordinary and customary meaning of the term and that gives effect to each term of the claim. *See In re Gabapentin Patent Lit.*, 503 F.3d 1254, 1263 (Fed. Cir.2007) (noting that "claims are interpreted with an eye towards giving effect to all terms in a claim").

[4] The court rejects the defendant's proposed construction because it imports claim limitations that are not supported by the patent specification or the prosecution history. *See CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005) ("[I]t is improper to 'import limitations from the specification into the claims.'") (citations omitted). Specifically, the term "mesh" and the limitation that the diameter be "constant along the longitudinal axis" are not found in the specification.

[5] The court adopts a construction that is consistent with the "ordinary and customary meaning" of the term. *Phillips*, 415 F.3d at 1312. The court rejects the defendant's proposed construction. Specifically, the limitation that the reduction in diameter be "along the longitudinal axis" is not supported in the specification. *See CollegeNet, Inc.*, 418 F.3d at 1231; *see also* '552 Patent, Col. 2, ll. 28-34, 56-60; Col. 6, ll. 20-30.

increasing or of being increased in diameter."[6]

7. The term "radially-expandable" in claim 1 of the '552 patent is construed to mean "capable of increasing or of being increased in diameter along a cross section of the cylindrical support means."[7]

8. The term "commissural supports" in claim 1 of the '552 patent is construed to mean "portions of the stent that support the commissural points of the valve."[8]

9. The term "projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof" in claim 1 of the '552 patent is construed to mean "projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis of the cylindrical support means."[9]

10. The term "by means of a technique of catheterization" in claim 1 of the '552 patent is construed to mean "use of a catheter to deliver the valve prosthesis."[10]

11. The term "thread structure" in claim 2 of the '552 patent is construed to mean "a portion of the stent comprising one or more segments, such as a grate, loop or helical

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[6] *See* footnote 3.

[7] *Cf.* footnote 5.

[8] The parties agree on the construction of this term.

[9] *See* footnote 3. The court notes that the parties' proposed constructions for this term are quite similar.

[10] The court adopts a construction that is consistent with the "ordinary and customary meaning" of the term. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). The court rejects the defendant's proposed construction. The defendant's proposed construction is not supported by the patent specification or the prosecution history.

shaped portion."[11]

B. The '462 Patent

1. The term "radially collapsible and expandable" in claim 1 of the '462 patent is construed to mean "capable of reducing or being reduced in diameter, and capable of increasing or of being increased in diameter, along a cross section of the stent."[12]

2. The term "cylindrical" in claim 1 of the '462 patent is construed to mean "having a shape of or relating to a cylinder."[13]

3. The term "cylindrical support means having a cylinder surface" in claim 1 of the '462 patent is construed to mean "a portion of the stent supporting the valve that has a shape of or relating to a cylinder, and that has a cylinder-shaped surface."[14]

4. The term "stent" in claim 1 of the '462 patent is construed to mean "a medical device

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[11] The court adopts a construction that is consistent with the patent specification. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367, 1371 (Fed. Cir. 2003) ("A fundamental rule of claim construction is that terms in a patent document are construed with the meaning with which they are presented in the patent document. Thus, claims must be construed so as to be consistent with the specification, of which they are a part."); *see also* '552 Patent, Col. 2, ll. 35-42.

[12] *Cf.* footnote 5.

[13] The court adopts a construction that is consistent with the "ordinary and customary meaning" of the term. *Phillips*, 415 F.3d at 1312. In other words, the court rejects the defendant's proposed construction that requires "a diameter that is constant along the longitudinal axis." (D.I. 51 at 6.)

[14] The court concludes that this is not a means-plus-function claim under 35 U.S.C. § 112(6) because claim 1 imparts sufficient structure so as to remove this element from the purview of § 112(6). *See Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1302 (Fed. Cir. 1999) ("Where a claim recites a function, but then goes on to elaborate sufficient structure . . . the claim is not in means-plus-function format."). In addition, the court adopts a construction that is consistent with the ordinary and customary meaning of the term and that gives effect to each term of the claim. *See In re Gabapentin Patent Lit.*, 503 F.3d at 263.

that is inserted into an anatomical vessel or passageway to provide support."[15]

5. The term "commissural points" in claim 1 of the '462 patent is construed to mean "points or locations where the leaflets of the valve are joined."[16]

6. The term "by way of catheterization" in claim 1 of the '462 patent is construed to mean "use of a catheter to deliver the valve prosthesis."[17]

7. The term "thread structure" in claim 2 of the '462 patent is construed to mean "a portion of the stent comprising one or more segments, such as a grate, loop or helical shaped portion."[18]

C. **The '614 Patent**

1. The term "movable from a collapsed shape to an expanded shape" in claim 1 of the '614 patent is construed to mean "capable of moving from a smaller shape to a larger shape."[19]

Dated: February 16, 2010

CHIEF, UNITED STATES DISTRICT JUDGE

[15] *See* footnote 2.

[16] *See* footnote 3.

[17] *See* footnote 10.

[18] *See* footnote 11.

[19] *See* footnote 13.

F

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,	:	
Plaintiffs,	:	
v.	:	C.A. No. 08-91 (GMS)
COREVALVE, INC. and MEDTRONIC COREVALVE, LLC.,	:	
Defendants.	:	

FINAL JURY INSTRUCTIONS

TABLE OF CONTENTS

PAGE

1. GENERAL INSTRUCTIONS 1
   - 1.1 INTRODUCTION 1
   - 1.2 JURORS' DUTIES 2
   - 1.3 EVIDENCE DEFINED 3
   - 1.4 DIRECT AND CIRCUMSTANTIAL EVIDENCE 4
   - 1.5 CONSIDERATION OF EVIDENCE 5
   - 1.6 STATEMENTS OF COUNSEL 6
   - 1.7 CREDIBILITY OF WITNESSES 7
   - 1.8 EXPERT TESTIMONY 8
   - 1.9 NUMBER OF WITNESSES / MEANS OF TESTIMONY 9
   - 1.10 BURDENS OF PROOF 10

2. THE PARTIES' CONTENTIONS 11
   - 2.1 THE PARTIES 11
   - 2.2 EDWARDS' CONTENTIONS 12
   - 2.3 COREVALVE'S CONTENTIONS 13
   - 2.4 SUMMARY OF PATENT ISSUES 14

3. INFRINGEMENT 15
   - 3.1 INFRINGEMENT OF PATENT CLAIMS 15
   - 3.2 CONSTRUCTION OF CLAIMS 16
   - 3.3 PATENT INFRINGEMENT – GENERALLY 18
   - 3.4 INFRINGEMENT OF OPEN ENDED OR "COMPRISING" CLAIMS 19
   - 3.5 LITERAL INFRINGEMENT 20
   - 3.6 INFRINGEMENT UNDER DOCTRINE OF EQUIVALENTS 21
   - 3.7 WILLFUL INFRINGEMENT 23

4. INVALIDITY DEFENSES 24
   - 4.1 SUMMARY OF THE INVALIDITY DEFENSE 24
   - 4.2 ENABLEMENT 25

4.3 LEVEL OF ORDINARY SKILL 26

5. DAMAGES 27
5.1 COMPENSATORY DAMAGES IN GENERAL 27
5.2 REASONABLE CERTAINTY 28
5.3 LOST PROFITS — "BUT FOR" TEST 29
5.4 LOST PROFITS — DEMAND 30
5.5 LOST PROFITS — CAPACITY 31
5.6 LOST PROFITS — AMOUNT OF PROFIT 32
5.7 REASONABLE ROYALTY — ENTITLEMENT 33
5.8 REASONABLE ROYALTY — DEFINITION 34
5.9 REASONABLE ROYALTY—RELEVANT FACTORS 35

6. DELIBERATION AND VERDICT 38
6.1 INTRODUCTION 38
6.2 DUTY TO DELIBERATE 40
6.3 COURT HAS NO OPINION 41

3.2 CONSTRUCTION OF CLAIMS

You have a copy of the '552 patent in your juror binder. As I already said, the claim at issue is Claim 1 of the '552 patent.

The meaning of a patent claim – what we call claim construction – is a question of law over which I have sole jurisdiction. I have already made the legal determination as to what the patent claim means. You must apply the definitions for certain terms in Claim 1 of the '552 patent as I construed them. In determining whether CoreValve infringes Claim 1 of the '552 patent, you may not assign your own meaning or understanding of these terms – you must follow my definitions. For any words in the claim for which I have not provided you with a definition, you should apply their ordinary meaning to one of skill in the art.

I will now provide you with a list of claim terms from Claim 1 of the '552 patent and the meaning of the terms the Court construed. For your convenience and reference, a copy of these claim terms are also set forth in Appendix A at the end of these instructions.

In Claim 1 of the '552 patent:

1. "elastical" means "capable of returning to an original shape when forces are removed";

2. "stent" means "a medical device that is inserted into an anatomical vessel or passageway to provide support";

3. "commissural points" means "points or locations where the leaflets of the valve are joined";

4. "cylindrical support means" means "a portion of the stent supporting the valve that has a shape of or relating to a cylinder." The term "cylindrical"

does not mean that the object described must be a cylinder with a diameter that is constant along its length or longitudinal axis. To put it another way, the term "cylindrical" as used in the patent in this case does not require the presence of a perfect geometric cylinder;

5. "radially collapsible" means "capable of reducing or of being reduced in diameter along a cross section of the cylindrical support means";

6. "circumferentially-expendable section" means "a section of the cylindrical support means that is capable of increasing or of being increased in diameter";

7. "radially-expandable" means "capable of increasing or of being increased in diameter along a cross section of the cylindrical support means";

8. "commissural supports" means "portions of the stent that support the commissural points of the valve";

9. "projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof" means "projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis of the cylindrical support means";

10. "by means of a technique of catheterization" means "use of a catheter to deliver the valve prosthesis."

APPENDIX A

U.S. Patent No. 5,411,552 ("the '552 patent'")

'552 CLAIM 1 TERMS	COURT'S CONSTRUCTION
"elastical"	"capable of returning to an original shape when forces are removed."
"stent"	"a medical device that is inserted into an anatomical vessel or passageway to provide support."
"commissural points"	"points or locations where the leaflets of the valve are joined."
"cylindrical support means"	"a portion of the stent supporting the valve that has a shape of or relating to a cylinder." The term "cylindrical" does not mean that the object described must be a cylinder with a diameter that is constant along its length or longitudinal axis. To put it another way, the term "cylindrical" as used in the patent in this case does not require the presence of a perfect geometric cylinder.
"radially collapsible"	"capable of reducing or of being reduced in diameter along a cross section of the cylindrical support means."
"circumferentially-expendable section"	"a section of the cylindrical support means that is capable of increasing or of being increased in diameter."
"radially-expandable"	"capable of increasing or of being increased in diameter along a cross section of the cylindrical support means."

'552 CLAIM 1 TERMS	COURT'S CONSTRUCTION
"commissural supports"	"portions of the stent that support the commissural points of the valve."
"projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof"	"projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis of the cylindrical support means."
"by means of a technique of catheterization"	"use of a catheter to deliver the valve prosthesis."

6

2011-1215, -1257

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

EDWARDS LIFESCIENCES AG and
EDWARDS LIFESCIENCES LLC,

Plaintiffs-Cross Appellants,

v.

COREVALVE, INC. and
MEDTRONIC COREVALVE, LLC,

Defendants-Appellants.

Appeals from the United States District Court for the District of Delaware
in Case No. 08-CV-0091, Chief Judge Gregory M. Sleet.

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May 18, 2011

CERTIFICATE OF INTEREST

Counsel for Defendants-Appellants CoreValve, Inc. and Medtronic CoreValve, LLC certify the following:

1. The full names of every party or amicus represented by us are:

   CoreValve, Inc. and Medtronic CoreValve, LLC

2. The names of the real parties in interest represented by us are:

   N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by us are:

   Medtronic Inc.

4. The names of all law firms and the partners or associates that appeared for the parties or amicus now represented by us in the trial court or that are expected to appear in this Court are:

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TABLE OF CONTENTS

PAGE

TABLE OF AUTHORITIES vi

STATEMENT OF RELATED CASES 1

JURISDICTIONAL STATEMENT 1

STATEMENT OF THE ISSUES 2

STATEMENT OF THE CASE 4

STATEMENT OF FACTS 5

A. Introduction 5

B. The Challenge: Impaired Aortic Valves 5

C. The '552 Patent 7

D. The Accused Device: CoreValve's Catheter-Implanted Artificial Heart Valve 11

E. European Litigation 15

F. District Court Proceedings: Claim Construction 16

G. District Court Proceedings: Trial Evidence 18

1. "Cylindrical support means" 18

2. "Projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof" 20

3. Evidence pertinent to enablement 23

H. District Court Proceedings: Verdict and Post-Trial Motions 25

I. Reexamination by the PTO 26

SUMMARY OF THE ARGUMENT 27

ARGUMENT 31

TABLE OF CONTENTS
(CONTINUED)

PAGE

I. THE DISTRICT COURT IMPROPERLY CONSTRUED "CYLINDRICAL SUPPORT MEANS" TO COVER NONCYLINDRICAL STRUCTURES. 32

A. The Intrinsic Evidence Supports The Ordinary Geometric Meaning Of "Cylindrical." 33

B. The District Court Improperly Construed "Cylindrical" To Include Any Shape "Relating To A Cylinder." 37

II. THE COREVALVE DEVICE DOES NOT INCLUDE COMMISSURAL SUPPORTS THAT PROJECT IN A DIRECTION GENERALLY PARALLEL TO THE LONGITUDINAL AXIS. 41

A. Edwards Failed To Prove That CoreValve's Commissural Supports Are "Projecting From" The Cylindrical Support Means. 42

1. The undisputed evidence established that "projecting from" means "protruding from" or "sticking out of." 42

2. CoreValve's integrated support structure does not include a plurality of commissural supports "projecting from" a cylindrical support means. 43

B. CoreValve's Commissural Supports Do Not Project In A Direction "Generally Parallel" To The Longitudinal Axis. 50

III. THE '552 PATENT IS NOT ENABLED FOR HUMAN USE 54

A. Claim 1 Encompasses A Device Suitable For Human Use. 55

B. The '552 Patent Disclosure Does Not Disclose How To Make A Heart Valve Prosthesis For Human Use 57

1. The quantity of experimentation needed shows that the '552 patent was not enabled 58

TABLE OF CONTENTS
(CONTINUED)

PAGE

2. The specification offers no guidance on how to make and use a prosthetic heart valve for human use. 61

IV. THE LOST PROFITS DAMAGES AWARD CANNOT BE SUSTAINED. 64

CONCLUSION 68

CONFIDENTIAL MATERIAL OMITTED

The material omitted on pages 4-5 and 26 contains information regarding Edwards' request for damages from the Parties' Statement Regarding Accounting of Monetary Damages and Interest for the Period March 16, 2010 - February 7, 2011, that was filed under seal. (Dkt. No. 439).

TABLE OF AUTHORITIES

Page(s)

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AK Steel Corp. v. Sollac,
344 F.3d 1244 (Fed. Cir. 2003) 56, 58

ALZA Corp. v. Andrx Pharm., LLC,
603 F.3d 935 (Fed. Cir. 2010) 54, 56, 57, 61, 62

Anchor Wall Sys. v. Rockwood Retaining Walls, Inc.,
340 F.3d 1298 (Fed. Cir. 2003) 34, 51

Automotive Techs. Int'l, Inc. v. BMW, Inc.,
501 F.3d 1274 (Fed. Cir. 2007) 31, 56, 57

Becton, Dickinson & Co. v. Tyco Healthcare Group,
616 F.3d 1249 (Fed. Cir. 2010) 31, 43, 49, 50

Cat Tech LLC v. TubeMaster, Inc.,
528 F.3d 871 (Fed. Cir. 2008) 51

Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.,
567 F.3d 1314 (Fed. Cir. 2009) 68

DSU Med. Corp. v. JMS Co.,
471 F.3d 1293 (Fed. Cir. 2006) 64

Edwards Lifesciences AG & Edwards Lifesciences LLC v. Medtronic, Inc., Medtronic CoreValve, LLC & Medtronic Vascular, Inc.,
No. 09-873-GMS (D. Del. filed Nov. 17, 2009) 1

Enzo Biochem, Inc. v. Calgene, Inc.,
188 F.3d 1362 (Fed. Cir. 1999) 54

Free Motion Fitness, Inc. v. Cybex Int'l, Inc.,
423 F.3d 1343 (Fed. Cir. 2005) 39

Gaus v. Conair Corp.,
363 F.3d 1284 (Fed. Cir. 2004) 50

Genentech, Inc. v. Novo Nordisk A/S,
108 F.3d 1361 (Fed. Cir. 1997) 57, 60

Grain Processing Corp. v. American Maize-Prods. Co.,
185 F.3d 1341 (Fed. Cir. 1999) 64, 65, 68

Helmsderfer v. Bobrick Washroom Equip., Inc.,
527 F.3d 1379 (Fed. Cir. 2008) 35

Hewlett-Packard v. Mustek Sys., Inc.,
340 F.3d 1314 (Fed. Cir. 2003) 42, 48, 53

Hologic, Inc. v. Senorx, Inc.,
___ F.3d ___, 2011 WL 651791 (Fed. Cir. Feb. 24, 2011) 31

International Rectifier Corp. v. IXYS Corp.,
361 F.3d 1363 (Fed. Cir. 2004) ..... *passim*

Kim v. ConAgra Foods, Inc.,
465 F.3d 1312 (Fed. Cir. 2006) 47, 53

Liebel-Flarsheim Co. v. Medrad, Inc.,
481 F.3d 1371 (Fed. Cir. 2007) 56

Marion v. TDI Inc.,
591 F.3d 137 (3d Cir. 2010), cert. denied, 131 S. Ct. 1479 (2011) 31

Phillips v. AWH Corp.,
415 F.3d 1303 (Fed. Cir. 2005) 33, 39

Playtex Prods., Inc. v. Procter & Gamble Co.,
400 F.3d 901 (Fed. Cir. 2005) 43

ResQNet.com v. Lansa, Inc.,
594 F.3d 860 (Fed. Cir. 2010) 64

Riles v. Shell Explo. & Prod. Co.,
298 F.3d 1302 (Fed. Cir. 2002) 65

Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.,
__ F.3d __, 2011 WL 651790 (Fed. Cir. Feb. 24, 2011) 31, 64, 65

Sitrick v. Dreamworks, LLC,
516 F.3d 993 (Fed. Cir. 2008) 56

Teleflex, Inc. v. Ficosa N. Am. Corp.,
299 F.3d 1313 (Fed. Cir. 2002) 36

Texas Instruments, Inc. v. Cypress Semiconductor Corp.,
90 F.3d 1558 (Fed. Cir. 1996) 47, 48, 53

Voda v. Cordis Corp.,
536 F.3d 1311 (Fed. Cir. 2008) 54

Wechsler v. Macke Int'l Trade, Inc.,
486 F.3d 1286 (Fed. Cir. 2007) 64

In re Wands,
858 F.2d 731 (Fed. Cir. 1988) 57

STATUTES

28 U.S.C. § 1295(a)(1) 1

28 U.S.C. § 1331 1

28 U.S.C. § 1338(a) 1

35 U.S.C. § 102(b) 10

35 U.S.C. § 103 10

35 U.S.C. § 112, ¶ 1 ..... 29, 54

35 U.S.C. § 271(a) 67

STATEMENT OF RELATED CASES

No other appeal in this civil action was previously before this Court or any other appellate court. Appellants' counsel are aware of one related district court case: *Edwards Lifesciences AG & Edwards Lifesciences LLC v. Medtronic, Inc., Medtronic CoreValve, LLC & Medtronic Vascular, Inc.*, No. 09-873-GMS (D. Del. filed Nov. 17, 2009).

JURISDICTIONAL STATEMENT

The district court had jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) because the asserted claims arise under the patent laws of the United States. A00113-A00153. On April 1, 2010, the jury returned a verdict in favor of Plaintiffs-Cross Appellants Edwards Lifesciences AG and Edwards Lifesciences LLC (collectively, "Edwards"). A00039-A00043. On April 29, 2010, Defendants-Appellants CoreValve, Inc. and Medtronic CoreValve LLC (collectively, "CoreValve") moved for judgment as a matter of law and a new trial. A08969-A08972, A08998-A09000. The district court entered judgment on the verdict on May 4, 2010. A00033-A00038. The court denied CoreValve's post-trial motions on February 7, 2011. A00001-A00032. On February 10, 2011, CoreValve filed a timely notice of appeal. A20036-A20038. This Court has jurisdiction under 28 U.S.C. § 1295(a)(1).

STATEMENT OF THE ISSUES

Claim 1 of Edwards' patent, U.S. Patent No. 5,411,552 (the "'552 patent"), is directed to a prosthetic aortic valve implantable by catheter. After over two decades of experimentation, neither the inventors nor their licensees have ever implanted a device taught by the '552 patent in a human patient. In contrast, the accused device, which was designed to mirror anatomical features of the aortic region, has been successfully implanted in over 10,000 human patients. A jury found the patent infringed and not invalid and awarded Edwards damages of over $73 million (including $72 million in lost profits), and the district court ordered an accounting of additional damages. The issues presented are:

1. Whether the district court erroneously construed the term "cylindrical" in Claim 1 to encompass any shape "relating to a cylinder" where the claim language contains no term modifying "cylindrical" and the court did not define either "cylinder" or "relating to."

2. Whether "commissural supports" that "project" from one side of the device in a direction "generally parallel" to the longitudinal axis, as required by Claim 1, are present in an accused device that supports the valve with an integrated structure angled at 30° to the longitudinal axis.

3. Whether Claim 1 was enabled where the patent is directed to a valve implantable in a human body, the device described in the patent was admittedly

unsuitable for human use, and no device based on the patent has been successfully implanted in a human body despite years of experimentation.

4. Whether the $72 million lost profits award should be vacated where undisputed evidence showed (a) CoreValve made an identical valve structure as early as fall 2004, (b) the accused device would have been noninfringing if CoreValve made it overseas, (c) CoreValve could have manufactured its device overseas by March 2007, and (d) Edwards first sold a competing product in August 2007.

STATEMENT OF THE CASE

Edwards and CoreValve manufacture and sell heart valve prostheses that are implantable by catheter. In February 2008, Edwards sued CoreValve, alleging infringement of the '552 patent and two other patents. A00113-A00118, A00056-A00064. Only Claim 1 of the '552 patent was pursued at trial. A10339.

The district court construed disputed claim terms in a *Markman* order issued May 27, 2009 (A00044-A00048) and amended February 16, 2010 (A00049-A00053). CoreValve challenges the court's construction of "cylindrical support means" to mean "a portion of the stent supporting the valve that has a shape of or relating to a cylinder." A00050. CoreValve agreed to an ordinary meaning instruction for the term "projecting," but as shown below neither Edwards, the court, nor the jury applied the ordinary meaning of that term to bring CoreValve's integrated structure within the terms of Claim 1.

A jury returned a verdict in favor of Edwards. A11973-A11981. The jury found that the CoreValve device literally infringed Claim 1 and that the '552 patent is not invalid for lack of enablement. *Id.* The jury awarded Edwards $72,645,555 in damages for lost profits and $1,284,861 as a reasonable royalty. *Id.* The district court denied CoreValve's post-trial motions for judgment as a matter of law and for a new trial (A00001-A00032). The court also ordered an accounting of damages incurred after the jury verdict, [[CONFIDENTIAL MATERIAL OMITTED

]] A20305-A20364, A20365-A20368.

STATEMENT OF FACTS

A. Introduction

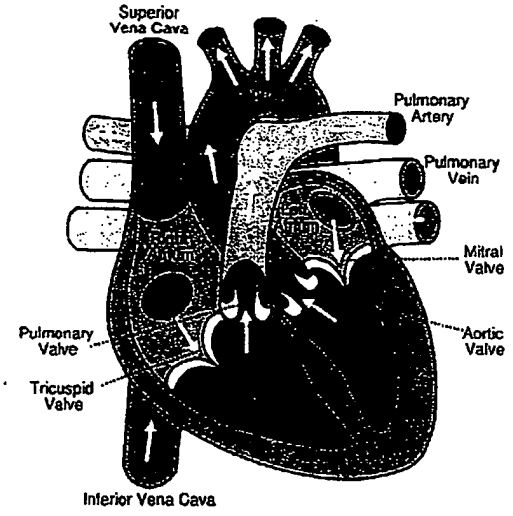
As described below, the accused device was the first prosthetic aortic valve ever approved for implantation in human patients via catheter rather than surgery. In the four years since that approval, surgeons have successfully implanted the device in more than 10,000 patients suffering from life-threatening aortic disease. This success resulted directly from CoreValve's innovative design changes to overcome defects in the prior art. In the case of the '552 patent, such defects prevented the patent licensees from developing a successful device suitable for human use despite more than two decades of experimentation.

Notwithstanding this striking contrast in both design and results, in the infringement proceedings below Edwards obtained a massive damages award and now seeks to enjoin CoreValve from continuing to make its device available to patients in need.

B. The Challenge: Impaired Aortic Valves

This case involves a new technology for medical devices used to replace defective heart valves. In the human body, several one-way valves regulate the flow of blood through the heart. A20080-A20081. For example, the aortic valve allows blood to pass from the left ventricle into the aorta when the heart beats, and

then snaps shut to prevent blood from moving back into the left ventricle between heart beats.



A12932.

The aortic valve can be impaired by aortic insufficiency or aortic stenosis. A20081-A20082. A diseased or damaged aortic valve can be replaced through open-heart surgery. A00061. In this procedure, a surgical team opens the patient's chest, stops the heart, circulates the blood through a machine, sews a replacement valve in place, restarts the heart, and closes the chest. *Id.* Like all major surgeries, open-heart surgery poses serious risks, especially for patients weakened by illness or age. *Id.* A less invasive, nonsurgical alternative to open-heart surgery is the implantation of a valve prosthesis—made up of a stent and valve—using a

catheter. CoreValve was the first to introduce a catheter-implanted valve prosthesis.

C. The '552 Patent

The '552 patent, entitled "Valve Pro[s]thesis For Implantation In The Body And A Catheter For Implanting Such Valve Pro[s]thesis," issued in 1995 based on an application claiming priority to a Danish application filed in 1990. A00056. The named inventors were Henning Andersen, John Hasenkam, and Lars Knudsen. *Id.* Edwards has since acquired all rights in the patent. A20088, A08661.

The '552 patent discloses a prosthetic valve attached to a stent that includes a "cylindrical support means" and "projecting" supports for the valve. A00061, A00063-A00064. The stent without the valve is depicted in Figure 1:

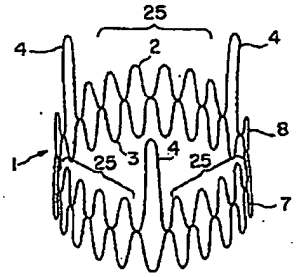


FIG. 1

A00057.

The specification identifies the three taller, "post"-like structures (4) in Figure 1 as "commissural supports." A00063. The tissue valve is attached to these

"commissural supports." "Commissural points" (5) are located where the valve leaflets meet just below the tips of the commissural supports, as shown below:

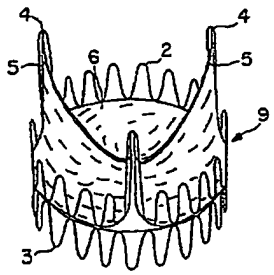


FIG. 2

A00057, A00063. The "commissural supports" must be "projecting" from one side of the "cylindrical support means" in a "direction generally parallel to the longitudinal axis." A00064. This design provides a reduction in weight compared to an exclusively cylindrical stent. A00063.

To implant the valve, a physician compresses it onto a balloon catheter and moves the catheter through a blood vessel to the implantation site. A00061-A00062. Figure 3 shows a partially inflated balloon catheter (11) introduced into the aorta (10) in the direction of arrow 12 (left to right). A00063.

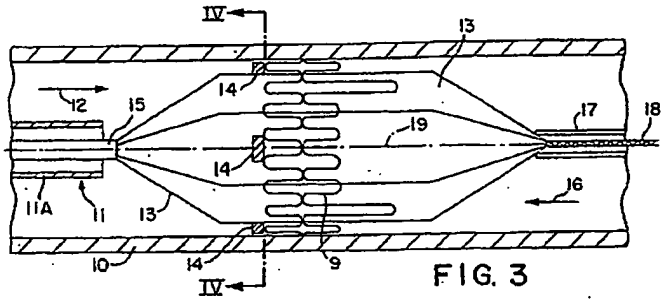


FIG. 3

Once the valve prosthesis is properly positioned (Figure 5), the physician inflates the balloon to expand the stent and valve (Figure 6). The balloon is then deflated and the catheter removed, leaving the expanded valve prosthesis in place (Figure 7). A00063.

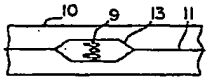


FIG. 5

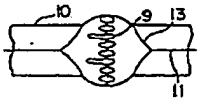


FIG. 6

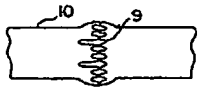


FIG. 7

Claim 1 of the '552 patent—the only claim at issue in this case— reads:

> A valve prosthesis for implantation in a body channel, the valve prosthesis comprising a collapsible elastical valve which is mounted on an elastical stent, the elastical valve having a plurality of commissural points, wherein the stent comprises:
>
> > ***cylindrical support means*** which is radially collapsible for introduction within the body channel and which has a plurality of circumferentially-expandable sections such that the ***cylindrical support means*** is radially expandable for being secured within the body channel; and
> >
> > a plurality of commissural supports ***projecting from one side of the cylindrical support means in a***

> ***direction generally parallel to the longitudinal axis thereof*** for supporting the commissural points of the collapsible valve, at least one circumferentially-expandable section of the cylindrical support means lying between each of the commissural supports, such that the collapsible valve may be collapsed and expanded together with the cylindrical support means for implantation in the body channel by means of a technique of catheterization.

A00064 (emphasis added).

The United States Patent and Trademark Office ("PTO") originally rejected the Andersen application under 35 U.S.C. §§ 102(b) and 103 in light of prior art disclosing valve prostheses comprising (1) a collapsible elastical valve with a plurality of commissural points and a radially expandable and collapsible stent (U.S. Patent No. 4,106,129 to Carpentier et al.); and (2) a collapsible elastical valve and a "flexible and bendable" stent (U.S. Patent No. 4,297,749 to Davis et al.). A20538-A20539, A20566-A20569. In response to the rejections, the applicants amended Claim 1 to add the language requiring the commissural supports to be "projecting" from the "cylindrical support means" in a "direction generally parallel to the longitudinal axis thereof." A20571-A20574.

Claim 1 contains three limitations relevant to this appeal: (1) "cylindrical support means" in the valve prosthesis; (2) commissural supports "projecting" from the cylindrical support means "in a direction generally parallel to the longitudinal axis"; and (3) "implantation in a body channel."

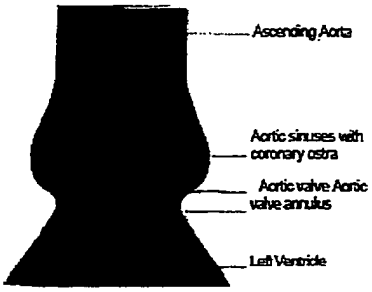
D. The Accused Device: CoreValve's Catheter-Implanted Artificial Heart Valve

As described below, the CoreValve device was carefully designed to overcome the known weaknesses and defects of the prior art, including the '552 patent.

In 2001, Dr. Jacques Seguin, a cardiologist who has performed over 7,000 open-heart surgeries, and Georg Bortlein founded CoreValve in France to develop a noninvasive catheter-based method of replacing aortic valves. A11116, A11250, A11260. Others had failed in their efforts, but CoreValve experimented with different materials, developed hundreds of prototypes, and extensively tested two "generations" of valves in humans before finalizing the design of the Generation 3 device (the "CoreValve device" that is accused here) in January 2006. A11118-A11146, A11496.

The CoreValve device reflected several fundamental design changes over the existing art—changes that led the PTO to issue patents covering the device's design even though CoreValve submitted the '552 patent to the PTO during patent prosecution. A31632, A33464. First, CoreValve designed the configuration of its device to mirror certain anatomical features of the implantation site—the junction between the ascending aorta and the left ventricle of the heart. A11285-A11288. As depicted below, at this site the diameter of the ascending aorta is more than

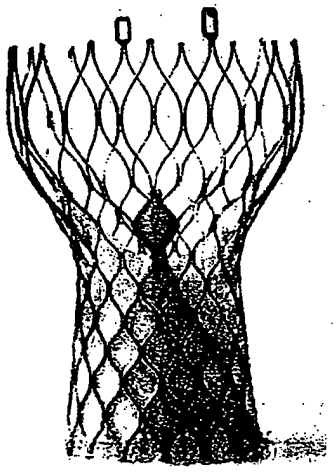
30% larger than the diameter of the small ring (or "annulus") that constricts the entrance to the left ventricle (A17915, A13003):



As a result, the annulus imposes far greater pressure on a stent than does the aorta, particularly since the annulus (unlike the aorta) is a strong muscle. A13003.

Because of the narrow diameter of the annulus, a cylindrical stent is poorly suited for implantation at this site. A11703-A11705. If the cylinder's diameter approximates the width of the annulus, it will not be securely anchored in either the aorta or the annulus. A11705-A11706. This can result in "migration" of the valve from the implantation site and death of the patient. A20190-A20191, A11703. Conversely, if the cylinder's diameter approximates the width of the aorta, it will close off the orifice portion of the coronary arteries. A12990. Furthermore, the differences in diameter between the aorta and annulus are so great that a cylindrical stent, once compressed and snaked into place with a catheter, cannot be "expanded" after implantation to accommodate the diameters in both regions at the same time. *Id.*

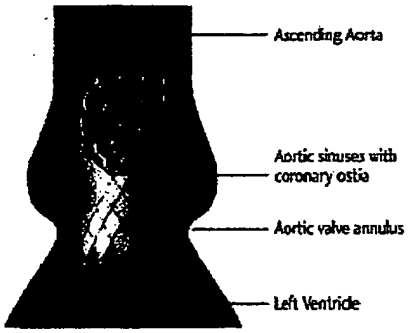
To solve these problems, CoreValve designed an integrated stent with diameters that vary significantly along its length. A11701-A11704. In this device, the upper end of the stent has a "bulbous" shape with a diameter that is more than twice the diameter of the bottom portion. A12946. This bulbous portion flares out at an angle of 30° from the center axis of the device. A11463, A11544-A11545. The stent's middle portion (or "waist") has a smaller diameter than the annulus, while the lower, "conical" portion gradually increases in diameter from the waist to the bottom at an angle of 5-7 degrees. A12989-A12990, A10737, A11285-A11286, A11565, A11901. The result is an integrated "chalice-shaped" device:



A12897.

This configuration provides important clinical advantages over a cylindrical stent. As depicted below, the upper "bulbous" portion of the stent optimizes anchoring in the aorta and thereby secures the stent in the vessel. A11286-

A11287, A11703-A11704. The stent's narrowed "waist" keeps the coronary arteries clear and enables the valve to function despite variations in the size of the aorta. A11286, A11720. The gradually increasing diameter of the "conical" lower portion secures the stent in the annulus and thereby prevents "migration" of the valve. A12987-A12990, A11703-A11704.



A12945.

The CoreValve inventors concluded that projecting posts would be prone to collapse under the stress of the valve's operation and therefore decided not to use them. A11131-A11132, A11693-A11694. Instead, the CoreValve device uses a "honeycomb" of "interlocking diamonds" to support the valve. A11541. The "diamonds" to which the valve is attached are on the 30° slope just above the narrow waist of the stent. A11463, A11542-A11543. The 30° angle enables the device to reduce the stress fatigue generated by the opening and closing of the

valve—much as an angled metal frame provides better support for a hammock suspended at the two ends of the frame. A11544-A11545.

In March 2007, the CoreValve device obtained European approval, making it the first catheter-delivered artificial aortic valve to be approved anywhere in the word for use in human patients. A11288, A20197-A20198. By the time of the trial below, physicians had implanted the device in approximately 10,000 patients. A11289.

E. European Litigation

In 2008, Edwards sued CoreValve in the United Kingdom and Germany, claiming that the CoreValve device infringed the European version of the '552 patent. A12929, A12961-A12962. The courts in both countries held that the CoreValve device did not meet the "cylindrical support means" limitation of the Edwards patent.[1]

---

[1] The relevant claim in the European version of the '552 patent reads:

> A valve prosthesis, preferably a cardiac valve prosthesis, for implantation in the body and comprising a collapsible elastical valve which is mounted on an elastical stent wherein the commissural points of the elastical collapsible valve are mounted on the cylindrical surface of the elastical stent characterized in that the stent is made from a radially collapsible and re-expandable ***cylindrical support means*** for folding and expanding together with the collapsible valve for implantation in the body by means of a technique of catheterization.

A17912.

The U.K. courts held that the term "cylindrical" should be given its "ordinary meaning," which the courts defined as having a "uniform circular cross-section at right angles to the axis of the circular cross section." A17914. The U.K. courts characterized Edwards' assertion that "cylindrical" did not require a "substantially constant diameter" as "strik[ing] a limitation out altogether." A17918-A17919. The U.K. courts further held that the CoreValve device did not meet the "cylindrical" limitation because it varied in diameter along its length to accommodate differences in diameter at the implantation site. A12946.

Similarly, the German courts construed the "cylindrical" limitation to require a "configuration having a circular diameter which remains essentially the same over the entire length of the device." A13001. Like the U.K. courts, the German courts expressly rejected Edwards' assertion that "cylindrical" did not require a constant diameter, reasoning that such a construction would render the term "superfluous." A13002. The German courts concluded that the CoreValve device did not meet the "cylindrical" limitation because the device featured differences in diameter along its length. A12987-A12990, A13004-A13006.

F. District Court Proceedings: Claim Construction

While the European actions were pending, Edwards brought the present action. By the time of trial, Edwards asserted only Claim 1 of the '552 patent, which the district court had construed after a *Markman* hearing. A10339.

The parties proposed the following constructions for "cylindrical support means":

CoreValve	Edwards
stent structure where the mesh has a diameter that is constant along the longitudinal axis	a portion of the stent supporting the valve that has a shape of or relating to a cylinder, including a barrel-like shape, but not limited to a cylinder shape in the strict geometrical sense

A00335. CoreValve argued that the term "cylindrical" should be given its "ordinary meaning" as a "geometric" figure in which the diameter remains constant along the longitudinal axis of the stent. A00399-A00404. By contrast, Edwards argued that "cylindrical" should be construed to include shapes somehow "relating to the shape of a cylinder," such as "barrel-like shapes" and other unspecified configurations that are not "geometric" cylinders. A00433-A00437.

The district court construed "cylindrical support means" to mean "a portion of the stent supporting the valve that has a *shape* of or *relating to* a cylinder." A00045, A00050 (emphasis added). In rejecting CoreValve's proposed construction, the court noted that "constant diameter along the longitudinal axis" does not appear in the specification. *Id.* The court did not explain why it adopted Edwards' construction of "cylindrical support means" to include shapes "relating to a cylinder." *Id.*

In construing the term "a plurality of commissural supports projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof," the district court construed "commissural supports" to mean "the portions of the stent that support the commissural points of the valve," and it construed "commissural points" to mean "points or locations where the leaflets of the valve are joined." A00045-A00046, A00050-A00051. The parties agreed that "projecting" and "generally parallel" should be given their plain and ordinary meaning. A08858-A08859.

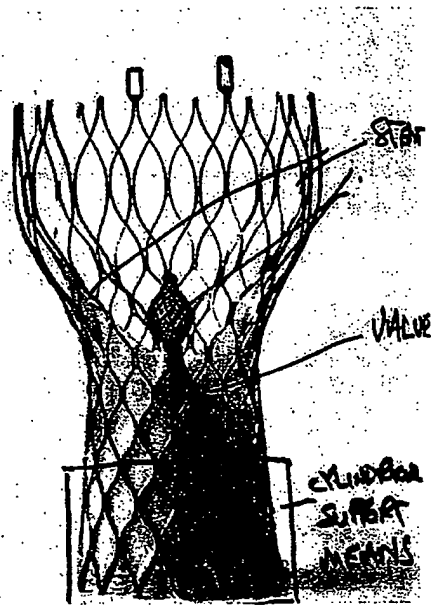
G. District Court Proceedings: Trial Evidence

An eight-day jury trial was held in March 2010. A00097-A00099. The witnesses included (1) the inventors of the '552 patent; (2) the developers of the accused CoreValve device; (3) other inventors who had developed an implantable heart valve without following the '552 patent; (4) the parties' liability experts—Dr. Leonard Pinchuk and Dr. Martin Rothman on behalf of CoreValve and Dr. Nigel Buller on behalf of Edwards; and (5) the parties' damages experts, Gregory Leonard for Edwards and Jeffrey Kinrich for CoreValve. The trial included substantial testimony relating to issues central to this appeal.

1. "Cylindrical support means"

To support its claim that the CoreValve device met the "cylindrical support means" limitation, Edwards relied on the testimony of its expert, Dr. Nigel Buller.

Noting that the district court's claim construction required that only a "portion" of the CoreValve stent had to meet the "cylindrical support means" limitation (A10857), Dr. Buller used a blue marker to draw a box around the area of the CoreValve stent that purportedly constituted the "cylindrical support means":



A31341. In testifying that the tapered section boxed above met the "cylindrical" limitation, Dr. Buller expressly relied on the district court's construction of "cylindrical support means" to be any "portion" of the stent supporting the valve that "has a shape of or relating to a cylinder." A10856.

In instructing the jury, the district court repeated its original claim construction language and added two new sentences stating that the "cylindrical support means" did *not* require a constant diameter along the length of its axis:

> 'cylindrical support means' means 'a portion of the stent supporting the valve that has a shape of or relating to a cylinder.' Now, *the term 'cylindrical' does not mean that the object described must be a cylinder with a diameter that is constant along its length or longitudinal axis.* To put it another way, the term 'cylindrical' as used in the patent in this case *does not require the presence of a perfect geometric cylinder.*

A11863 (emphasis added).

In closing argument, Edwards' counsel repeatedly emphasized this instruction. He first stressed that, under the district court's instruction, the term "cylindrical" was broad enough to include the "tapered" lower portion of the CoreValve device that Dr. Buller had circled:

> And [Dr. Buller] demonstrated where the cylindrical support means was [in the CoreValve device]. *And, yes it is slightly tapered on the bottom.* But the Judge's instructions make it clear that the word cylindrical support means does not require it to be *absolutely vertical.*

A11900-A11901 (emphasis added). Edwards' counsel then argued that CoreValve's description of the lower portion of the device as "cone-shaped" did not matter because the "judge has instructed you that *cylindrical doesn't mean cylinder*." A11958 (emphasis added).

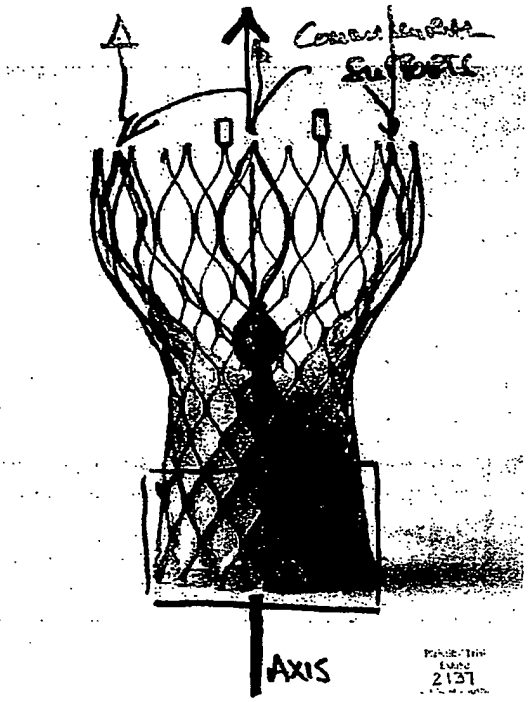
2. "Projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof"

In addressing the "projecting" limitation, the CoreValve experts (Pinchuk and Rothman) both testified that a skilled artisan in 1990 would have understood

the term "projecting from one side of the cylindrical support means" to refer to a commissural support that "protruded from" or "stuck out of" the cylindrical support means. A11538, A11707-A11709. They further testified that the CoreValve device does not meet this limitation because the device does not include identifiable commissural supports that "protrude" from any cylindrical support means. *Id.* Instead, the CoreValve device is an "integral structure"—"much like a honeycomb"—in which each of the "interlocking diamonds" is indistinguishable from the other. A11541.

In addressing the "generally parallel" limitation, CoreValve's experts testified that a skilled person would have understood that the phrase "generally parallel" does not describe a vertical axis and a line that intersects the vertical axis at a 30° angle. A11543, A11714-A11718. The CoreValve experts therefore concluded that the CoreValve device also failed to meet the "generally parallel" limitation. A11543-A11545, A11714-A11718.

Dr. Buller testified on behalf of Edwards that the CoreValve device met both the "projecting" and "generally parallel" limitations. He used a red marker to draw the longitudinal axis on a photograph of the CoreValve device and then a green marker to draw what he claimed to be the "commissural supports":



A31342.

Dr. Buller acknowledged that the preferred embodiments in the '552 patent depict the "projecting" commissural supports as taller loops that are clearly distinguishable from the rest of the cylindrical stent. A10937-A10940.[2] He nevertheless testified that the CoreValve device meets the "projecting" limitation because the "*whole structure*, one can say, is *projecting generally upwards*." A10971 (emphasis added). Dr. Buller explained that by "whole structure," he meant the "whole of the structure that *goes up to the end of the stent*," even though

[2] Buller also acknowledged that the two rectangular tabs atop the CoreValve device are not commissural supports but simply lock the device onto the catheter. A10946-A10947.

the commissural points of the valve are mounted in the middle of that structure. *Id.* (emphasis added). He analogized the upper half of the CoreValve device to a spoon or fork that has "bends to it" (*i.e.*, the neck bends away from the vertical axis) but the "whole structure" still points "generally upwards." *Id.* Finally, Dr. Buller contended that a skilled artisan might consider a 30° angle to be "generally parallel" to the longitudinal axis. A10972.

At the close of the evidence, the district court gave the following instruction on the "projecting" limitation:

> "projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof" means "projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis of the cylindrical support means."

A11864.

3. Evidence pertinent to enablement

Addressing the enablement issue, the named inventors admitted that they never tried to implant their valve in a human body. A20133, A20234. Instead, from September 1989 to March 1992, they attempted to implant their device in 41 pigs, but were "successful" or "partially successful" only 14 times. See A23460-A24169. Even in the 14 "successful" trials, the pigs receiving an implanted valve lived no more than five hours, and most lived only one hour or less. A20119-A20121, A20172, A23460-A24169. In these cases, the inventors had "great

difficulty" in keeping the device in the annulus of the animal, primarily because of the "migration" of the stent away from the site of implantation. A10903-A10904.

The inventors acknowledged that their device was unsuitable for clinical use in humans. A20138-A20139. Rather, "many important questions remain[] to be answered about the stent-valve," and "many more complex and long-term animal studies must be performed before even *speculation* concerning clinical use is begun." A31403-A31409 (emphasis added).

The evidence at trial showed that neither Edwards nor any of the other '552 patent licensees has ever been able to develop a device for human use based on the '552 patent. Stanford Surgical (later renamed Heartport), which licensed the patent from 1993-2000, made no progress in developing a device suitable for human use. A20139-A20145, A11889, A24529. Nor did Percutaneous Valve Technology ("PVT") after it purchased the license in December 2000, even though PVT enlisted highly regarded interventional cardiologist Alain Cribier to assist in the effort. A20257-A20264. Dr. Cribier ultimately concluded that the '552 patent design was "impossible to use in clinical practice." A11379-A11380. PVT agreed, concluding that the '552 patent "sadly does not describe a method or design that, if constructed, is percutaneous and functional over any durable period." A11674-A11675. PVT therefore abandoned its efforts to develop a valve prosthesis for human use based on the "projecting commissural supports"

described in the '552 patent. A11235-A11236, A24539-A24555 (at A24546), A31591-A31608 (at A31594). Instead, PVT developed the "Cribier valve" which did not use the projecting commissural supports required by the '552 patent. A11366-A11367, A11371, A11383.

Edwards acquired PVT in December 2003 and renamed the Cribier valve the "SAPIEN valve." A20256-A20257, A20264, A10632, A23270-A23362. Edwards obtained approval in Europe to sell one version of its SAPIEN device in August 2007. A20266. At the time of trial, the SAPIEN device had not been approved for use in the United States. A10618, A20269.

H. District Court Proceedings: Verdict and Post-Trial Motions

The jury returned a verdict in favor of Edwards. A00039-A00043. As relevant here, the jury found that the CoreValve device literally infringes Claim 1 and that Claim 1 is not invalid for lack of enablement. *Id.* The jury awarded Edwards $72,645,555 in lost profit damages—the full amount of estimated by Edwards' expert—and $1,284,861 in reasonable royalty damages. *Id.*

The district court denied CoreValve's post-trial motions for JMOL and a new trial. A00001-A00032. Although the jury had found that CoreValve willfully infringed the '552 patent, the district court denied Edwards' motions for enhanced damages and attorneys' fees. A00021-A00024. It also denied Edwards' motion for a permanent injunction to prohibit CoreValve from making the CoreValve

device in the United States. A00025-A00029. Finally, the court ordered an accounting of damages incurred since the date of the jury verdict. A00029. [[

CONFIDENTIAL
MATERIAL OMITTED

]] A20305-A20364, A20365-A20368.

I. Reexamination by the PTO

In July 2010, CoreValve submitted a request for *ex parte* reexamination of the '552 patent. A19929-A19976. CoreValve argued that several of Edwards' positions in this litigation raised a "substantial new question of patentability." *Id.* CoreValve submitted portions of the public record from the litigation, including (1) the district court's construction of "cylindrical support means"; (2) color copies of Dr. Buller's slides with his drawn-in-green "projecting commissural supports" in the CoreValve device; and (3) Dr. Buller's testimony that a 30° deviation could be "generally parallel" to the longitudinal axis. *Id.*

On September 10, 2010, the PTO granted the Request, finding that two prior art references, viewed in light of Edwards' positions in this litigation, raised a "substantial new question of patentability." *Order Granting Request for Ex Parte Reexamination*, USPTO Appl. No. 90/009779, Sept. 10, 2010, http://portal.uspto.gov/external/portal/pair. The PTO cited Dr. Buller's trial testimony that the CoreValve device meets the "cylindrical" limitation even though

its sides are not parallel. *Id.* at 6-8. The PTO also found "of particular interest" the slides that Dr. Buller "marked up" to show the "projecting commissural supports." *Id.* The PTO therefore commenced an *ex parte* re-examination of the '552 patent, which remains pending.

SUMMARY OF THE ARGUMENT

The '552 patent inventors failed in their attempt to devise a catheter-delivered prosthetic aortic valve for human use. In over two decades of experimentation, neither they nor successive licensees were able to implant a device based on the '552 patent in a human patient. The cylindrical shape and projecting supports that are central to the design of the claimed invention do not provide the stability and strength required for a workable replacement aortic valve. In contrast, the CoreValve inventors succeeded because they devised features directed to the actual anatomy of the human heart, enabling the CoreValve device to save many thousands of lives. Edwards now seeks to garner enormous damages from CoreValve's innovation and success. This Court should reverse the judgment below to protect both lives and innovation.

CoreValve developed a chalice-shaped stent of varying diameters with a bulbous upper portion flaring 30° out from a narrow waist and a bottom portion with a more gradually increasing diameter. CoreValve also devised a stent structure consisting of a honeycomb of rounded, interconnecting diamonds, and it

attached the commissural points of the valve to the angled slope of the stent above the waist, with no need for projecting commissural supports that are prone to collapse. Precisely because of its differences from the '552 patent, this design provided optimal strength and stability.

The district court erred in construing "cylindrical" and in sustaining the jury verdict on infringement, non-enablement, and damages.

I.

The district court improperly construed "cylindrical support means" to include any structure that has a "*shape of or relating to a cylinder*," thereby authorizing the jury to find that CoreValve's noncylindrical device infringed Claim 1. The court should have given "cylindrical" its ordinary geometrical meaning, as this Court did with the term "polygonal" in *International Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363 (Fed. Cir. 2004). The claim language does not modify "cylindrical" with an adjective like "substantially" or "generally," and the specification shows that the inventors intended "cylindrical" to bear its plain geometric meaning. By contrast, nothing in the claim language or specification indicates any intent to use a different meaning.

II.

The CoreValve device does not have commissural supports "projecting" in a direction "generally parallel" to the longitudinal axis of the support means. The

magic marker of Edwards' expert cannot change an integrated mesh stent into something that projects from one of its own ends.

The evidence was undisputed that nothing protrudes or sticks out from the CoreValve device, which supports the valve with the integrated honeycomb structure of its chalice-shaped stent. Edwards nonetheless contended, based solely on conclusory expert testimony, that the entire CoreValve device projects generally upwards, thereby meeting the "projecting" limitation. Such an expert *ipse dixit*, lacking factual support and conflicting with the ordinary meaning of claim terms, cannot sustain an infringement verdict.

Likewise lacking competent evidentiary support was the jury's conclusion that the CoreValve commissural supports project in a direction "generally parallel" to the longitudinal axis of the support means. The undisputed evidence showed that the commissural points lie on the 30°-angled slope above the waist of the CoreValve device. The infringement verdict cannot be sustained by Edwards' expert's strained analogy to a fork to characterize a 30° deviation as "generally parallel."

III.

Claim 1 of the '552 patent also is invalid because it fails to satisfy the enablement requirement of 35 U.S.C. § 112, ¶ 1. The specification makes clear that the full scope of the claim includes a valve suitable for implantation in a

human body channel. At the time of the patent application, there was no known means to achieve that purpose using the disclosed device. Most of the pigs in which the exemplary device was implanted died within minutes of implantation, and none survived more than five hours. Put bluntly, implantation of the device claimed in the '552 patent killed even the hardiest veterinary "patient," and no one dared implant it in a human. Indeed, after two decades of extensive experimentation, no one implementing the patent's teachings has developed a device suitable for human use. Accordingly, the full scope of Claim 1 was not enabled at the time of the patent application, mandating judgment of invalidity.

IV.

Finally, if the judgment is not otherwise reversed, the award of lost profits damages should be vacated as contrary to law. The date of first infringement triggers the hypothetical effort to use a noninfringing substitute, which here means manufacturing the same device overseas. The only evidence of *first* infringement places that date in fall 2004, when CoreValve first made its Generation 2 device. The frame structure of the Generation 2 device is indisputably identical to that in the accused Generation 3 device, making them identical for infringement purposes. In fall 2004, CoreValve's facilities were in Europe. Had CoreValve called off its then-impending move to California, manufacture of the Generation 3 device in Europe would not have infringed the '552 patent (assuming it otherwise would

have). The only evidence on the point showed that CoreValve could have manufactured its device overseas by March 2007, before Edwards was authorized to sell (and profit from) a single SAPIEN valve. The lost profits award should be vacated.

ARGUMENT

Standard of Review. Claim construction rulings are reviewed *de novo*. *Hologic, Inc. v. Senorx, Inc.*; ___ F.3d ___, 2011 WL 651791, at *4 (Fed. Cir. Feb. 24, 2011). Denials of motions for judgment as a matter of law also are reviewed *de novo* under the law of the Third Circuit, where the district court sits. *Marion v. TDI, Inc.*, 591 F.3d 137, 146 (3d Cir. 2010), cert. denied, 131 S. Ct. 1479 (2011). JMOL of non-infringement is mandated "where the record is critically deficient of the minimum quantum of evidence" necessary to support a jury verdict. *Becton, Dickinson & Co. v. Tyco Healthcare Group*, 616 F.3d 1249, 1253 (Fed. Cir. 2010). Compliance with the enablement requirement is a question of law reviewed *de novo*, based on underlying facts reviewed for clear error. *Automotive Techs. Int'l, Inc. v. BMW, Inc.*, 501 F.3d 1274, 1281 (Fed. Cir. 2007). Eligibility for lost profits is reviewed *de novo*, with findings on necessary elements reviewed for substantial evidence. *Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, __ F.3d __, 2011 WL 651790, at *13 (Fed. Cir. Feb. 24, 2011).

As demonstrated below, CoreValve is entitled to a revised construction of the claim term "cylindrical support means," to judgment as a matter of law on both infringement and invalidity, and to an order vacating the awarded lost profits.

I. THE DISTRICT COURT IMPROPERLY CONSTRUED "CYLINDRICAL SUPPORT MEANS" TO COVER NON-CYLINDRICAL STRUCTURES.

The district court construed "cylindrical support means" as "a portion of the stent supporting the valve that has *a shape of or relating to a cylinder*." A00050 (emphasis added). As the court told the jury, under that construction "the term cylindrical does not mean that the object described must be a cylinder." A11863. By encompassing any shape "relating to a cylinder," the court's construction erroneously departed from the ordinary meaning of "cylindrical," which is simply the adjectival form of "cylinder," a geometric term with a plain and precise meaning.

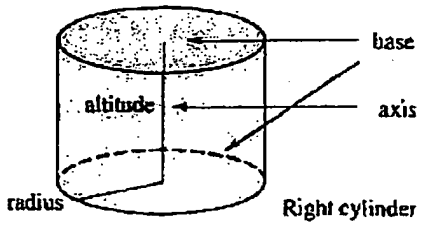
A geometric claim term without words of "modification or qualification" must be given its precise meaning. *Int'l Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1372 (Fed. Cir. 2004) (construing "polygonal" in accordance with the precise geometric meaning of "polygon"). The district court's construction of "cylindrical" to include any shape "relating to" a cylinder—without defining either "cylinder" or "relating to"—deviated from the term's plain meaning and effectively read the "cylindrical" limitation out of the claim.

A. The Intrinsic Evidence Supports The Ordinary Geometric Meaning Of "Cylindrical."

In construing claim terms, courts should rely primarily on the intrinsic record: the claim language, specification, and prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-17 (Fed. Cir. 2005) (en banc). In this case, the claim language and specification both support the conclusion that the term "cylindrical" should be given its ordinary geometric meaning (and the prosecution history is silent on the point).

Patent claim terms are to be given their "ordinary and customary meaning," as understood by one skilled in the art at the time of filing, unless the patentee expressed a clear intent to deviate from that meaning. *Phillips*, 415 F.3d at 1312-13. Nothing in the '552 patent reflects an intent—much less a clearly expressed intent—to give "cylindrical" anything other than its ordinary geometric meaning.

The term "cylindrical" is the adjectival form of the geometric term "cylinder." A00635. As reflected in contemporaneous dictionaries and textbooks, a skilled artisan would have understood "cylinder" to be a geometric shape formed by moving a straight line in a circular path around another parallel line (or axis), resulting in a three-dimensional shape with a constant diameter. See A00635, A00637, A00641, A00645-A00646.



A00645.[3]

The plain language of Claim 1 describes "cylindrical support means" without using any words of "modification or qualification" such as "generally" or "substantially" to broaden the scope of the geometric term. *Int'l Rectifier*, 361 F.3d at 1372. Similar "descriptive terms are commonly used in patent claims to avoid a strict numerical boundary to the specified parameter." *Anchor Wall Sys. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1310-11 (Fed. Cir. 2003). If a patentee uses a mathematical or geometric term *without* a modifier, however, the term receives its ordinary—and precise—meaning. *Id.*; *Int'l Rectifier*, 361 F.3d at 1372.

While the '552 patent does not qualify "cylindrical" in Claim 1, it does use modifiers to broaden the meaning of other geometric terms. For example, Claim 1 uses the phrase "*generally* parallel" to describe the relationship between the "commissural supports" and the device's longitudinal axis—showing that the two

[3] The diagram shows a "right" cylinder, but all cylinders have constant diameters, even when the angle of the longitudinal axis deviates from 90°. See A00645.

lines need not be exactly "parallel" to satisfy the limitation. A00064 (emphasis added). Similarly, the specification uses "*substantially* cylindrical" to describe an embodiment in which one part of the structure is not a perfect geometric cylinder. A00063 (emphasis added). Because the '552 patentees elsewhere used terms of "modification or qualification" to broaden the meaning of specific geometric terms, their decision to use the phrase "cylindrical support means" *without* qualification should be given especially heavy weight. *Int'l Rectifier*, 361 F.3d at 1372.

The '552 specification confirms that "cylindrical" should be given its ordinary geometric meaning. First, the specification expresses no clear intent to depart from the ordinary geometric meaning of "cylindrical." *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008). Second, the specification repeatedly describes the claimed invention using "cylindrical" in its geometric sense. For example, the figures in the specification show the support means as a cylinder with a constant diameter or uniform cross-section:

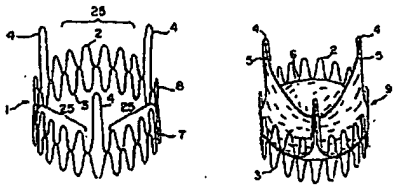


FIG. 1

FIG. 2

A00057.

Third, the specification provides "context" that reinforces the idea of a supporting stent in the shape of a cylinder. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1326-27 (Fed. Cir. 2002). For example, the specification describes the stent as constructed from wire "rings" that are sutured together—clearly indicating a stent with a uniform circumference (and hence a uniform diameter) along its axis. A00063-A00064. In addition, the specification repeatedly refers to the device's singular "diameter" and "circumferentially-expandable sections," further confirming that "cylindrical" is used in accordance with its ordinary geometric meaning. *Id.*

Confirming this meaning of "cylindrical," the U.K. and German courts construed the term in the European version of the '552 patent to reflect the geometric characteristics of a "cylinder" under its "ordinary and customary" meaning—a three-dimensional shape with a constant diameter (or, equivalently, a uniform cross-section):

Court	Construction of "Cylinder" or "Cylindrical"
U.K. lower court	A three dimensional shape having a "substantially constant diameter" (A12945)
U.K. appeals court	A three-dimensional shape having a "uniform circular cross-section at right angles to the axis of the circular cross-section" (A17914)
German lower court	A three dimensional shape having a "uniform diameter over its length" (A12970)

Court	Construction of "Cylinder" or "Cylindrical"
German appeals court	A three-dimensional shape having a "circular diameter which remains essentially the same over the entire length of the device" (A13001)

The German and U.K. courts expressly rejected Edwards' assertion that the term "cylindrical" does not require a shape with a constant diameter, reasoning that such a construction would render the "cylindrical" limitation "superfluous" or "strike [the] limitation out altogether." A13002, A17918-A17919.

Thus, as reflected in both the intrinsic and contemporaneous evidence and constructions of the European courts, the "ordinary and customary" meaning of "cylinder" is a three-dimensional geometric shape with a constant diameter.

B. The District Court Improperly Construed "Cylindrical" To Include Any Shape "Relating To A Cylinder."

The district court agreed with Edwards that the "cylindrical" support need not have a "diameter ... constant along the longitudinal axis" but instead could have a shape that merely "relat[ed] to a cylinder." A00050. In so doing, the court provided *no* analysis of the claim language, the specification, or any intrinsic evidence to support its construction. Instead, in a footnote the court simply dismissed CoreValve's "diameter . . . constant along the longitudinal axis" construction on the ground that the phrase is not found in the specification. *Id.*

The court's construction directly conflicts with this Court's decision in *International Rectifier*, which construed a similar geometric term. There, the patent-in-suit claimed a semiconductor transistor in a base described as a "polygonal region." *Int'l Rectifier*, 361 F.3d at 1370-72. The district court construed "polygonal" to require a base region that is "generally, but not necessarily perfectly, polygonal"—a "closed figure with generally (not necessarily perfectly) straight sides." *Id.* at 1370.

In reversing that construction, this Court explained that the "ordinary and customary" meaning of "polygonal" is a "closed plane figure bounded by straight lines." *Id.* The Court also noted that the patentee did not use any terms of modification to broaden the geometric meaning of "polygonal." *Id.* at 1372. The Court therefore concluded that the district court erred by "relaxing" the requirements of "polygonal" to "allow round corners and not straight edges," thereby ignoring the patentee's "choice of words":

> The patentee . . . could have claimed the regions more broadly but chose to use the word "polygonal" without modification or qualification. The district court was not free to attribute new meaning to the term *or to excuse the patentee from the consequences of its own word choice.*

Id. at 1371-72 (emphasis added).

The same logic applies here. As in *International Rectifier*, 361 F.3d at 1371-72, the district court here "relax[ed]" the requirements of the geometric term

"cylindrical" and disregarded intrinsic evidence showing that the patentees used a well-known geometric term without "modification or qualification." The court's *Markman* opinion did not cite *International Rectifier* or discuss the "plain meaning" of the patentee's own word choice. Instead, the court apparently accepted Edwards' argument that the term "cylindrical" should be construed in light of a single dictionary definition. A00433; see A00611.

By elevating that dictionary definition over the intrinsic record, the district court flouted this Court's repeated admonition that there is often "a disconnect between the patentee's responsibility to describe and claim his invention, and the dictionary editors' objective of aggregating all possible definitions for particular words." *Phillips*, 415 F.3d at 1321. Hence, a claim term should not "presumptively receive its broadest dictionary definition or the aggregate of multiple dictionary definitions." *Free Motion Fitness, Inc. v. Cybex Int'l, Inc.*, 423 F.3d 1343, 1349 (Fed. Cir. 2005). The rationale is clear: "if the district court starts with the broad dictionary definition [and] fails to fully appreciate how the specification implicitly limits that definition, the error will systematically cause the construction of the claim to be unduly expansive." *Phillips*, 415 F.3d at 1321.

The Court's admonition in *Phillips* identifies the precise error here: Instead of analyzing the intrinsic evidence, the district court adopted a dictionary definition of the broadest possible scope and construed "cylindrical" to encompass *any shape*

"relating to a cylinder." The court then compounded its error by failing to define the term "cylinder" or provide any guidance on the meaning of the phrase "relating to a cylinder."

The result was a construction of "cylindrical" that made no mention of the geometric characteristics of a cylinder—and did not define the claim's limits. Instead, as Edwards made clear in closing argument, the court's construction (and the resulting jury instruction) gave only negative guidance: "*cylindrical doesn't mean cylinder.*" A11958 (emphasis added). This standardless construction permitted a finding of infringement so long as the shape of the accused device "related" in some unspecified way to an undefined geometric term ("cylinder"). On this basis, a triangular prism could be said to "relate to" a cylinder because both figures have parallel bases and a uniform length, or a sphere could be said to "relate to a cylinder" because both figures have diameters and curved surfaces.

By construing "cylindrical" to have no specific geometric meaning, the district court effectively read the limitation out of the claim and nullified its notice function. Its construction should be reversed and the infringement judgment vacated.

In addition, CoreValve is entitled to judgment as a matter of law of no literal infringement because, under the proper construction, no reasonable jury could find that the "support means" in the CoreValve device is "cylindrical." While Dr.

Buller's magic marker tried to isolate the conical bottom section from the rest of the stent, even Edwards had to admit that the bottom section is "tapered" (A11901), which necessarily means it lacks a constant diameter.

II. THE COREVALVE DEVICE DOES NOT INCLUDE COMMISSURAL SUPPORTS THAT PROJECT IN A DIRECTION GENERALLY PARALLEL TO THE LONGITUDINAL AXIS.

As described above, the CoreValve device was designed to meet anatomical constraints. Two design features provided the backdrop to the two primary infringement issues at trial: (1) does the CoreValve device include "commissural supports" that "project from" one side of the cylindrical support means?, and (2) if so, do they project in a direction "generally parallel" to the device's longitudinal axis?

The district court construed "commissural points" to mean "points or locations where the leaflets of the valve are joined," and "commissural supports" to mean "portions of the stent that support the commissural points of the valve." A00050-A00051. Because the parties agreed that the ordinary meaning governed "projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof," the district court simply construed "thereof" to reference the "cylindrical support means." *Id.* Under these constructions, CoreValve's commissural supports do not "project from" the

cylindrical support means, much less in a direction "generally parallel" to the vertical axis.

A. Edwards Failed To Prove That CoreValve's Commissural Supports Are "Projecting From" The Cylindrical Support Means.

1. The undisputed evidence established that "projecting from" means "protruding from" or "sticking out of."

The trial testimony on the "projecting" limitation was undisputed. The CoreValve experts testified that one skilled in the art in 1990 would understand the term "projecting" to refer to commissural supports that "protrude from" or "stick[] out of" the cylindrical support means. A11538, A11707, A11709. This testimony comported with contemporaneous dictionaries, which defined "projecting" as "protruding," "jutting out," or "extending forward or out." A10183; see *Hewlett-Packard v. Mustek Sys., Inc.*, 340 F.3d 1314, 1321 n.3 (Fed. Cir. 2003) ("general purpose dictionaries" may be used in "interpreting jury instructions").

Edwards' expert, Dr. Buller, neither disputed this definition nor offered an alternative. Rather, he agreed that in Figures 1 and 2 in the '552 patent the three commissural supports "project" from a cylindrical support means because they all "stick up" from the body of the stent. A10929-A10930. He also agreed that the three "posts" enable the stent to "achieve a much taller structure with less weight than compared with one that was all made up with little loops all the way to the

top." A10809. He never suggested that "projecting" had some special meaning to skilled persons in 1990.

Finally, both sides' experts agreed that Claim 1 requires the commissural supports to project from another separate component of the stent—the "cylindrical support means." A10864, A11537-A11541. In this way, the claim requires two structural elements that serve as "reference points" for the "projecting from" limitation. See *Becton Dickinson*, 616 F.3d at 1255; *Playtex Prods., Inc. v. Procter & Gamble Co.*, 400 F.3d 901, 908 (Fed. Cir. 2005) ("flattened" is a "comparative term" that requires a "reference point"). Under this requirement, the commissural supports must "project from" the "cylindrical support means," not from some other part of the device.

2. CoreValve's integrated support structure does not include a plurality of commissural supports "projecting from" a cylindrical support means.

No commissural supports "protrude from" or "stick out of" the support means in the CoreValve device, as they do in the embodiments of the '552 patent. The CoreValve inventors concluded that "post" structures would likely collapse under the stress of the valve's operation. A11131-A11132, A11693-A11694. For this reason, they fundamentally changed the support system for the commissural points, as is evident from visual comparison:

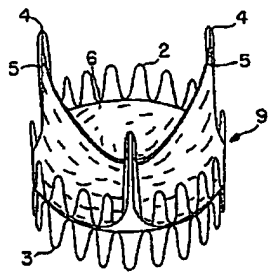
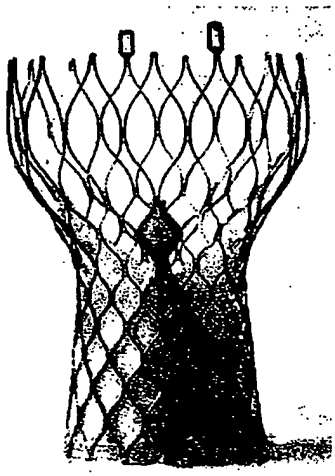


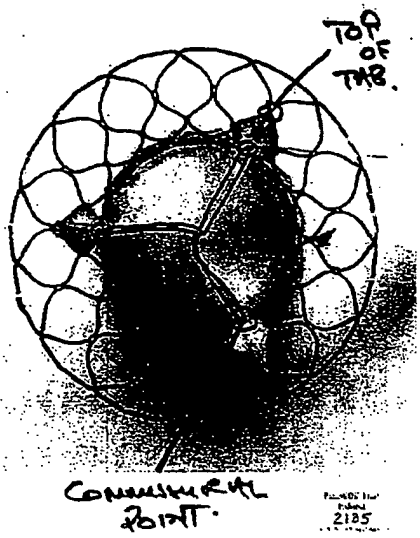
FIG. 2



A00057, A12897.

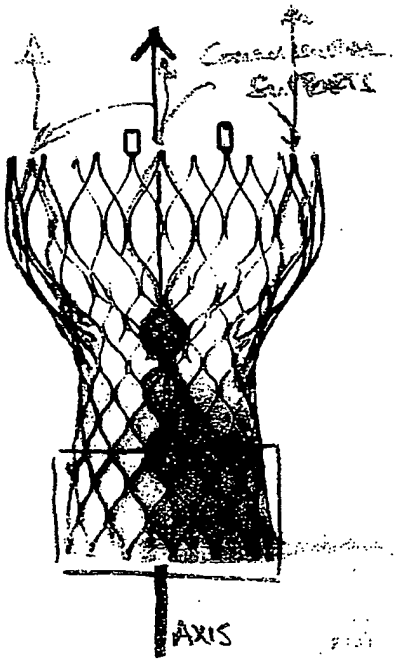
Rather than rely on three "projecting" posts, the CoreValve device supports the commissural points using an integrated wire mesh of rounded, interconnecting diamonds in which no part of the device "protrudes" or "juts out" from the rest of the stent. A11538. The commissural supports are integrated into the "honeycomb" of rounded diamonds that circle the middle of the stent at a 30° angle from the longitudinal axis. A11542-A11546, A11715-A11719. This design enables the stent to reduce stress more effectively by "sharing the load" among the network of supporting rounded diamonds. A11544-A11545, A11711.

Edwards did not dispute any of these points at trial. Dr. Buller, for example, freely admitted that in the CoreValve device the commissural points are not affixed to projecting "posts," but instead lie in the *middle* of the stent—as he illustrated with a "top-down" photograph of the device:



A10855. Dr. Buller further admitted that, unlike the easily-identifiable posts in the '552 patent, the rounded diamonds used to support the commissural points in the CoreValve device cannot be distinguished from other diamonds until the valve is actually sutured in place. A10975-A10976.

Edwards nonetheless insisted at trial that the CoreValve device's commissural supports "project[] from [one side of] the cylindrical support means," just like the three posts in the embodiments of the '552 patent. A10971, A10863-A10865, A10953. To support this assertion, Edwards relied solely on Dr. Buller's testimony and his use of a green marker to outline three "projecting" commissural supports on the *surface* of the accused device:



A31342. Based on this drawing, Dr. Buller testified that the CoreValve device's commissural supports meet the "projecting" limitation because the device "as a whole" purportedly "projects generally upwards." A10866-A10867, A10967-A10968.

Dr. Buller presented *no evidence of any kind* to support his unique view of "projecting." He provided no test results or other data showing that the specific diamonds within his green outlines (and no other diamonds) support the commissural points in the accused device. Nor did he provide any particularized explanations to justify his conclusions. He did not explain, for example, how the rounded diamonds he marked differ from the other diamonds in the stent, or how

the diamonds at the top of the stent could possibly support commissural points lying in the middle of the stent. Instead, he simply presented *ipse dixit* conclusions in the form of his green outlines:

> And the structure that supports the commissures is the column or tower that rises up from the cylinder support means to the top of the device.
>
> And I'm outlining one of them. Again, one is shown at the front of the device. And this is the structure going up. It includes the tab on which the commissural point is mounted.
>
> So I hope my green shows up at the back.
>
> But this is the structure that projects upwards from the cylindrical supports means and is the structure that has the support for the commissural points.

A10864.

Such conclusory assertions cannot support a verdict of infringement. This Court repeatedly has set aside jury verdicts resting on generalized expert testimony that provided no "particularized" factual basis for the experts' conclusions. *Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312, 1320 (Fed. Cir. 2006); *Texas Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567-68 (Fed. Cir. 1996). In *Kim*, for example, the Court upheld a district court decision vacating a jury verdict because the patentee's expert did not support her conclusory assertions with tests of the accused product. 465 F.3d at 1320. Similarly, in *Texas Instruments*, the Court set aside the jury's infringement verdict because the patentee's experts failed

to provide any "particularized" explanation of how the accused device infringed the patent. 90 F.3d at 1568; see also *Hewlett-Packard*, 340 F.3d at 1323 (evidence supporting infringement verdict must include "particularized testimony and linking argument").

These decisions are especially applicable here where Edwards relied on expert testimony that was not only conclusory but also inconsistent. In his direct examination, Dr. Buller maintained that the CoreValve device has three commissural supports consisting of the diamonds located within each of his green outlines. On cross-examination, however, he conceded that *all* of the diamonds (or "cells")—"the entire structure"—support the commissural points:

> Q: So this cell here also supports the commissural point. Right?
>
> A: *All of the cells to greater or lesser degree do.* It's an integral structure, just like Andersen is teaching.
>
> Q: *So all of the cells on this device are useful in supporting the commissural points. That's what you are telling us?*
>
> A: *All of them are useful yes.*
>
> Q: So I could have picked this one or this one or this one or this one, and that would also be a portion of the valve that supports the commissural support—the commissural point. Right?
>
> A: *All of the structure of both Andersen's preferred embodiment and this infringing device, in my opinion, supports the valve.*

A10968 (emphasis added). Indeed, according to Dr. Buller, the device would fail if the metal between his green outlines were removed from the stent. A10950.

This concession transformed Dr. Buller's theory of the nature of the "commissural supports" in the accused device. As noted above, the district court construed "commissural supports" to mean the "portions of the stent that support the commissural points of the valve." A00051. But if the *entire structure* of the device supports the commissural points, then the entire structure—and not just the rounded diamonds he outlined in green—constitutes the "commissural supports."

Dr. Buller's testimony showed that the CoreValve device does not infringe the "projecting" limitation as a matter of law. Claim 1 requires the commissural supports to "project from" one side of a specific component of the stent—the cylindrical support means. These two required structural elements—commissural supports and cylindrical support means—plainly cannot be met if the "whole structure" constitutes the "commissural supports" because the "whole structure" cannot possibly "project from" one of its own component parts.

This Court addressed a similar infringement argument in *Becton Dickinson*, 616 F.3d at 1255. The Court rejected the patentees' assertion that a claim requiring two "separate structural elements" (a "hinged arm" and a "spring") could be met by a device containing a single component that performed both functions. The Court reasoned that "[i]f the hinged arm and the spring means are one and the

same, then the hinged arm must be connected to itself and must extend between itself and a mounting means, a physical impossibility." *Id.* at 1256. The Court therefore concluded that the accused device did not infringe because it did "not contain a spring means that is a separate structural element from the hinged arm and its hinges." *Id.*

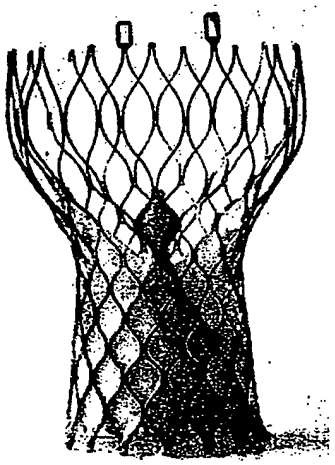
Similarly, in this case, the "projecting" limitation requires "two separate structural elements"—the commissural supports must "project from" the cylindrical support means. But Dr. Buller's testimony showed that the CoreValve commissural supports are the "whole structure" (which necessarily includes the cylindrical support means), and the "whole structure" cannot "project from" itself. *Becton Dickinson*, 616 F.3d at 1255-56. As a matter of law, then, the CoreValve device lacks "a plurality of commissural supports" that project from the cylindrical support means, entitling CoreValve to judgment in its favor on Edwards' literal infringement claim. See also *Gaus v. Conair Corp.*, 363 F.3d 1284, 1288 (Fed. Cir. 2004).

B. CoreValve's Commissural Supports Do Not Project In A Direction "Generally Parallel" To The Longitudinal Axis.

Undisputed evidence also showed that the CoreValve commissural supports do not project "in a direction *generally parallel* to the longitudinal axis." A00064 (Col. 8, lns. 9-11) (emphasis added). This Court has held that "the phrase 'generally parallel' envisions some amount of deviation from exactly parallel."

Anchor Wall, 340 F.3d at 1311. Consequently, CoreValve's commissural supports need not project in a direction *perfectly parallel* to the longitudinal axis. But they cannot deviate so far from parallel as to make the "generally parallel" limitation "functionally meaningless." *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 885 (Fed. Cir. 2008).

The district court instructed the jury to apply the plain meaning of "generally parallel" to one skilled in the art. A08858-A08859. Undisputed evidence showed that the CoreValve device has a chalice-like shape that includes a 30° angle to the longitudinal axis of the frame and a pronounced curvature in its bulbous upper half:



A10971, A11463, A11544-A11545. Undisputed evidence also showed that the CoreValve commissural points lie on the "slopes" of the 30° angle that circles the

middle of the stent just above its narrow waist. A10855, A10967, A10970, A11716, A11545-A11546.

CoreValve expressly designed the stent to have an angled structure (rather than parallel sides) to avoid contact with the walls of the aorta and to enable the valve to function correctly regardless of variations in the size of the vessel. A11719-A11720. In addition, the 30° angle provides an ideal attachment site for the valves by producing a hammock-like effect that enhances stability and reduces stress fatigue from the valve's operation. A11544-A11545.

The CoreValve experts testified that the 30° angle at which the commissural supports extend from the longitudinal axis could not be characterized as "generally parallel" under any interpretation of the phrase. A11543, A11714-A11718. Edwards did not dispute either the 30° angle or the pronounced curvature in the bulbous portion of the stent. Instead, Edwards relied exclusively on Dr. Buller's claim that CoreValve's commissural supports could be analogized to a fork that points "generally upwards" despite its "bends." A10971. Dr. Buller insisted that the "fork" analogy applies because the "generally parallel" limitation means only that "the whole structure, *looked at from top to bottom*, has to be orientated in a direction generally in line with the longitudinal axis." A10867 (emphasis added).

The validity of Dr. Buller's analogy depends entirely on his claim that CoreValve's commissural supports encompass the top part of the stent that extends

above the commissural points. A10866-A10867. But if the commissural supports encompass only the portion of the stent that ends with the commissural points (on the slope of the 30° angle), then the supports could not be analogized to a "fork" or otherwise be deemed "generally parallel" to the longitudinal axis. A00064 (Col. 8, lns. 9-11).

As noted above, Dr. Buller provided no test results or other data to support his counterintuitive view that CoreValve's commissural supports include the entire top half of the stent, when the commissural *points* are affixed to the middle of the structure. See *Kim*, 465 F.3d at 1320. He simply drew a green outline on a photograph of the accused device and pronounced the figure a "commissural support." See *supra*, p. 46. Such "conclusory" and highly "generalized" testimony cannot sustain an infringement verdict. See *Texas Instruments*, 90 F.3d at 1567-68.

In sum, CoreValve is independently entitled to entry of judgment of noninfringement as a matter of law on either of two alternative grounds—the "projecting" or the "generally parallel" limitations. See *Hewlett-Packard*, 340 F.3d at 1322-23 (JMOL rather than new trial is appropriate when patentee fails to present at trial sufficient evidence of infringement as a matter of law).

Edwards failed to prove literal infringement as a matter of law, and it cannot rely on the doctrine of equivalents. Although Claim 1 in the U.S. patent

application originally required (as in the analogous European patent) that the commissural points be "mounted on the cylinder surface of the elastical stent" (A20458), the patentees added the limitation requiring that the "commissural supports" be "projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis" in response to obviousness and anticipation objections. See *supra* p. 10, citing A20538-A20539, A20566-A20569, A20571-A20574. The patentees thereby disclaimed any equivalents to those limitations. See, e.g., *Voda v. Cordis Corp.*, 536 F.3d 1311, 1325 (Fed. Cir. 2008). They cannot regain that disclaimed subject matter now.

III. THE '552 PATENT IS NOT ENABLED FOR HUMAN USE.

No patent claim is valid unless the specification "enable[s] any person skilled in the art ... to make and use" the claimed invention. 35 U.S.C. § 112, ¶ 1. To be enabling, the patent specification "must teach those skilled in the art how to make and use the full scope of the claimed invention" as broadly as it is claimed and "without 'undue experimentation.'" *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010). Enablement is determined as of the patent application's effective filing date. *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371-72 (Fed. Cir. 1999). A claimed invention with multiple aspects must enable the "full scope" of the claims. *Id.* Here, the evidence was clear and

convincing—indeed, materially undisputed—that the '552 patent does not enable a valve prosthesis suitable for human use, as the full scope of Claim 1 requires.

Because no reasonable jury could have found the claimed invention enabled on this record, the district court should have granted judgment as a matter of law in favor of CoreValve.

A. Claim 1 Encompasses A Device Suitable For Human Use.

The full scope of Claim 1 indisputably includes a heart valve suitable for use in humans. Neither the parties nor the district court ever suggested that Claim 1 does not encompass a valve prosthesis suitable for human use. Indeed, Edwards' opening statement told the jury that "[t]he patent is intended to replace open-heart surgery in human beings, not to do testing on animals." A10554-A10555.

The patent itself substantiates that purpose. Claim 1 recites "a valve prosthesis for implantation in a body channel" (A00064 (Col. 7, lns. 57-59)), and the specification makes clear that "body" includes "human body." It states that an aortic valve prosthesis will "make[] it possible for *the patient to resume a substantially normal life*" (A00061 (Col. 2, lns. 24-27) (emphasis added)), and notes that "patients" at high risk for surgery "can be offered implantation of ... cardiac valves." A00062 (Col. 3, lns. 5-7). Only human "patients" can be "offered" treatment choices. The specification then observes that "the after-treatment will advantageously be shorter than normally, which means fewer

hospital days for *the patient*" (*id.*, Col. 3, lns. 8-10 (emphasis added)), many of whom are "elderly people who cannot be offered a surgical cardiac operation." *Id.* (Col. 3, lns. 57-59).

In fact, the only reference to veterinary use is in the context of experimental development for human application. The specification describes the design used for pig testing and then states that "the cardiac valve prosthesis for use in human beings has a corresponding form." A00063 (Col. 5, lns. 38-39).

That is not to say that the patent does not cover implantation in animals. But a claimed invention with multiple aspects must enable the "full scope" of the claim. *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003). Thus, this Court recently affirmed a finding of non-enablement for a means of achieving extended release of a drug, where the claims encompassed both osmotic and non-osmotic means but the specification enabled only osmotic means. *Alza*, 603 F.3d at 940. The Court similarly held that technology claims that were "broad enough to cover both movies and video games" were not enabled because the specification did not teach how the required functions "would be accomplished in movies." *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 1000 (Fed. Cir. 2008); see also *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1378-79 (Fed. Cir. 2007) (where "the full scope of the claimed inventions includes injectors with and without a pressure jacket, [t]hat full scope must be enabled"); *Automotive Techs.*, 501 F.3d at

1285 ("the specification must enable the full scope of the claims that includes both electronic and mechanical side impact sensors, which the specification fails to do").

Because the full scope of Claim 1 plainly includes suitability for use in humans, the claimed valve prosthesis must have been enabled for implantation in a human heart as of the patent's effective filing date. Because it was not, Claim 1 is invalid.

B. The '552 Patent Disclosure Does Not Disclose How To Make A Heart Valve Prosthesis For Human Use.

"Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable." *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997). The '552 patent provided, at most, "only a starting point, a direction for further research." *Automotive Techs.*, 501 F.3d at 1284.

In assessing whether claims have been enabled, this Court applies the factors initially articulated in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988); see *Alza*, 603 F.3d at 940. Those factors are: (1) the quantity of experimentation necessary; (2) the amount of guidance disclosed in the patent; (3) the presence or absence of working examples in the patent; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability of the art; and (8) the breadth of the claims. *Id.* In this case, application of the *Wands* factors

shows that a person of skill in the art could not have made or used a heart valve prosthesis for implantation in a human body based on the '552 specification without undue experimentation. Indeed, no one has succeeded in doing so, although many have tried.

At the time of the patent application, the prospect of replacing an aortic valve in a human via catheterization was a "wild idea." A20094. Yet the '552 patent provides no guidance and contains no working examples. After noting that the "valve prosthesis produced is used for performing tests in pigs," the specification states only that a "corresponding form" is required for human implantation. A00063 (Col. 5, lns. 35-39). But it gives no indication as to what that "form" might be or how it would "correspond" to the described structure. The best evidence of this deficiency is the inability of anyone to develop the claimed invention for human use.

1. The quantity of experimentation needed shows that the '552 patent was not enabled.

In *AK Steel*, 344 F.3d at 1244, this Court found a patent non-enabled where the defendant "presented documentary and testimonial evidence [that] at least a significant amount of experimentation would have been necessary to practice the claimed invention." Here, too, significant experimentation was necessary to make and use the asserted valve prosthesis for implantation in a human heart.

At trial, Edwards' witnesses acknowledged that, as of the filing date, the sole working embodiment could be used only in pigs (though it quickly killed even them) and that the inventors had not developed a device for use in humans. A20119-A20121, A20170-A20172, A10813-A10814, A10915-A10916. The inventors acknowledged that, at that time, a skilled artisan would have had to undertake extensive experimentation to solve distinct problems in developing the prosthesis for human use, in particular how to design a device sufficiently compressible to fit into human arteries and sufficiently stable to withstand the pressures of the valve's operation.

According to inventor Henning Andersen, "a lot of research" was required before their prototype based on the '552 patent could be used in humans. A20227-A20228. In fact, a 1993 article by Dr. Andersen stated that the prototype required "long term follow-up studies in laboratory animals before human application be considered," in part because "[t]he device's dimensions have to be reduced for femoral intrusion." A31536.

Inventor John Hasenkam also admitted that the prototype device based on the '552 patent "could not be implanted in a human" (A20167), noting that "many more complex and long term animal studies must be performed before even speculation concerning [human] clinical use is begun." A20184. For example, at the time of the patent filing, Hasenkam was "not able to determine certain very

important characteristics of the device such as whether it could stay fixed in the aortic annulus." *Id.* Hasenkam also "knew back in 1990 that the stent valves that [he was] building were too bulky [for the] human femoral artery." A20169.

In a contemporaneous paper, co-inventor Dr. Knudsen characterized "the experiments undertaken" as merely "a preliminary technical investigation." A11663. He acknowledged that "many important questions still remain open," and that "questions such as size reduction, material and design optimization, and stent valve sterilization, remain unsolved." *Id.* He and his colleagues did not "attempt to resolve any of those important questions." *Id.* Rather, "much more work had to be done before anybody ever even contemplated using this for a human." A11663-A11664.

Edwards' expert, Dr. Buller, agreed that the device disclosed in the '552 patent "was a device to perform testing on" and "not a device to move in and treat patients." A10815. He too called the pig implantation performed by the inventors "very preliminary work," leaving "lots of questions remain[ing] to be answered." A10904.

In sum, the inventors had nothing more than an interesting idea, and "[t]ossing out the mere germ of an idea does not constitute enabling disclosure." *Genentech*, 108 F.3d at 1366.

2. The specification offers no guidance on how to make and use a prosthetic heart valve for human use.

Undisputed empirical evidence confirms that undue experimentation was necessary to make a heart valve prosthesis based on the '552 patent. In the 20 years since the initial patent application was filed, and despite strong financial incentives, no one, including Edwards, has been able to develop a human heart valve prosthesis according to the teachings of the '552 patent. As Dr. Rothman put it, no device "has been approved for human use that is designed according to the claim limitations of Claim 1." A11742-A11743; see also A11525-A11529. That inability to develop the invention for the application touted in the specification is powerful evidence of nonenablement. *Alza*, 603 F.3d at 942.

The failures of these developers resulted from defects in the '552 patent design. Among other problems, the claimed invention could not withstand the blood pressure to which an aortic heart valve is subjected. A11528-A11531. Contemporaneous materials from the PVT developers said that its dimensions were "much too large for percutaneous placement." A31538-A31544; see also A11693-A11694. Given these and other technical obstacles, it is not surprising that, despite repeated efforts, "[n]either Stanford Surgical nor Heartport ever developed a device for implantation in a human." A20204.

It took many years before a valve prosthesis of any sort was percutaneously implanted in a human heart, and that was not developed based on the '552 patent.

Alain Cribier—co-founder of PVT and a person acknowledged to be "well regarded" in the field in 1990 (A10915-A10916)—had to devote ten years of development work before he could successfully implant a bioprosthetic heart valve sutured onto a balloon expandable stent into a human patient. A20146, A20264, A11366-A11367, A11371, A11383, A11389. To do so, Cribier had to use an *alternative* design, having concluded that "technical limitations impaired any human application" of the device described in the '552 patent. A11381, A31924.

In *Alza*, this Court relied on testimony from the plaintiff's own employees to conclude that their inability to develop non-osmotic dosage forms showed that the patent claims at issue were non-enabled. 603 F.3d at 942. The same conclusion follows here. Stan Rowe, one of the founders of PVT and now a product developer at Edwards, authored a document entitled "Andersen Patent Limitations" which contained his "criticism of the Andersen technology in general at that time." A11665-A11667. He wrote that the '552 patent "sadly does not describe a method or design that if constructed is percutaneous and functional over any durable period." A11674, A31544. Rowe explained that the disclosed device was "much too large" and lacked "sufficient strength" for human implantation. A31544. PVT tested the patent disclosure and found it did not work, concluding that the "stent protrusions" did not "fulfill their function" of supporting the valve bend against hydraulic pressure. A24543, A31594.

Alain Cribier, who is now a paid consultant for Edwards (A11386), similarly found the design disclosed in the '552 patent useless for developing a device suitable for human implantation. In his own patent application, Cribier stated that the '552 design was "inherently fragile," had "a high risk of massive regurgitation," and was "impossible to use in clinical practice." A31392 (Col. 2, lns. 66-67), A31393 (Col. 3, lns. 11-15), A11378-A11379. Among other problems, "such a light stent structure is too weak to allow the implantable valve to be forcibly imbedded into the aortic annulus." A11378. At trial, Cribier reiterated his view that the '552 prototype had limitations "that would very likely prevent any possible human application ... because of the size, for example." A11382.

Edwards now has rights to the SAPIEN valve, a commercial embodiment of the Cribier patent (see *supra* pp. 24-25). Development of the SAPIEN valve took over a decade after the priority date. A20264, A10631-A10632. According to Netanel Benichou, a former PVT employee now employed by Edwards who was one of the lead design engineers of the SAPIEN valve, the '552 patent contributed nothing to the development of that valve. A11386-A11387, A11398.

In sum, the evidence is clear and convincing that the '552 patent disclosures did not enable a person of ordinary skill in the art to make or use the claimed valve prosthesis for human use without undue experimentation. Accordingly, Claim 1 is

not enabled as a matter of law, the verdict should be reversed, and judgment of invalidity should be entered in favor of CoreValve.

IV. THE LOST PROFITS DAMAGES AWARD CANNOT BE SUSTAINED.

This Court has increasingly scrutinized and reversed damages awards that "relied on speculative and unreliable evidence divorced from proof of economic harm linked to the claimed invention." *ResQNet.com v. Lansa, Inc.*, 594 F.3d 860, 868 (Fed. Cir. 2010). The $72 million lost profits award here "is inconsistent with sound damages jurisprudence" and should be vacated. *Id.*

Infringement damages must rest on "a fair and accurate reconstruction of the 'but for' market" in the absence of infringement, taking into account "alternative actions the infringer foreseeably would have undertaken had he not infringed." *Grain Processing Corp. v. American Maize-Prods. Co.*, 185 F.3d 1341, 1350-51 (Fed. Cir. 1999). Any such assessments must reflect "sound economic proof" (*id.* at 1350), which in turn "requires some grounding in sound economic and factual predicates." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1309 (Fed. Cir. 2006).

"[T]he availability of lost profits is a question of law for the court." *Wechsler v. Macke Int'l Trade, Inc.*, 486 F.3d 1286, 1293 (Fed. Cir. 2007). Lost profits are unavailable unless the patent holder proves both its own "manufacturing and marketing capability to exploit the demand" and "an absence of acceptable noninfringing substitutes" available to the infringer. *Siemens*, 2011 WL 651790, at

*13. If noninfringing substitutes were available during the period of infringement, the infringer could have maintained its market position after it stopped infringing, making compensation by a reasonable royalty the only appropriate measure. See *Riles v. Shell Explo. & Prod. Co.*, 298 F.3d 1302, 1311 (Fed. Cir. 2002).

The parties did not dispute that Edwards lacked any "capability to exploit the demand" for catheter-implantable artificial heart valves until August 2007, when it received regulatory approval in Europe. The parties also agreed that, in the "but for" world, CoreValve would have sold an "acceptable noninfringing substitute[]"—indeed, the same device it actually sold—by manufacturing the accused device in France or another country where Edwards lacked patent rights. A11034-A11037, A11615-A11617. Thus, the controlling question is *when* CoreValve would have been able to manufacture the devices overseas and sell products that were made without infringing a U.S. patent. If the latest date supported by the evidence is before August 2007, CoreValve is entitled to judgment on lost profits damages; if that date is any time before trial, CoreValve is entitled to a new trial on lost profits damages.

This Court examines "the nature of the market" at the dates of first infringement and of first claimed lost profits to determine whether and when the infringer would have been able to use an acceptable noninfringing alternative. *Grain Processing*, 185 F.3d at 1350, 1353. The parties agreed that CoreValve's

hypothetical efforts to avoid infringement should be evaluated as of the date of first infringement.

The evidence indisputably showed that the CoreValve device first infringed (if it infringed at all) when CoreValve first made the Generation 2 stent frame in August or September 2004. A11495, A11518. Edwards admitted that CoreValve's Generation 2 frame was identical to the frame of the accused Generation 3 device for purposes of infringement. A11453, A10973-A10974. Indeed, Edwards accused the Generation 2 device of infringing the '552 patent in an April 2005 letter. A22940-A22941.

There was no dispute that CoreValve originally operated in France, and in fact continued to work on the catheter for the CoreValve device in Europe even after moving development of the stent and valve to California in September 2004. A11011, A11015, A11151-A11152. Nor is there any dispute that, had CoreValve sought to avoid infringing the '552 patent in fall 2004, it would not have moved its manufacturing and development operations to California, but would have moved operations to another site in Europe or elsewhere. A11323, A11478-A11480. Even if CoreValve had moved some operations to California and decided to move them *back* to Europe (or elsewhere) only after receiving Edwards' April 2005 cease-and-desist letter, the only evidence addressing the duration of the relocation process in that period indicated that CoreValve would have completed the move

before receiving approval to market the accused device in Europe in March 2007. A11482. CoreValve could have relocated much more quickly in those years, when it was only conducting clinical trials, than after it began commercial manufacturing. See *id.* The noninfringing substitute manufactured overseas would have been available and sold long before Edwards was in a position to make or lose any relevant profits.

The jury's lost profits award—which necessarily assumes that CoreValve would not have been able to manufacture overseas even by 2010—rests entirely on an unsupported premise: that the date of first infringement did not occur until January 2006, when CoreValve "froze" the design of the accused Generation 3 device. Edwards' expert, Gregory Leonard, assumed that was the date of first infringement solely because Edwards' lawyers so instructed him. A11034-A11035. He identified no evidence supporting that assumption, which could not possibly be correct. A design freeze is not an infringing act under 35 U.S.C. § 271(a), and the device design could not be "frozen" unless devices using that design had been made (and thus infringed) earlier.

In short, undisputed evidence "show[ed] that the substitute" of manufacturing in Europe "was 'available' during this period" after August 2007, when Edwards first obtained approval to market its own device, "based on alternative actions that [CoreValve] reasonably could have taken to avoid

infringement." *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1331 (Fed. Cir. 2009) (quoting *Grain Processing*, 185 F.3d at 1353). The lost profits award should be vacated.

* * *

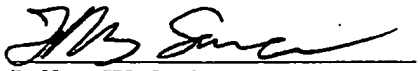
At bottom, Edwards seeks to use an unwarranted patent for a failed invention to block others from developing an innovative and radically different prosthetic valve that actually works. Whereas the CoreValve device is directed to actual anatomical features, enabling it to save many thousands of lives, the '552 patent design—with its cylindrical shape and projecting supports—is fundamentally defective and has never been successfully implanted even in animals, much less human beings. Allowing Edwards to wield the '552 patent to free-ride on—and garner enormous damages from—the success of the life-saving invention would be inconsistent with patent law and policy.

CONCLUSION

The judgment should be reversed and judgment entered in favor of CoreValve.

Dated: May 18, 2011

Respectfully submitted,



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ADDENDUM

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 08-91-GMS
COREVALVE, INC. and, MEDTRONIC COREVALVE, LLC	)	
Defendants.	)	

MEMORANDUM

I. INTRODUCTION

In this patent infringement action, plaintiffs Edwards Lifesciences AG and Edwards Lifesciences LLC (collectively, "Edwards" or "the plaintiffs") allege that a medical device manufactured by defendants CoreValve, Inc. and Medtronic CoreValve, LLC ("CoreValve") infringe the asserted claim of the patent-in-suit. (D.I. 1.) The court held an eight-day jury trial in this matter on March 23 through April 1, 2010. (D.I. 326-333.) At trial, CoreValve properly moved for judgment as a matter of law ("JMOL") on a number of grounds pursuant to Rule 50(a) of the Federal Rules of Civil Procedure (see D.I. 303-304, 308, and 310), and the court denied CoreValve's motions. (See Tr. 1264-70.)

On April 1, 2010, the jury returned a unanimous verdict in favor of Edwards on all claims. The jury found that CoreValve's Generation 3 ReValving System (the "Gen 3" device) directly infringed claim 1 of United States Patent No. 5,411,552 ("the '552 Patent"), the only asserted claim in this case. (D.I. 313.) The jury further found that CoreValve's infringement was willful, and rejected CoreValve's claim of non-enablement with respect to the asserted

claim. (Id.) The jury awarded Edwards $72,645,555 in lost profits and $1,284,861 in reasonable royalties. (Id.) The court entered judgment on the verdict on May 4, 2010. (D.I. 324.) Presently before the court are the parties' post-trial motions.[1] Having considered the entire record in this case, the substantial evidence in the record, the parties' post-trial submissions, and the applicable law, the court will deny all the parties' post-trial motions with the exception of: Edwards' motion for pre-judgment and post-judgment interest (D.I. 344), which the court will grant; and Edwards' motion for permanent injunction and accounting (D.I. 356), which it will grant in part and deny in part. The court's reasoning follows.

II. BACKGROUND OF THE TECHNOLOGY

The patent-in-suit relates to medical device technology. Specifically, the '552 Patent relates to a "valve prosthesis, preferably a cardiac valve prosthesis, for implantation in the body . . ." ('552 Patent, col. 1, ll.13-15.) The object of the invention, and the key innovation upon which the parties focused at trial, is to provide a valve prosthesis that can be implanted in the body without the need for surgical intervention, but rather through use of a catheter. With respect to cardiac valves, the invention thus permits a valve to be implanted without the need for open heart surgery and the risks that come with such surgery. The claimed prosthesis comprises: "A collapsible elastical valve which is mounted on an elastic stent, the elastical valve having a plurality of commissural points" where the valve is attached to the stent. ('552 Patent, claim 1.) Relevant to the pending motions, the asserted claim requires that the stent include "cylindrical

[1] These motions are: CoreValve's Renewed Motion for Judgment as a Matter of Law (D.I. 318), CoreValve's Motion for a New Trial or Alternatively to Amend Judgment (D.I. 320), Edwards' Motion for Attorney Fees (D.I. 339), Edwards' Motion for Enhanced Damages Pursuant To 35 U.S.C. § 284 (D.I. 341), Edwards' Motion for Prejudgment and Postjudgment Interest (D.I. 344), CoreValve's Motion to Stay Judgment Pending Post-Trial Motions (D.I. 348), Edwards' Motion for Permanent Injunction, Accounting and Related Relief (D.I. 356), CoreValve's Local Rule 7.1.3(c)(2) Motion to Strike (D.I. 391), and CoreValve's Motion to Supplement Court Record (D.I. 417).

support means" and "a plurality of commissural supports projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof." (Id.)

III. DISCUSSION

A. Renewed JMOL Motions

To prevail on a renewed motion for judgment as a matter of law following a jury trial and verdict, the moving party "'must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings.'" *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998) (quoting *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984)). "Substantial evidence" is defined as "such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." *Perkin-Elmer Corp.*, 732 F.2d at 893.

The court should only grant the motion "if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993) (citing *Wittekamp v. Gulf Western Inc.*, 991 F.2d 1137, 1141 (3d Cir. 1993)). "In determining whether the evidence is sufficient to sustain liability, the court may not weigh the evidence, determine the credibility of witnesses, or substitute its version of the facts for the jury's version." *Lightning Lube*, 4 F.3d at 1166 (citing *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 190 (3d Cir. 1992)). Rather, the court must resolve all conflicts of evidence in favor of the non-movant. *Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1348 (3d Cir. 1991); *Perkin-Elmer Corp.*, 732 F.2d at 893.

"The question is not whether there is literally no evidence supporting the party against whom the motion is directed but whether there is evidence upon which the jury could properly find a verdict for that party." *Lightning Lube*, 4 F.3d at 1166 (quoting *Patzig v. O'Neil*, 577 F.2d 841, 846 (3d Cir. 1978)). In conducting such an analysis, "the court may not determine the credibility of the witnesses nor 'substitute its choice for that of the jury between conflicting elements of the evidence.'" *Syngenta Seeds, Inc. v. Monsanto Co.*, 409 F. Supp. 2d 536, 539 (D. Del. 2005) (quoting *Perkin-Elmer Corp.*, 732 F.2d at 893).

1. "Projecting"

CoreValve asserts that it is entited to judgment as a matter of law ("JMOL") because its accused device does not meet the limitation of the asserted claim "projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof." Here, a brief review of the discussions surrounding this phrase during the claim construction process illustrates that CoreValve's renewed JMOL motion on this issue is actually an effort to reopen claim construction and grant CoreValve summary judgment based on a construction that the court never adopted. Initially the parties offered these proposed constructions for the phrase:

Edwards: The commissural supports *project* from *one side* of the cylindrical support means in a direction generally parallel to the longitudinal axis of the cylindrical support means, namely, the commissural supports may not necessarily be parallel to that longitudinal axis in a strict geometric sense	**CoreValve**: *Extending away* from *one end* of the cylindrical support means in a direction generally parallel to the longitudinal axis of the cylindrical support means

(D.I. 45 at 12 (emphasis added).) The parties' proposed constructions differed in at least two respects. First, Edwards' construction included language (specifically, everything after "namely") reminiscent of the language they proposed in their construction of the term

"cylindrical." Second, whereas Edwards' proposed construction left unaltered the "project[ing] from one side" claim language, CoreValve proposed a construction that replaced "projecting" with "extending away" and "one side" with "one end."

With respect to the latter difference, CoreValve's claim construction answering brief stated that its proposed construction "is important to specify that the supports do not extend from a ***side*** of the cylindrical support means, but rather from its end." (D.I. 64 at 16 (emphasis in original).) Edwards took issue with CoreValve's proposed "extending away from one end" construction in its answering brief. Edwards argued that "'[e]xtending away' is inaccurate because a portion of the commissural supports in the preferred embodiment shown in Figure 2 overlap and thus do not extend away from one end of the cylindrical support means." (D.I. 62 at 14.) At the *Markman* hearing, Edwards stated that the dispute regarding the "extending away from one side" limitation was over "a very minor detail" (id. at 30-31), and CoreValve agreed that their positions on the meaning of this phrase were "very close." (D.I. 100 at 74.) Edwards did repeat its opposition to the "extending away" limitation as "an unnecessary limitation which isn't there." (Id. at 30.) CoreValve's sole statement regarding its "extending away" proposal at the hearing was:

> Now, [Edwards' counsel] didn't like the fact that we said extending away. We were trying to give another word for projecting. If the parties want to use projecting, that's probably fine with us as well. We didn't intend to change anything by "projecting."

(Id. at 74.) No mention was made between the distinction between "one end" and "one side," nor did CoreValve press the court further to adopt its "extending away construction," despite the fact that Edwards had specifically repeated its opposition to CoreValve's proposal.

Given the parties' indication that they did not view the differences between their

proposals as substantial, the court adopted a construction of the term that left the claim language intact and gave the term its plain and ordinary meaning. (D.I. 271 at 3.) The court noted that the parties' proposed constructions were "quite similar." (Id.) Neither CoreValve nor Edwards filed a motion for reconsideration or clarification regarding the court's construction of this term. CoreValve filed no motions in limine asking the court to clarify or further limit the meaning of this term. The term was not mentioned at all in the pretrial conference. (See D.I. 276.) CoreValve did not file any pre-trial objections with the court asserting that the infringement analysis for this term in Dr. Nigel Buller's expert report violated the court's claim construction order, nor does CoreValve argue now that Dr. Buller's testimony regarding the limitation at trial differed from the analysis in his report.[2]

CoreValve is now, in effect, asking the court to read its proposal into the court's construction of the disputed term, and test the jury's verdict against that far more limiting construction. In support of its argument as to the unreasonableness of the jury's verdict, CoreValve cites dictionary definitions of "projecting" in an effort to establish the term's plain and ordinary meaning, and then notes that there is nothing projecting from the top *end* of CoreValve's device. These arguments are, in effect, an attempt to reopen claim construction for the disputed term. At this stage in the proceedings, CoreValve's claim construction arguments are untimely, and the court rejects its renewed JMOL motion on that basis alone.[3] Edwards

[2] To the best of the court's knowledge, the only time that CoreValve raised this claim term before trial was its letter request to file a motion for summary judgment (D.I. 129), in which CoreValve also attempted to relitigate the court's constructions of "cylindrical" and "cylindrical support means" (see section III.A.4, *infra*). The court denied that letter request and a related subsequent "Motion for Clarification" (see D.I. 156) as untimely efforts to revisit claim construction. (*See* D.I. 149; D.I. 191.)

[3] Moreover, even if the court were to open claim construction for this term, the definitions CoreValve provided divorce the word "projecting" from the context in which it appears in the claims, and CoreValve's arguments gloss over the fact that the claim requires commissural supports projecting from one *side* rather than from one *end* of the support means.

specifically objected to CoreValve's "extending away" and "one end" limitations and noted that Figure 2 showed overlapping supports. Despite this, CoreValve indicated at the *Markman* hearing that it did not view its proposal as substantially different from Edwards'. If CoreValve wished for the court to further clarify the plain and ordinary meaning of the term with respect to their "extending away" and "one end" proposals, they could have insisted that the court rule on their proposed construction instead of stating that their proposed construction would not change the meaning of the term. Failing that, CoreValve could have filed a timely motion seeking clarification of the court's construction as to this term.

The test is not how CoreValve or even the court would interpret the plain and ordinary meaning of "projecting." Rather, the test is whether there is sufficient evidence to support the jury's implicit finding that the commissural supports on CoreValve's device "project[] from *one side* of the cylindrical support means," given the plain and ordinary meaning of that phrase in the context of the disputed claim. At trial, Dr. Buller gave testimony that provided a reasonable basis for the jury to conclude that CoreValve's device meets the requirements of the disputed claim term.[4] CoreValve's effort to create a more specific and limiting meaning of this term and test the jury's verdict against that meaning is untimely and unavailing.

[4] Specifically, Dr. Buller used a photograph of CoreValve's device that was often used during trial to illustrate for the jury the location of the commissural points, commissural supports, and cylindrical support means. (*See* D.I. 337 at A894-96 (PTX 2135-2137.) Dr. Buller testified that the "top" portion of CoreValve's device as shown in PTX 2136-37 contained the commissural supports (Tr. 768:21-771:2; PTX 2137) while the "bottom" portion contained the cylindrical support means. (Tr. 769:24-25; PTX 2136.) He then explained, using the court's construction of the claim, how the commissural supports project from one side of the cylindrical support means, and how the commissural supports run generally parallel to the cylindrical support means. (Tr. 771:5-773:23.) It is true that these supports overlap with the cylindrical support means but, as Edwards notes, this is consistent with the specification and drawings of the '552 Patent. (*See* '552 Patent, Fig. 2 & col. 5:9-28.) In any case, and as discussed above, CoreValve's proposal to further limit the meaning of the "projecting from one side" limitation is untimely.

Moreover, CoreValve's effort to dismiss Dr. Buller's illustrations of CoreValve's device as "litigation-inspired" are unavailing. CoreValve did not object when Edwards moved to have those drawings moved into evidence. (Tr. 1003:14-20.) Furthermore, and as Edwards notes, experts routinely highlight and explain the components of an accused device in light of the asserted claim limitations. Indeed, the court is puzzled as to how infringement could ever be shown if experts were not permitted to refer to the accused device.

For similar reasons, the court rejects CoreValve's assertion that no reasonable jury could find that CoreValve's commissural support project "in a direction *generally parallel* to the longitudinal axis." CoreValve's argument depends on adopting a more limiting construction of the claim term than was included in the court's *Markman* order. Specifically, it requires that the "commissural supports" be limited so that the cells above the tabs that constitute the commissural points are excluded. The court's claim construction order, however, contains no such requirement. Indeed, both parties agreed that the proper construction of "commissural supports" is simply "portions of the stent that support the commissural supports of the valve." (D.I. 271 at 3.) CoreValve did not seek and the court did not impose a limitation excluding cells above the tab from being part of the "commissural supports." As with the "projecting from one side" portion of this limitation, Dr. Buller gave testimony that provided a reasonable basis for the jury to conclude that CoreValve's device meets the requirements of the disputed claim term.[5] Consequently, the court denies CoreValve's renewed JMOL motion with respect to this limitation.[6]

2. Willful Infringement

CoreValve next argues that the evidence presented at trial was not sufficient to support the jury's finding of willfulness. Under the rubric established by *In re Seagate Tech., LLC*,

[5] *See* footnote 4, *supra*. Dr. Buller testified that the "portions of the stent that support the commissural points of the valve" (the court's construction of "commissural points") consists of "the structure . . . that rises up from the cylinder support means to the top of the device." (Tr. 770:2-5.) Given the honeycomb-like structure of CoreValve's device, this structure runs along most of the length of the stent; as CoreValve's own witness stated: "The CoreValve stent has the commissural supports, supported in a honeycomb structure." (Tr. 1465:2-8.) Dr. Buller then testified that supporting structure, as a whole, runs in a direction generally parallel to the longitudinal axis even though there are curves within the structure. (*See* Tr. 771:22-773:23.) The jury could reasonably have accepted Dr. Buller's testimony.

[6] CoreValve also argues that Edwards cannot resort to the doctrine of equivalents ("DOE") to prove infringement of the "commissural supports" claim term due to prosecution history estoppels. (See D.I. 335 at 9.) Since the jury found literal infringement of this claim, however, it did not (and did need to) determine DOE infringement. (See D.I. 313 at 2.) Consequently, the court finds that the DOE issue is moot.

willful infringement requires first that the patentee show that the infringer acted despite an objectively high likelihood that its actions constituted infringement. 497 F.3d 1360, 1371 (Fed. Cir. 2007). The existence of this risk is "determined by the record developed in the infringement proceeding." *Id.* If the objective risk prong is satisfied, the patentee must then show that the infringer either knew or should have known of this objective risk. *Id.* By its nature, the issue of willfulness in patent infringement hinges both on the fact finder's assessments of the credibility of witnesses and on the fact finder drawing inferences from the evidence presented to it. "The drawing of inferences, particularly in respect of an intent-implicating question such as willfulness, is peculiarly within the province of the fact finder that observed the witnesses." *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1225 (Fed. Cir. 2006). Since this case was tried before a jury, the court will not lightly disturb the jury's finding of willfulness.

In support of its arguments for a JMOL of non-willfulness, CoreValve cites the testimony of fact witnesses who testified as to the development of the Gen 3 device and their belief that the device did not infringe. (See D.I. 335 at 11.) The jury was under no obligation, however, to accept the testimony of CoreValve's witnesses. For instance, the jury was free to reject – and apparently did reject – Mr. Bortlein's assertion that he designed the Gen 3 device so that it contained no projecting commissural supports. (See D.I. 335 at 11 (citing Tr. 1035:4-1038:2).) Assessments of such testimony fall squarely within the province of the jury. CoreValve also cites the PTO's decision to grant CoreValve patents covering the Gen 3 device. While CoreValve correctly notes that evidence of such patents is potentially relevant to the issue of willfulness, it is not for the court to decide how much weight the jury should have given to CoreValve's patents in this case. Moreover, as Edwards notes in its answering brief, the record

contains considerable evidence from which a jury could have inferred willfulness. (See D.I. 369 at 10.) For these reasons, the court will deny CoreValve's renewed motion for JMOL on the issue of willfulness.

3. Non-Enablement

CoreValve next argues that no reasonable jury could have rejected CoreValve's non-enablement defense to claim 1. Non-enablement is an invalidity defense that must be established by clear and convincing evidence. *E.g.*, *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1375 (Fed. Cir. 2001). To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without "undue experimentation." *E.g.*, *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997).

CoreValve's motion confuses the standard under which enablement is determined by discussing enablement in terms of attributes that must be enabled "to cover the CoreValve device" rather than in terms of the language and scope of the actual claims. Specifically, CoreValve argues:

> [T]o cover *the CoreValve device*, claim 1 must encompass a device with "commissural supports projecting from one side . . . in a direction generally parallel" that is also (1) self-expanding, (2) suitable for use in humans, (3) suitable for delivery via minimally invasive techniques such as through the transfemoral artery, and (4) securable in the aortic annulus, like CoreValve's Gen 3.

(D.I. 335 at 12-13 (emphasis added).) CoreValve then proceeded to argue that each of the numbered attributes was not enabled by the '552 Patent.[7]

[7] Notably, CoreValve made no effort to argue that the '552 Patent did not enable "commissural supports projecting from one side . . . in a direction generally parallel," which was the only language from the actual claims that appeared in this section of CoreValve's motion. CoreValve only argued that there was nothing "projecting" in

CoreValve's recitation of what "claim 1 must encompass" in order "to cover the CoreValve device" is a misleading characterization of what must be enabled under § 112. It is the asserted claims rather than the accused device which must be "enabled" by the patent-in-suit. *See, e.g., Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1306 (Fed. Cir. 2001). In this case, the court did not construe the asserted claims to cover the four attributes of the accused device that CoreValve raises in its non-enablement argument, and CoreValve does not appear to make any effort to tie those attributes back to the actual claim language or to argue that actual limitations appearing in the asserted claim are not enabled. While it is true that the specification must enable the full scope of the asserted claim, there is no requirement that the claims must cover all features of the accused device. As the Federal Circuit has explained:

> The dispositive question of enablement does not turn on whether the accused product is enabled. Rather, "[t]o be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation."

Durel, 256 F.3d at 1306 (internal citation omitted).[8]

By that standard, since the court cannot discern from CoreValve's motion which limitations of the asserted claims are purportedly not enabled, CoreValve's motion does not even raise a colorable non-enablement defense against which the court can test the jury's verdict.

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the '552 Patent's only example of a "self-expandable" device. Self-expansion is not, however, required by or mentioned in the asserted claim.

[8] In *Invitrogen Corp. v. Clontech Laboratories, Inc.*, the Federal Circuit explained the reasoning underlying this approach to enablement:

> Enablement does not require the inventor to foresee every means of implementing an invention at pains of losing his patent franchise. Were it otherwise, claimed inventions would not include improved modes of practicing those inventions. Such narrow patent rights would rapidly become worthless as new modes of practicing the invention developed, and the inventor would lose the benefit of the patent bargain.

429 F.3d 1052, 1071 (Fed. Cir. 2005).

Certainly, considering the clear and convincing standard that non-enablement defenses must meet, CoreValve has failed to show that no reasonable jury could conclude that claim 1 of the '552 Patent is enabled.

4. "Cylindrical support means"

The next ground upon which CoreValve moves for JMOL relates to the court's construction of "cylindrical support means." CoreValve asked the court to revisit its construction of this term repeatedly throughout the pre-trial process and during the trial itself. CoreValve's repeated efforts to revisit claim construction led the court to warn CoreValve's counsel at trial to "stop pushing the issue." (Tr. 1649:11-18.) CoreValve chose to ignore the court's warning, and has once again raised the issue in their renewed JMOL motion. The court will deny the motion as (another) untimely effort to reopen claim construction and test the jury's verdict against a construction that did not appear in the court's *Markman* order.

The court will not comment further on the substance of the motion. Since attempts to relitigate claim construction have become increasingly prevalent, however, the court feels it necessary to lay out the history behind CoreValve's efforts to revisit claim construction on this issue. The court's claim construction order specifically rejected CoreValve's proposed constructions of "cylindrical support means" and "cylindrical," and specifically noted that the court rejected CoreValve's suggestion that "cylindrical" as that word is used in the disputed terms requires that the diameter be "constant along the longitudinal axis" as in the case of perfect geometric cylinders. (See D.I. 109 at 2 & 4; D.I. 271 at 2 & 4.) CoreValve did not file a motion for reargument during the ten day time frame imposed under Local Rule 7.1.5.[9] Once that period

[9] Local Rule 7.1.5 has since been amended to provide a fourteen day period for filing motions for reargument.

passed, the claim construction phase of the pre-trial process was complete.

Just a few weeks later, however, CoreValve attempted to revisit the constructions of "cylindrical" and "cylindrical support means" in its letter request to file a motion for summary judgment. (D.I. 129.) Despite the court's specific instruction that cylindrical did not mean "constant along the longitudinal axis" in the context of the disputed claims, CoreValve's letter argued that the court's claim construction was "grounded" in the geometric definition of a perfect cylinder with "straight parallel sides." (Id. at 2.) The court denied the letter request in an order that concluded by stating that "the court agrees with the plaintiffs, and will deny, as untimely, the defendant's request for reconsideration of the court's May 27, 2009 *Markman* order." (See D.I. 149.)

Undeterred, CoreValve filed a "Motion for Clarification" (D.I. 156) that contained a jumble of arguments stemming from CoreValve's insistence that "cylindrical" should be construed as referring to its "ordinary meaning" of cylinder (id. at 3) as "a shape with straight parallel sides." (Id. at 2.) CoreValve warned that if the court failed to "resolve" this issue, "the parties would inevitably litigate claim construction issues before the jury." The motion concluded with the following request:

> If the Court's use of the word "cylinder" in its claim construction was intended to refer to shapes that did not have the properties of a cylinder, as reflected by its ordinary meaning, then CoreValve respectfully requests clarification of the Court's view of the meaning of that term pursuant to *O2 Micro*, as a matter of law. If, on the other hand, the Court intends the parties to litigate before the jury whether the accused device has a shape "of or relating to a cylinder" under the ordinary meaning of the word "cylinder" as set forth in CoreValve's letter brief (D.I. 129), then CoreValve respectfully requests that the Court delete the last sentence from its [aforementioned order denying CoreValve's letter request to file a summary judgment motion].

(Id. at 3.)

The court denied this motion in an order dated January 7, 2010:

> Arguments concerning claim construction should have been presented at the *Markman* hearing or in the briefs filed with the court in connection with the *Markman* hearing. The defendant did not file a motion for re-argument within the ten-day period after the *Markman* order was issued, as is required under Local Rule 7.1.5, and the court will not permit the parties to argue or re-argue matters of claim construction at this stage.

(D.I. 191.) Upon further consideration, however, the court recognized that without further intervention, CoreValve's prediction that the parties might litigate claim construction issues before the jury might prove to be a self-fulfilling prophesy. Consequently, the court announced at the pretrial conference that it would make a minor amendment to footnote 13 in order to specify how it was rejecting CoreValve's argument. The court then issued an order formalizing this amendment, which changed the last sentence of footnote 13 of the court's *Markman* order so that it read "the court rejects the defendant's proposed construction that requires 'a diameter that is constant along the longitudinal axis'" instead of simply "[t]he court rejects the defendant's proposed construction." (*Compare* D.I. 271 at 4, note 13, *with* D.I. 109 at 4, note 13.)

The court fervently hoped that this amendment would deter CoreValve from raising this claim construction issue again at trial. Unfortunately, it did not take long for CoreValve to dash those hopes. At trial, CoreValve witness Dr. Martin Rothman testified as follows when asked whether CoreValve's device had a shape "of or related to a cylinder" as required by the court's construction:

> Well, to my mind, again, the "related to," we're not taught related by how much. And I take the cylinder to have parallel sides or virtually parallel sides and that is my definition, general definition of a cylinder.

(Tr. 1636:23-1637:3.) Shortly thereafter, CoreValve's counsel asked the court at sidebar

whether they could make a proffer of "evidence concerning the cylindrical rotation that would be pursuant to [CoreValve's] proposed claim construction." (Tr. 1649:11-13.) The court denied the request and warned CoreValve to "stop pushing the issue." (Tr. 1649:14-18.) On cross examination, Dr. Rothman again testified, in response to a question as to the meaning of "cylinder" in the context of the claims, that he took "cylinder" to mean an object whose "diameter . . . remain[s] constant" between the sides. (Tr. 1693:12-16.) Dr. Rothman insisted that he applied the court's claim construction, but his testimony clearly conflicted with the court's clear statement in its claim construction order that "cylindrical" within the meaning of the claims does not require "a diameter that is constant along the longitudinal axis."

With hope springing eternal, the court believed that the end of the jury trial, combined with the court's explicit warning at sidebar, would finally lead CoreValve to recognize that it would accomplish nothing by continuing to harass the court with belated claim construction arguments. Once again, the court apparently hoped for too much. In its post-trial motions, CoreValve once again is urging the court to adopt their proposed constructions of "cylindrical" and "cylindrical support means" and test the jury's verdict against those constructions. (See D.I. 335 at 16-19.) It has raised this argument both in its renewed JMOL motion and in its motion for a new trial (see *infra*, section III.B).

When parties repeatedly attempt to revisit claim construction months after the court issues its *Markman* order, it wastes the court's time and undermines the court's ability to resolve legal issues in an efficient and timely manner. Moreover, such efforts are bound to fail, since counsel on both sides are well aware that this court simply will not permit the sort of wholesale relitigation of a disputed claim term that CoreValve has sought (and sought and sought again).

The problem is even more serious where, as here, the party presents a witness who testifies and provides an interpretation of claim term that is plainly at odds with the court's claim construction order. In addition to violating the Federal Circuit's repeated directives that claim construction issues not be brought up at trial, presenting such testimony creates the potential for jury confusion. Such conduct is simply unacceptable in light of trial counsels' duties as officers of the court.

If a party disagrees with one or more of the court's claim constructions, the appropriate course is for the party to make its record during the *Markman* phase and pursue that issue on appeal. If appropriate, the party may also file a motion for reargument under Local Rule 7.1.5, bearing in mind that such motions are only "sparingly granted." *See* Local Rule 7.1.5(a). If the party fails to file such a motion, they cannot later reopen the issue by repeatedly harassing the court with untimely motions, requests, and proffers of evidence relating to their rejected claim construction. Such actions serve no constructive purpose.[10] In the future, parties who engage in such conduct may face sanctions.

5. Damages

The court also rejects CoreValve's renewed JMOL motion with respect to damages. For the reasons stated below in Part III.B, the court concludes that a reasonable jury could have concluded that the first date of infringement was January 2006 and that Edwards would have been able to meet demand and make the necessary sales. A reasonable jury could likewise have rejected CoreValve's contention that it would not have been able to move its manufacturing operations abroad (thus allowing CoreValve to avoid infringement) before January 2006.

[10] The court notes that a party's ability to appeal from the court's *Markman* order to the Federal Circuit after the trial is complete is not, to its knowledge, enhanced in any way by repeated efforts to revisit the issue at later stages in the trial process.

Edwards cites evidence presented at trial that the expense of moving operations from Irvine, California to an overseas location would have been expensive and disruptive, and would have deprived CoreValve of key design experts. (E.g., Tr. 917:17-918:4; 925:3-927:8; 944:3-947:18.) For these reasons, the court will deny CoreValve's motion.

B. New Trial Motion

CoreValve also moves the court to grant a new trial on a number of bases. First, CoreValve argues that the verdict was contrary to the weight of the evidence for the reasons spelled out in its renewed JMOL motion. The court rejects these arguments for the reasons laid out in sections III.A.1-3, *supra*.[11]

CoreValve also requests a new trial because, it argues, the court's instruction as to "comprising" claims (see Jury Instruction 3.4) allowed the jury to read "projecting" out of the asserted claims. Jury Instruction 3.4 provides as follows:

> The preamble to Claim 1 of the '552 patent uses the phrase "the stent comprises." This claim is open-ended. The word "comprising" means "including" or "containing." As such, the claim is not limited to only what is in the claim.
>
> If you find that the CoreValve GEN 3 ReValving system includes all of the elements of Claim 1 of the '552 patent, the fact that the CoreValve GEN 3 ReValving system also may include features or components not required by the claims is irrelevant. The presence of additional features or components in the GEN 3 ReValving system would not avoid infringement of claim 1.

(D.I. 311, Final Jury Instructions at 19.) CoreValve does not argue that any portion of this instruction is legally incorrect. Nor could it – the meaning of "comprising" as an open-ended transition in patent claims is well-established and understood, supported by decades of Federal Circuit case law. *E.g.*, *CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir.

[11] CoreValve's arguments concerning "projecting" and "cylindrical support means" were yet another example of their efforts to reopen claim construction.

2007) ("In the patent claim context the term 'comprising' is well understood to mean 'including but not limited to.'").

Instead, CoreValve argues that the court erred in refusing to add the phrase "unless those additional features cause the accused device to lack a claim limitation" to the end of the instruction. The court is, frankly, at a loss to see how such an addendum is necessary in light of the fact that the instruction specifically begins with the words: "*If* you find that the CoreValve GEN 3 ReValving system *includes all of the elements* of Claim 1 of the '552 patent." (D.I. 311, Final Jury Instructions at 19 (emphasis added).) Moreover, the very next instruction reiterated that the jury could only find literal infringement of the asserted claim "if CoreValve's GEN 3 product includes each and every element in the asserted claim. . . . If CoreValve's GEN 3 product does not contain one or more elements recited in Claim 1, then CoreValve does not literally infringe that claim." (Id. at 20.) The court's instruction on the open-ended nature of "comprising" was accurate and straightforward. Including CoreValve's proposed addition would have been unnecessarily duplicative at best. At worst, it would have been misleading and confusing, since an instruction including the word "unless" might be construed as presenting a (non-existent) exception to the rule that additional features beyond those satisfying the limitations of a "comprising" claim are irrelevant. CoreValve's motion for a new trial based on this instruction is therefore denied.

For similar reasons, the court rejects CoreValve's motion for a new trial based on the instruction regarding the term "cylindrical." CoreValve specifically requested before trial that the instruction state: "On the other hand, an object described as cylindrical must function as a cylinder." The court denied this request. CoreValve now moves for a new trial because the final

construction relating to this term "emphasized the breadth of the claim term . . . by highlighting what the limitation does *not* require (a 'diameter constant along its length' or 'the presence of a perfect geometric cylinder')" without including "any explanation of what the claim limitation *does* require." (D.I. 336 at 10 (emphasis in original).) This portion of CoreValve's motion boils down to yet another effort to reopen claim construction on the terms "cylindrical" and "cylindrical support means." CoreValve's objection ignores the fact that the court's claim construction order specifically addresses the issue of whether a "cylindrical" object within the meaning of the claim must be a perfect geometric cylinder with a diameter that is constant along its length, but makes no reference to whether the object must "function as a cylinder." There is no requirement that the court "counterbalance" the construction adopted in its claim construction order with language proposed by the party whose construction it rejected.

CoreValve also moves for a new trial "to correct the exclusions of evidence about the conclusions of foreign courts concerning similarly-worded claims." (See D.I. 336 at 8-9.) However, as the "similarly-worded" characterization of the claims in question suggests, the claims for which CoreValve sought to introduce evidence are not the same as the claim asserted in this case. Indeed, as Edwards points out in its answering brief, the European claims at issue in the British and German cases differed in material ways from the '552 Patent, which was not and apparently could not be asserted in the European cases. Moreover, the parties do not appear to dispute that foreign courts have procedures, legal standards, and substantive laws that often differ substantially from those of American courts in patent infringement cases. In the court's judgment, these differences created a risk of unfair prejudice and jury confusion far outweighing the evidence's probative value. CoreValve's motion is, therefore, denied.

Lastly, CoreValve asks the court to either limit the jury's damages award to no more than $1.2 million, or grant a new trial on the issue of damages. (D.I. 336 at 12.) CoreValve contends that the jury based its damages award on a date of first infringement that was unsupported by the evidence presented at trial. (Id. at 13.) Moreover, CoreValve presented evidence that Edwards did not have the capacity to fulfill most of CoreValve's infringing sales. (Id. at 14.) According to CoreValve, the evidence presented at trial also shows that many of CoreValve's customers would have refused to use an Edwards device, indicating that Edwards did not lose potential customers to CoreValve. (Id. at 15-16.)

In response, Edwards contends that the jury was entitled to reject CoreValve's proposed date of first infringement, which was calculated based on the manufacture of a device that was not accused of infringement at trial. (D.I. 370 at 15-16.) Edwards contends that the jury also properly rejected CoreValve's noninfringing alternative of moving abroad because Edwards demonstrated that CoreValve had limited capital and could not design a marketable product abroad. (Id. at 16-17.) Moreover, Edwards contends that Edwards and CoreValve were in direct competition to train the same highly rated heart centers in the use of their products, resulting in lost profits to Edwards. (Id. at 18.) According to Edwards, the jury's verdict on lost profits is reasonable because it reflects damages only for the patients treated by CoreValve's infringing device which Edwards had the capacity to treat. (Id. at 18-19.)

The court concludes that the weight of the evidence in support of the damages award is not so lacking that, without remittitur or a new trial, a miscarriage of justice would result. The jury was entitled to reject CoreValve's proffered first date of infringement and accept Edwards' calculation based on the date that the infringing device was first manufactured. (Tr. 1521:12-

1522:23, 1549:6-24.) Moreover, Edwards presented sufficient evidence for the jury to reasonably conclude that Edwards lost customers to CoreValve, despite CoreValve's contention that Edwards was unable to meet existing demand. (Tr. 521:9-522:22; D.I. 329 at 964:6-967:16.) The jury's lost profits calculation, based on the number of patients treated with CoreValve's device who could have been treated by Edwards at the time, was also reasonable in light of the evidence presented at trial. (Tr. 958:1-961:12.) Furthermore, the jury was entitled to discredit CoreValve's contention that doctors would refuse to use Edwards' device, particularly since Edwards presented medical evidence showing that a patient in need of a transcatheter heart valve device would suffer a short, poor quality of life without one. (Tr. 909:9-911:11.) Thus, the court will uphold the jury verdict as it applies to the award of damages.

C. Motion for Enhanced Damages

Edwards seeks enhanced treble damages for CoreValve's willful infringement of the patent-in-suit. Pursuant to 35 U.S.C. § 384, a court may "increase the damages up to three times the amount found or assessed." An increased damages award requires a showing of willfulness. *Seagate*, 497 F.3d at 1368. A finding of willfulness, however, does not mandate enhanced damages, much less treble damages. *See Cybor Corp. v. FAS Techs, Inc.*, 138 F.3d 1448, 1461 (Fed. Cir. 1998) (citing *Modine Mfg. Co. v. The Allen Group, Inc.*, 917 F.2d 538, 543 (Fed. Cir. 1990); *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826 (Fed. Cir. 1992). "Rather, '[t]he paramount determination [for enhanced damages] . . . is the egregiousness of the defendant's conduct based on all the facts and circumstances.'" *Electro Scientific Indus., Inc. v. General Scanning, Inc.*, 247 F.3d 1341, 1353 (Fed. Cir. 2001) (citation omitted). Thus, enhancement of damages is within the discretion of the district court and is informed by the totality of the circumstances.

See State Indus., Inc. v. Mor-Flo Indus., Inc., 948 F.2d 1573, 1576 (Fed. Cir. 1991).

Factors the court may take into consideration when determining whether, and to what extent, to exercise its discretion include: (1) whether the infringer deliberately copied the ideas or design of another; (2) whether the infringer, when he knew of the other's patent protection, investigated the scope of the patent and formed a good-faith belief that it was invalid or that it was not infringed; (3) the infringer's behavior as a party to the litigation; (4) the infringer's size and financial condition; (5) the closeness of the case; (6) the duration of the infringer's misconduct; (7) any remedial action by the infringer; (8) the infringer's motivation for harm; and (9) whether the infringer attempted to conceal its misconduct. *Read Corp.*, 970 F.2d at 826. The ultimate question remains, however, "whether the infringer, acting in good faith and upon due inquiry, had sound reason to believe that it had the right to act in the manner that was found to be infringing." *SRI Intern., Inc. v. Advanced Technology Labs., Inc.*, 127 F.3d 1462, 1464-65 (Fed. Cir. 1997).

Upon consideration of the parties' submissions and the *Read* factors, the court finds that enhanced damages are not warranted in this case under 35 U.S.C. § 284. Although the jury found that CoreValve's infringement of the asserted claim was willful, the court finds that the issue was sufficiently close that enhanced damages are not warranted. CoreValve mounted a substantial challenge to Edwards' infringement contentions and presented considerable evidence in support of their assertions of non-infringement. *See Delta-X v. Baker Hughes Prod. Tools*, 984 F.2d 410, 413 (Fed. Cir. 1993) ("[A]n infringer may generally avoid enhanced damages with a meritorious good faith defense and a substantial challenge to infringement.") CoreValve's defenses, although ultimately unsuccessful, were not frivolous and – their repeated efforts to

reopen claim construction notwithstanding – were litigated in apparent good faith. Moreover, the court cannot discern any evidence that CoreValve copied Edwards' invention or attempted to conceal their infringement. Therefore, the court finds that enhancement of damages is inappropriate in this case.

D. Motion for Attorney's Fees

Because the court does not find this case to be exceptional by clear and convincing evidence as required by 35 U.S.C. § 285, the court will not award attorneys' fees and costs. In deciding whether to award attorney's fees, the court must undertake a two-step inquiry. *Interspiro USA, Inc. v. Figgie Intern. Inc.*, 18 F.3d 927, 933 (Fed. Cir. 1994). First, the court "must determine whether there is clear and convincing evidence that the case is 'exceptional.'" *Id.* (quotation omitted). Second, the court must determine whether "an award of attorney fees to the prevailing party is warranted." *Id.* Exceptional cases include: "inequitable conduct before the PTO; litigation misconduct; vexatious, unjustified, and otherwise bad faith litigation; a frivolous suit or willful infringement." *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1034 (Fed. Cir. 2002) (citation omitted).

An award of attorney fees under § 285 is not intended to be an "ordinary thing in patent cases," and should be limited to circumstances in which it is necessary to prevent "a gross injustice" or bad faith litigation. *Forest Labs., Inc. v. Abbott Labs.*, 339 F.3d 1324, 1329 (Fed. Cir. 2003); *see also Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1375 (Fed. Cir. 2001) (affirming an award of attorney fees under § 285 for the "extreme litigation misconduct" of falsifying evidence); *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547 (Fed. Cir. 1989) (affirming an award under § 285 following repeated violations of a permanent

injunction and a district court finding of a "strategy of vexatious activity").

The defendants' conduct in this case does not rise to a level of bad faith or vexatious litigation that warrants an award of attorneys' fees and costs. The court was, admittedly, dismayed at CoreValve's repeated efforts to reargue claim construction issues well after the *Markman* phase was complete, and this conduct weighs in favor of an award of attorney's fees. For the most part, however, the record demonstrates that both sides defended their respective positions throughout this litigation in apparent good faith. *See Forest Labs., Inc. v. Ivax Pharms., Inc.*, No. 03-891-JJF, 2008 U.S. Dist. LEXIS 14623, at *6-7 (D. Del. Feb. 26, 2008) (noting that "hard-fought" litigation does not necessarily constitute "vexatious or bad faith litigation" for purposes of awarding attorney fees under § 285). The court therefore finds that none of the parties are entitled to an award for attorneys' fees and costs in this case.

E. Prejudgment and Postjudgment Interest

The court will grant Edwards' motion for prejudgment and postjudgment interest (D.I. 344) and set the interest rate at the Prime Rate, compounded quarterly. "'The Federal Circuit has given district courts great discretion' when determining the applicable interest rate for an award of prejudgment interest." *IPPV Enterprises, LLC v. EchoStar Comm'n Corp.*, No. Civ. A. 99-577-KAJ, 2003 WL 723260, at *3 (D. Del. Feb. 27, 2003) (citation omitted). "Courts have recognized that the prime rate best compensate[s] a patentee for lost revenues during the period of infringement because the prime rate represents the cost of borrowing money, which is 'a better measure of the harm suffered as a result of the loss of the use of money over time.'" *IMX, Inc. v. LendingTree, LLC*, 469 F.Supp.2d 203, 227 (D. Del. 2007) (citing *Mars, Inc. v. Conlux USA Corp.*, 818 F.Supp. 707, 720-21 (D. Del. 1993), *aff'd*, 16 F.3d 421 (Fed. Cir. 1993)).

CoreValve's arguments to the contrary notwithstanding, the court concludes that the prime rate is a reasonable approximation of Edwards' cost of borrowing money during the relevant period. Accordingly, the court will order CoreValve to pay prejudgment and postjudgment interest at the prime rate, compounded quarterly.[12]

F. Permanent Injunction and Accounting

Edwards' final motion requests that the court issue a permanent injunction and order an accounting with respect to infringing sales made after March 15, 2010. The court will grant Edwards' motion in part and deny it in part. Specifically, the court will deny Edwards' request for a permanent injunction but will grant its request for an accounting.

A district court "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283. "According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction. *Id.* "Courts awarding permanent injunctions typically do so under circumstances where [the] plaintiff practices its invention and is a direct market competitor." *Advanced Cardiovascular Sys. v. Medtronic Vascular, Inc.*, 579 F. Supp. 2d 554, 558 (D. Del. 2008).

[12] Since the court is denying Edwards' motions for enhanced damages and attorney's fees, the court denies the motion as moot to the extent that it requests interest on those items.

While the *eBay* standard makes clear that past harm is relevant to the irreparable harm analysis, an injunction is by definition a prospective remedy. *See, e.g., i4i Ltd. Partnership v. Microsoft Corp.*, 598 F.3d 831, 861-62 (Fed. Cir. 2010) ("Although injunctions are tools for prospective relief designed to alleviate future harm, by its terms the first *eBay* factor looks, *in part*, at what has already occurred" (emphasis added)). In this case, the irreparable harm factor weighs against granting a permanent injunction for several closely-related reasons. First, the "irreparable" component of the injury that Edwards alleges stems from CoreValve's past conduct, and would continue even if a permanent injunction were issued. Edwards makes no allegations of *prospective* lost customers or harms that are truly irreparable unless the court issues a permanent injunction. On the contrary, the court concludes that with respect to the irreparable harms that Edwards alleges, Edwards would not benefit substantially from an injunction being issued at this stage, several years after CoreValve's accused product entered the market.

Tellingly, the heading of the irreparable harm section of Edwards' opening brief states: "Irreparable Harm is Shown by How CoreValve Caused Edwards to Lose First-Mover Advantage and Market Share." (D.I. 357 at 6.) As the past-tense phrasing of the heading indicates, the injury that Edwards identifies as irreparable stems from events that occurred well before trial. At its core, the irreparable injury that Edwards asserts stems from the fact that CoreValve was the first to enter the market for the technology in question. (See id. at 8.) As a result, Edwards argues:

> Edwards lost a substantial share of the market because of CoreValve's willful infringement, and Edwards lost the opportunity to establish relationships and train medical centers that it otherwise could have had CoreValve not been on the market. Moreover, Edwards' reputation as a global leader in the science of heart

> valves has been compromised by CoreValve's early unauthorized entry into the market and continued willful infringement.

(Id. at 8-9.)

A permanent injunction would not change the fact that CoreValve was the first to bring its technology to market, nor would it reverse the reputational damage done to Edwards as a result of CoreValve getting its product to market before Edwards. Edwards does not explain how the alleged competitive market advantage that CoreValve established before the trial would be remedied by a permanent injunction stretching into the future. Consequently, the court cannot conclude that Edwards' alleged irreparable injuries are redressable by injunction.

Second, Edwards' allegations of irreparable harm are undercut because CoreValve's infringement stems not from sales of the accused product, all of which occurred outside the United States, but rather from the manufacturing of the accused product in the United States.[13] Thus, Edwards must establish that CoreValve's *manufacturing* operations *in the United States* are continuing and will continue to cause irreparable harm if not enjoined. Edwards, however, does not appear to dispute that CoreValve would be able to move its remaining manufacturing operations to Mexico almost immediately if the court enjoined it from continuing to manufacture its products in the United States.[14] (See, e.g., D.I. 402 at 1 ("Even now, CoreValve admits that it has been moving off shore to Mexico since January 2010 and could immediately ramp up

[13] Edwards requests that the court issue a far wider injunction covering "all modes of infringement," apparently including infringement under § 271(f), even though the jury only decided the issue of infringement under § 271(a). Indeed, the court specifically ruled that Edwards could not raise § 271(f) infringement at trial in this case due to lack of notice. (See D.I. 280.) Moreover, infringement of the '552 Patent, including § 271(f) infringement, as a result of MedTronic's activities in Mexico is currently the subject of a separate infringement suit between the same parties in this court, *Edwards Lifesciences AG v. Medtronic, Inc.*, 09-873-GMS. The court will not issue an injunction covering potential modes of infringement that it has not yet adjudicated, and that have not yet had an opportunity for a full hearing.

[14] While the jury's verdict carried with it an implicit finding that CoreValve would not have been able to move its manufacturing operations abroad by January 2006, it carried no such implicit finding with respect to whether CoreValve could do so today.

manufacturing there."); id. at 7-8; D.I. 357 at 15.) Thus, CoreValve would remain in the market with little or no interruption even if the court were to enjoin its infringing manufacturing operations in the United States, and an injunction thus would not affect the alleged harm.

As to the second *eBay* factor, any harm that Edwards does continue to suffer as a result of CoreValve continuing its United States manufacturing operations can be redressed by a monetary remedy. As with the other *eBay* factors, the burden for establishing the inadequacy of legal remedies falls on the plaintiff. *E.g.*, *eBay*, 547 U.S. at 391 (stating that the plaintiff must satisfy the four-factor test and demonstrate the presence of each factor). In its brief with respect to this factor, Edwards argues that since CoreValve is the only competitor in the market, monetary damages are insufficient. (See D.I. 357 at 10.) Edwards cites no evidence or testimony in the record, however, in support of its assertion that monetary damages would be inadequate to compensate Edwards if CoreValve were permitted to continue its United States manufacturing operations. (See id. at 10-11.) Instead, its section addressing this factor is "nothing more than attorney argument." *See Telcordia Techs., Inc. v. Cisco Systems, Inc.*, 592 F. Supp. 2d 727, 748 (D. Del. 2009). As it did in this case, Edwards can bring suit against CoreValve and seek damages if CoreValve continues its infringing manufacturing operations in spite of the judgment of infringement. Moreover, Edwards has licensed the '552 Patent to a competitor, 3F Therapeutics, for a field of use that overlaps significantly with that of Edwards' Sapien product. (See A116.) While not determinative, such licensing activity is further evidence that monetary damages would be adequate to compensate Edwards for any future infringing manufacturing operations by CoreValve.[15] *See, e.g.*, *Telcordia*, 592 F. Supp. 2d at 748 n. 10.

[15] Since the court is denying Edwards' request for a permanent injunction, the parties may, of course negotiate a license regarding the patent-in-suit. As the Federal Circuit has stated:

The remaining two *eBay* factors do not alter the court's analysis, since the only practical effect of a permanent injunction would be that CoreValve would be forced to move its United States manufacturing operations for the accused product to Mexico. Consequently, Edwards' market position and the parties' ability to sell their products would remain substantially the same regardless of whether an injunction is issued. The court fails to see what hardship Edwards would suffer if CoreValve were permitted to continue manufacturing its product in the United States, as opposed to in Mexico, that could not be compensated through remedies at law. The public interest would not be substantially advanced or harmed by the issuance of an injunction, since CoreValve would be able to continue manufacturing accused product abroad without seriously affecting the supply of the product available to the public. Consequently, the court will deny Edwards' motion for a permanent injunction.

The court will grant, however, Edwards' request for an accounting of the number of CoreValve Revalving System devices made, used, sold, offered for sale, imported or supplied in or from the United States and corresponding revenue from March 16, 2010 through the date of the order accompanying this memorandum.[16]

G. Other Post-Trial Motions

In addition to renewed JMOL and new trial motions discussed above, there are also three

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> In most cases, where the district court determines that a permanent injunction is not warranted, the district court may wish to allow the parties to negotiate a license amongst themselves regarding future use of a patented invention before imposing an ongoing royalty. Should the parties fail to come to an agreement, the district court could step in to assess a reasonable royalty in light of the ongoing infringement.

Paice LLC v. Toyota Motor Corp., 504 F.3d 1293, 1315 (Fed. Cir. 2007).

[16] It does not appear that CoreValve opposes Edwards' accounting request. (*See* D.I. 392.) The court's order with respect to accounting is made with the understanding that CoreValve remains liable only for the type of infringement that was the subject of the jury's verdict. That is to say, Edwards' damages are limited to lost profits and reasonable royalties, plus pre-judgment and post-judgment interest at the Prime Rate, resulting from CoreValve's manufacturing of infringing devices in the United States. *See* note 13, *supra*.

other post-trial motions currently pending: CoreValve's Motion to Stay Judgment Pending Post-Trial Motions (D.I. 348), CoreValve's Local Rule 7.1.3(c)(2) Motion to Strike (D.I. 391),[17] and CoreValve's Motion to Supplement Court Record (D.I. 417). The court will deny each of these motions without comment.

IV. CONCLUSION

For the reasons stated above, the court will grant Edwards' motion for pre-judgment and post-judgment interest (D.I. 344), grant-in-part and deny-in-part Edwards' motion for permanent injunction, accounting and related relief (D.I. 356), and deny the remaining pending motions.

Dated: February 7, 2011

CHIEF, UNITED STATES DISTRICT JUDGE

[17] The motion is styled "Motion to Strike Under Local Rule 7.1.3(c)(2) Portions of Edwards' Reply Briefs in Support of Its Motions for Enhanced Damages and Attorneys' Fees." (D.I. 391.)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC, Plaintiffs, v. COREVALVE, INC. and, MEDTRONIC COREVALVE, LLC Defendants.	)	C.A. No. 08-91-GMS

ORDER

For the reasons set forth in the court's Memorandum of this same date, IT IS HEREBY ORDERED that:

1. CoreValve's Renewed Motion for Judgment as a Matter of Law (D.I. 318) is DENIED in all respects.
2. CoreValve's Motion for a New Trial or Alternatively to Amend Judgment (D.I. 320) is DENIED in all respects.
3. Edwards' Motion for Attorney Fees (D.I. 339) is DENIED.
4. Edwards' Motion for Enhanced Damages Pursuant To 35 U.S.C. § 284 (D.I. 341) is DENIED.
5. Edwards' Motion for Prejudgment and Postjudgment Interest (D.I. 344) is GRANTED. The court awards Edwards prejudgment and postjudgment interest, based on the prevailing prime rate, compounded quarterly.
6. CoreValve's Motion to Stay Judgment Pending Post-Trial Motions (D.I. 348) is DENIED.

7. Edwards' Motion for Permanent Injunction, Accounting and Related Relief (D.I. 356) is GRANTED IN PART AND DENIED IN PART. Specifically, the court denies Edwards' request for a permanent injunction, but grants its request for an accounting with respect to the number of CoreValve Revalving System devices made, used, sold, offered for sale, imported or supplied in or from the United States and corresponding revenue from March 16, 2010 through the date of the order.[1]

8. CoreValve's Local Rule 7.1.3(c)(2) Motion to Strike (D.I. 391) is DENIED.

9. CoreValve's Motion to Supplement Court Record (D.I. 417) is DENIED.

Dated: February 7, 2011

CHIEF, UNITED STATES DISTRICT JUDGE

[1] Within ten (10) days from the date of this order, CoreValve shall provide Edwards with an accounting of the number of CoreValve Generation 3 THV devices made, used, sold, offered for sale, imported or supplied in or from the United States and corresponding revenue from March 16, 2010 through the date of the order, in a format acceptable to Edwards, from which Edwards can calculate its monetary damages not accounted for in the April 1, 2010 jury verdict or other post-judgment orders by the court. Within forty (40) days from the date of this order, the parties shall file a joint statement stating the amount of pre- and post-judgment monetary damages and interest attributable to this accounting. In accordance with the memorandum and order of this date, interest shall be set at the prime rate compounded quarterly, and the order for accounting is made with the understanding that CoreValve remains liable in this case only for the type of infringement that was the subject of the jury's verdict. *See* Memorandum at 29, note 16.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 08-91-GMS
COREVALVE, INC. and, MEDTRONIC COREVALVE, LLC	)	
Defendant.	)	

JUDGMENT

This action came before the Court for a trial by jury. The issues have been tried and the jury rendered its verdict on April 1, 2010. The verdict was accompanied by a verdict form (D.I. 313), a copy of which is attached hereto. Therefore,

IT IS HEREBY ORDERED AND ADJUDGED that judgment be and is hereby entered in favor of the plaintiffs, EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC, AND against the defendants, COREVALVE, INC. and MEDTRONIC COREVALVE, LLC, in the amount of SEVENTY TWO MILLION SIX HUNDRED FORTY FIVE THOUSAND FIVE HUNDRED FIFTY FIVE DOLLARS ($72,645,555.00) in lost profits for infringement of the U.S. Patent No. 5,411,552; AND in the amount of ONE MILLION TWO HUNDRED EIGHTY FOUR THOUSAND EIGHT HUNDRED SIXTY ONE DOLLARS ($1,284,861.00) for reasonable royalty.

Dated: May 4, 2010

UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC, Plaintiffs, v. COREVALVE, INC. and MEDTRONIC COREVALVE, LLC Defendants.	C.A. No. 08-091-GMS

VERDICT FORM

We, the jury, having duly deliberated on the evidence presented by the parties, answer the interrogatories posed by the Court as follows:

I. PATENT INFRINGEMENT

QUESTION 1:

Has Edwards proven by a preponderance of the evidence that the CoreValve Generation 3 ReValving System literally infringes Claim 1 of the '552 Patent?

YES ___√___ (for Edwards) NO _____ (for CoreValve)

If you answered "yes" to Question 1, go to Question 3.

If you answered "no" to Question 1, go to Question 2.

QUESTION 2:

Has Edwards proven by a preponderance of the evidence that the CoreValve Generation 3 ReValving System infringes Claim 1 of the '552 Patent under the Doctrine of Equivalents?

YES _____ (for Edwards) NO _____ (for CoreValve)

If you answered "yes" to Question 2, go to Question 3.

If you answered "no" to both Questions 1 and 2, go to Question 4.

II. WILLFUL PATENT INFRINGEMENT

QUESTION 3:

Has Edwards proven by clear and convincing evidence that CoreValve's infringement of Claim 1 of the '552 Patent was willful?

YES ___√___ (for Edwards) NO _____ (for CoreValve)

Please go to Question 4.

III. PATENT VALIDITY

QUESTION 4:

Has CoreValve proven by clear and convincing evidence that Claim 1 of the '552 Patent is invalid because it is not enabled?

YES _____ (for CoreValve) NO ___✓___ (for Edwards)

Please go to Question 5.

IV. EDWARDS' DAMAGES

If you found that CoreValve has infringed Claim 1 of the '552 Patent (either literally or under the Doctrine of Equivalents), and that CoreValve did not prove that Claim 1 of the '552 Patent is invalid, you must decide the amount of damages adequate to compensate Edwards for CoreValve's infringement.

QUESTION 5:

If you believe that Edwards has proven by a preponderance of the evidence that it is entitled to lost profits for a portion of CoreValve's infringing sales, please enter the amount of lost profits:

Answer: $ 72,645,555.00

QUESTION 6:

For those CoreValve infringing sales for which you did not award Edwards lost profits, what is the amount of reasonable royalty to which Edwards is entitled?

Answer: $ 1,284,861.00

Dated: April 1, 2010

Foreperson

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC, Plaintiffs, v. COREVALVE, INC. and MEDTRONIC COREVALVE, LLC Defendants.	C.A. No. 08-091-GMS

VERDICT FORM

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I. PATENT INFRINGEMENT

QUESTION 1:

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If you answered "yes" to Question 1, go to Question 3.

If you answered "no" to Question 1, go to Question 2.

QUESTION 2:

Has Edwards proven by a preponderance of the evidence that the CoreValve Generation 3 ReValving System infringes Claim 1 of the '552 Patent under the Doctrine of Equivalents?

YES _____ (for Edwards) NO _____ (for CoreValve)

If you answered "yes" to Question 2, go to Question 3.

If you answered "no" to both Questions 1 and 2, go to Question 4.

II. WILLFUL PATENT INFRINGEMENT

QUESTION 3:

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YES ___✓___ (for Edwards) NO _____ (for CoreValve)

Please go to Question 4.

III. PATENT VALIDITY

QUESTION 4:

Has CoreValve proven by clear and convincing evidence that Claim 1 of the '552 Patent is invalid because it is not enabled?

YES _____ (for CoreValve) NO ___✓___ (for Edwards)

Please go to Question 5.

IV. EDWARDS' DAMAGES

If you found that CoreValve has infringed Claim 1 of the '552 Patent (either literally or under the Doctrine of Equivalents), and that CoreValve did not prove that Claim 1 of the '552 Patent is invalid, you must decide the amount of damages adequate to compensate Edwards for CoreValve's infringement.

QUESTION 5:

If you believe that Edwards has proven by a preponderance of the evidence that it is entitled to lost profits for a portion of CoreValve's infringing sales, please enter the amount of lost profits:

Answer: $ 72,645,555.00

QUESTION 6:

For those CoreValve infringing sales for which you did not award Edwards lost profits, what is the amount of reasonable royalty to which Edwards is entitled?

Answer: $ 1,284,861.00

Dated: April 1, 2010

Foreperson

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 08-91-GMS
COREVALVE, INC.,	)	
Defendant.	)	

AMENDED ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 5,411,552; 6,168,614; AND 6,582,462

After having considered the submissions of the parties and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent Nos. 5,411,552 (the "'552 patent"), 6,582,462 (the "'462 patent"), and 6,168,614 (the "'614 patent"):

A. **The '552 Patent**

1. The term "elastical" in claim 1 of the '552 patent is construed to mean "capable of returning to an original shape when forces are removed."[1]

2. The term "stent" in claim 1 of the '552 patent is construed to mean "a medical device that is inserted into an anatomical vessel or passageway to provide support."[2]

[1] The parties agree on the construction of this term.

[2] The court adopts a construction that is consistent with the "ordinary and customary meaning" of the term. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). The court rejects the defendant's proposed construction. The defendant's proposed construction is not supported by the patent specification or the prosecution history. Specifically, the terms "meshed" and "tube" are not found in the specification and, if accepted, would exclude certain

3. The term "commissural points" in claim 1 of the '552 patent is construed to mean "points or locations where the leaflets of the valve are joined."[3]

4. The term "cylindrical support means" in claim 1 of the '552 patent is construed to mean "a portion of the stent supporting the valve that has a shape of or relating to a cylinder."[4]

5. The term "radially collapsible" in claim 1 of the '552 patent is construed to mean "capable of reducing or of being reduced in diameter along a cross section of the cylindrical support means."[5]

6. The term "circumferentially-expandable section" in claim 1 of the '552 patent is construed to mean "a section of the cylindrical support means that is capable of

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embodiments of the invention. *See SanDisk Corp. v. Memorex Products, Inc.*, 415 F.3d 1278, 1285 (Fed. Cir. 2005) ("A claim construction that excludes a preferred embodiment . . . 'is rarely, if ever, correct.'") (citations omitted).

[3] The court adopts a construction that is consistent with the ordinary and customary meaning of the term and that gives effect to each term of the claim. *See In re Gabapentin Patent Lit.*, 503 F.3d 1254, 1263 (Fed. Cir.2007) (noting that "claims are interpreted with an eye towards giving effect to all terms in a claim").

[4] The court rejects the defendant's proposed construction because it imports claim limitations that are not supported by the patent specification or the prosecution history. *See CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005) ("[I]t is improper to 'import limitations from the specification into the claims.'") (citations omitted). Specifically, the term "mesh" and the limitation that the diameter be "constant along the longitudinal axis" are not found in the specification.

[5] The court adopts a construction that is consistent with the "ordinary and customary meaning" of the term. *Phillips*, 415 F.3d at 1312. The court rejects the defendant's proposed construction. Specifically, the limitation that the reduction in diameter be "along the longitudinal axis" is not supported in the specification. *See CollegeNet, Inc.*, 418 F.3d at 1231; *see also* '552 Patent, Col. 2, ll. 28-34, 56-60; Col. 6, ll. 20-30.

increasing or of being increased in diameter."[6]

7. The term "radially-expandable" in claim 1 of the '552 patent is construed to mean "capable of increasing or of being increased in diameter along a cross section of the cylindrical support means."[7]

8. The term "commissural supports" in claim 1 of the '552 patent is construed to mean "portions of the stent that support the commissural points of the valve."[8]

9. The term "projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof" in claim 1 of the '552 patent is construed to mean "projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis of the cylindrical support means."[9]

10. The term "by means of a technique of catheterization" in claim 1 of the '552 patent is construed to mean "use of a catheter to deliver the valve prosthesis."[10]

11. The term "thread structure" in claim 2 of the '552 patent is construed to mean "a portion of the stent comprising one or more segments, such as a grate, loop or helical

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[6] *See* footnote 3.

[7] *Cf.* footnote 5.

[8] The parties agree on the construction of this term.

[9] *See* footnote 3. The court notes that the parties' proposed constructions for this term are quite similar.

[10] The court adopts a construction that is consistent with the "ordinary and customary meaning" of the term. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). The court rejects the defendant's proposed construction. The defendant's proposed construction is not supported by the patent specification or the prosecution history.

shaped portion."[11]

B. **The '462 Patent**

1. The term "radially collapsible and expandable" in claim 1 of the '462 patent is construed to mean "capable of reducing or being reduced in diameter, and capable of increasing or of being increased in diameter, along a cross section of the stent."[12]

2. The term "cylindrical" in claim 1 of the '462 patent is construed to mean "having a shape of or relating to a cylinder."[13]

3. The term "cylindrical support means having a cylinder surface" in claim 1 of the '462 patent is construed to mean "a portion of the stent supporting the valve that has a shape of or relating to a cylinder, and that has a cylinder-shaped surface."[14]

4. The term "stent" in claim 1 of the '462 patent is construed to mean "a medical device

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[11] The court adopts a construction that is consistent with the patent specification. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367, 1371 (Fed. Cir. 2003) ("A fundamental rule of claim construction is that terms in a patent document are construed with the meaning with which they are presented in the patent document. Thus, claims must be construed so as to be consistent with the specification, of which they are a part."); *see also* '552 Patent, Col. 2, ll. 35-42.

[12] *Cf.* footnote 5.

[13] The court adopts a construction that is consistent with the "ordinary and customary meaning" of the term. *Phillips*, 415 F.3d at 1312. In other words, the court rejects the defendant's proposed construction that requires "a diameter that is constant along the longitudinal axis." (D.I. 51 at 6.)

[14] The court concludes that this is not a means-plus-function claim under 35 U.S.C. § 112(6) because claim 1 imparts sufficient structure so as to remove this element from the purview of § 112(6). *See Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1302 (Fed. Cir. 1999) ("Where a claim recites a function, but then goes on to elaborate sufficient structure . . . the claim is not in means-plus-function format."). In addition, the court adopts a construction that is consistent with the ordinary and customary meaning of the term and that gives effect to each term of the claim. *See In re Gabapentin Patent Lit.*, 503 F.3d at 263.

that is inserted into an anatomical vessel or passageway to provide support."[15]

5. The term "commissural points" in claim 1 of the '462 patent is construed to mean "points or locations where the leaflets of the valve are joined."[16]

6. The term "by way of catheterization" in claim 1 of the '462 patent is construed to mean "use of a catheter to deliver the valve prosthesis."[17]

7. The term "thread structure" in claim 2 of the '462 patent is construed to mean "a portion of the stent comprising one or more segments, such as a grate, loop or helical shaped portion."[18]

C. **The '614 Patent**

1. The term "movable from a collapsed shape to an expanded shape" in claim 1 of the '614 patent is construed to mean "capable of moving from a smaller shape to a larger shape."[19]

Dated: February 16, 2010

CHIEF, UNITED STATES DISTRICT JUDGE

[15] *See* footnote 2.

[16] *See* footnote 3.

[17] *See* footnote 10.

[18] *See* footnote 11.

[19] *See* footnote 13.

CERTIFICATE OF SERVICE

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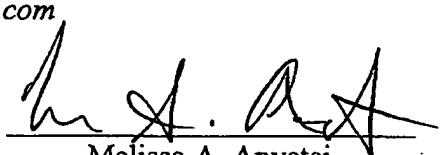

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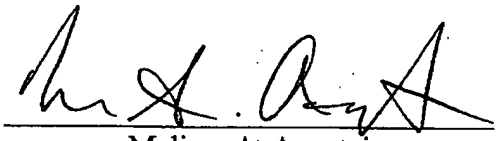

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Dated: May 18, 2011

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2011-1215, -1257

United States Court of Appeals

For the Federal Circuit

EDWARDS LIFESCIENCES AG and

EDWARDS LIFESCIENCES LLC,

Plaintiffs-Cross Appellants,

v.

COREVALVE, INC. and

MEDTRONIC COREVALVE, LLC,

Defendants-Appellants,

APPEALS FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE
IN CASE NO. 08-CV-0091, CHIEF JUDGE GREGORY M. SLEET

PLAINTIFFS – CROSS APPELLANTS' NON-CONFIDENTIAL OPPOSITION BRIEF AND CROSS-APPEAL BRIEF

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2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

   Not applicable

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are:

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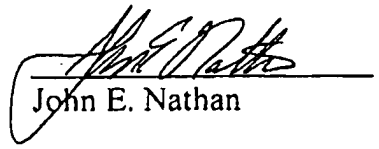
By: 
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TABLE OF CONTENTS

Page

STATEMENT OF RELATED CASES 1

STATEMENT OF JURISDICTION 1

STATEMENT OF THE ISSUES 1

STATEMENT OF THE CASE 2

STATEMENT OF FACTS 5

A. Invention of THV 5

B. Andersen '552 Patent 14

C. CoreValve's Infringing Generation 3 Product 17

D. District Court *Markman* Orders 19

E. Jury Verdict 20

F. Post-Trial Decisions 21

1. CoreValve's JMOL and related motions 21

2. Permanent Injunction 21

3. Protective Order 22

SUMMARY OF ARGUMENT 23

I. "Cylindrical Support Means" Construction 23

II. Generation 3 Meets the "Projecting ... in a Direction Generally Parallel" Limitation 25

III. Enablement 26

IV. Lost Profits 27

V. Permanent Injunction 28

VI. Protective Order 29

ARGUMENT 30

I. THE DISTRICT COURT CORRECTLY CONSTRUED "CYLINDRICAL SUPPORT MEANS" 30

A. Ordinary Meaning of "Cylindrical" is "A Shape of or Relating to a Cylinder" 31

Page

B. Intrinsic Evidence Confirms "Cylindrical" Refers to Shapes Broader than a Perfect Geometric Cylinder 33

C. CoreValve's Intrinsic Evidence Arguments Are Without Merit 36

D. The District Court Did Not Err in Declining to Further Define "Relating to a Cylinder" 41

II. SUBSTANTIAL EVIDENCE SUPPORTED THE JURY'S DETERMINATION THAT GENERATION 3 MEETS THE "PROJECTING ... IN A DIRECTION GENERALLY PARALLEL" LIMITATION 42

A. Generation 3 Employs Commissural Supports Projecting from One Side of Its Cylindrical Support Means 44

1. "Projecting" is not limited to physically "sticking out" or "protruding" 44

2. Claim 1 covers an integral structure 47

B. Generation 3's Commissural Supports Are Projecting "in a Direction Generally Parallel" to the Longitudinal Axis of Its Cylindrical Support Means 51

III. SUBSTANTIAL EVIDENCE SUPPORTED THE JURY'S VERDICT THAT COREVALVE FAILED TO PROVE NONENABLEMENT BY CLEAR AND CONVINCING EVIDENCE 54

A. The Successful Pig Tests Correlated to Tests in Humans 55

B. The '552 Patent Discloses Embodiments for Use in Humans 55

C. The Length of Time it Took to Commercialize the Andersen *Invention Was Due to Skepticism, Inattention and Routine* Development Work 57

D. Both CoreValve's Generation 3 and Edwards' SAPIEN Products Are Based on the '552 Patent 59

IV. THE JURY'S LOST PROFITS AWARD WAS SUPPORTED BY SUBSTANTIAL EVIDENCE 61

V. THE DISTRICT COURT ERRED IN DENYING A PERMANENT INJUNCTION 65

A. Standard of Review 67

Page

B. [[CONFIDENTIAL MATERIAL OMITTED]]..... 67

C. Irreparable Harm..... 69

1. Patentee's right to exclude..... 69

2. Infringement itself can constitute irreparable harm..... 70

3. Prospective irreparable harm..... 70

(a) [[CONFIDENTIAL MATERIAL OMITTED]]..... 72

(b) First-mover advantage harm continues..... 72

(c) Reputational harm to Edwards continues..... 75

D. Inadequate Remedies at Law..... 76

1. A compulsory license to Edwards' only THV competitor does not afford adequate compensation for infringement..... 76

2. The District Court misinterpreted the 3F license..... 78

E. Balance of Hardships..... 79

F. Public Interest..... 80

VI. THE PROTECTIVE ORDER RULING SHOULD BE REVERSED..... 81

CONCLUSION..... 84

CONFIDENTIAL MATERIAL OMITTED

The material omitted on pages 4, 21, 28, 62, 66-70, 72 and 79 contains information regarding CoreValve's ongoing manufacturing activities from the Parties' Statements Regarding Accounting of Monetary Damages and Interest for the Period March 16, 2010 – February 7, 2011, which was filed under seal. (Dkt. No. 439, A20305-64).

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Page(s)

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Abbott Labs. v. *Syntron Bioresearch, Inc.*,
334 F.3d 1343 (Fed. Cir. 2003) 48

Acumed LLC v. *Stryker Corp.*,
551 F.3d 1323 (Fed. Cir. 2008) 69, 70, 74, 78

Adams Respiratory Therapeutics, Inc. v. *Perrigo Co.*,
616 F.3d 1283 (Fed. Cir. 2010) 36

AK Steel Corp. v. *Sollac*,
344 F.3d 1234 (Fed. Cir. 2003) 56

Alltech, Inc. v. *Cenzone Tech., Inc.*,
No. 06 CV0153 JM, 2007 WL 5793393 (S.D. Cal. Jan. 4, 2007) 40

ALZA Corp. v. *Andrx Pharm., LLC*,
603 F.3d 935 (Fed. Cir. 2010) 54

Am. Gramophone Co. v. *Leeds & Catlin Co.*,
170 F. 327 (2d Cir. 1909) 80

Am. Piledriving Equip., Inc. v. *Geoquip, Inc.*,
637 F.3d 1324 (Fed. Cir. 2011) 38

Am. Seating Co. v. *USSC Group, Inc.*,
514 F.3d 1262 (Fed. Cir. 2008) 62

Anchor Wall Sys., Inc. v. *Rockwood Retaining Walls, Inc.*,
340 F.3d 1298 (Fed. Cir. 2003) 37, 39

Applied Med. Res. Corp. v. *U.S. Surgical Corp.*,
435 F.3d 1356 (Fed. Cir. 2006) 28, 63

Arlington Indus., Inc. v. *Bridgeport Fittings, Inc.*,
632 F.3d 1246 (Fed. Cir. 2011) 31, 38

Atlanta Attachment Co. v. *Leggett & Platt, Inc.*,
No. 1:05-CV-1071-ODE, 2007 WL 5011980 74

Becton, Dickinson & Co. v. *Tyco Healthcare Grp., LP*,
616 F.3d 1249 (Fed. Cir. 2010) 50

Biotec Biologische Naturverpackungen GmbH v. *Biocorp, Inc.*,
249 F.3d 1341 (Fed. Cir. 2001) 61

Broadcom Corp. v. *Qualcomm Inc.*,
543 F.3d 683 (Fed. Cir. 2008) 45, 74, 75, 77, 78

Cannon Rubber Ltd. v. *The First Years, Inc.*,
163 Fed. App'x. 870 (Fed. Cir. 2005) 50

Cardinal Chem. Co. v. *Morton Int'l, Inc.*,
508 U.S. 83 (1993) 80

CFMT, Inc. v. *YieldUp Int'l Corp.*,
349 F.3d 1333 (Fed. Cir. 2003) 26

Chiron Corp. v. *Genentech, Inc.*,
363 F.3d 1247 (Fed. Cir. 2004) 56

Cordis Corp. v. *Boston Sci. Corp.*,
561 F.3d 1319 (Fed. Cir. 2009) 35

Cordis Corp. v. *Medtronic AVE, Inc.*,
511 F.3d 1157 (Fed. Cir. 2008) 24, 32, 41

Depuy Spine, Inc. v. *Medtronic Sofamer Danek, Inc.*,
567 F.3d 1314 (Fed. Cir. 2009) 61, 62

Document Generation Corp. v. *Allscripts, LLC*,
No. 6:08-CV-479, 2009 WL 1766096 (E.D. Tex. June 23, 2009) 83

Durel Corp. v. *Osram Sylvania Inc.*,
256 F.3d 1298 (Fed. Cir. 2001) 56

eBay Inc. v. *MercExchange, LLC*,
547 U.S. 388 (2006) ..... passim

Ecolab, Inc. v. *FMC Corp.*,
569 F.3d 1335 (Fed. Cir. 2009) 67

Finisar Corp. v. *DirecTV Grp., Inc.*,
523 F.3d 1323 (Fed. Cir. 2008) 43

Gaus v. *Conair Corp.*,
363 F.3d 1284 (Fed. Cir. 2004) 50

Grain Processing Corp. v. *Am. Maize-Prods. Co.*,
185 F.3d 1341 (Fed. Cir. 1991) 62

Hewlett-Packard Co. v. *Mustek Systems, Inc.*,
340 F.3d 1314 (Fed. Cir. 2003) 46

i4i, Ltd. P'ship v. *Microsoft Corp.*,
598 F.3d 831 (Fed. Cir. 2010) 37, 65, 71, 76

In re Deutsche Bank Trust Co. Ams.,
605 F.3d 1373 (Fed. Cir. 2010) 82, 83, 84

In re Wands,
858 F.2d 731 (Fed. Cir. 1988) 54, 57

Innogenetics, N.V. v. *Abbott Labs.*,
512 F.3d 1363 (Fed. Cir. 2008) 67

International Rectifier Corp. v. *IXYS Corp.*,
361 F.3d 1363 (Fed. Cir. 2004) 39, 40

Inverness Med. Switz. GmbH v. *Warner Lambert Co.*,
309 F.3d 1373 (Fed. Cir. 2002) 35

Invitrogen Corp. v. *Clontech Labs., Inc.*,
429 F.3d 1052 (Fed. Cir. 2005) 56

John Mezzalingua Assocs., Inc. v. *Arris Int'l, Inc.*,
No. 03-C-353-C, 2003 WL 23282752 (W.D. Wis. Nov. 14, 2003) 24, 32

Johns Hopkins Univ. v. *CellPro, Inc.*,
152 F.3d 1342 (Fed. Cir. 1998) 56

Kenexa Brassring Inc. v. *Taleo Corp.*,
Civ. No. 07-521-SLR, 2009 WL 393782 (D. Del. Feb. 18, 2009) 83

Kim v. *ConAgra Foods, Inc.*,
465 F.3d 1312 (Fed. Cir. 2006) 46

Litecubes, LLC v. *N. Light Prods., Inc.*,
523 F.3d 1353 (Fed. Cir. 2008) 45, 46

MBO Labs., Inc. v. *Becton, Dickinson & Co.*,
474 F.3d 1323 (Fed. Cir. 2007) 38

Medtronic, Inc. v. *Daig Corp.*,
789 F.2d 903 (Fed. Cir. 1986) 39

Microsoft Corp. v. *i4i Ltd. P'ship*,
564 U.S. ___, 2011 WL 2224428 (June 9, 2011) 54

Nazomi Commc'ns, Inc. v. *Arm Holdings, PLC*,
403 F.3d 1364 (Fed. Cir. 2005) 30

Panduit Corp. v. *Stahlin Bros. Fibre Works, Inc.*,
575 F.2d 1152 (6th Cir. 1978) 61

Phillips v. *AWH Corp.*,
415 F.3d 1303 (Fed. Cir. 2005) ..... passim

Playtex Prods., Inc. v. *Procter & Gamble Co.*,
400 F.3d 901 (Fed. Cir. 2005) 41, 50

Power-One, Inc. v. *Artesyn Techs., Inc.*,
599 F.3d 1343 (Fed. Cir. 2010) 41

Princo Corp. v. *ITC*,
563 F.3d 1301 (Fed. Cir. 2009) 60

Randall May Int'l, Inc. v. *DEG Music Prods., Inc.*,
378 Fed. App'x. 989 (Fed. Cir. 2010) 24, 30

Richardson v. *Suzuki Motor Co., Ltd.*,
868 F.2d 1226 (Fed. Cir. 1989) 69

Sage Prods., Inc. v. *Devon Indus., Inc.*,
126 F.3d 1420 (Fed. Cir. 1997) 49

Sanders v. *Mosaic Co.*,
No. 2010-1418, 2011 WL 1491248 (Fed. Cir. Apr. 20, 2011) 31

Sanofi-Synthelabo v. *Apotex, Inc.*,
470 F.3d 1368 (Fed. Cir. 2006) 67, 80

Siemens Med. Solutions USA, Inc. v. *Saint-Groban Ceramics & Plastics*,
637 F.3d 1269 (Fed. Cir. 2011) 61

Smith Int'l., Inc. v. *Hughes Tool Co.*,
718 F.2d 1573 (Fed. Cir. 1983) 69

Spectralytics, Inc. v. *Cordis Corp.*,
Nos. 2009-1564, 2010-1004, 2011 WL 2307402
(Fed. Cir. June 13, 2011) 69

Texas Instruments, Inc. v. *Cypress Semiconductor Corp.*
90 F.3d 1558 (Fed. Cir. 1996) 46

TiVo Inc. v. *EchoStar Commc'ns Corp.*,
446 F. Supp. 2d 664 (E.D. Tex. 2006) 74

TiVo, Inc. v. *EchoStar Commc'ns Corp.*,
516 F.3d 1290 (Fed. Cir. 2008) 47

TiVo Inc. v. *EchoStar Corp.*,
No. 2009-1374, 2011 WL 1486162 (Fed. Cir. Apr. 20, 2011) 74

Transocean Offshore Deepwater Drilling, Inc. v.
Maersk Contractors USA, Inc.,
617 F.3d 1296 (Fed. Cir. 2010) 26, 57

Vasudevan Software, Inc. v. *Int'l Bus. Machs. Corp.*,
No. C09-05897, 2010 WL 3629830 (N.D. Cal. Sept. 14, 2010) 83

W.L. Gore & Assocs., Inc. v. *Garlock, Inc.*,
842 F.2d 1275 (Fed. Cir. 1988) 68

Xerox Corp. v. *Google, Inc.*,
270 F.R.D. 182 (D. Del. 2010) 83

STATUTES

28 U.S.C. § 1295(a)(1) 1

28 U.S.C. § 1331 1

28 U.S.C. § 1338(a) 1

35 U.S.C. § 112 ..... 3, 26

35 U.S.C. § 283 21

35 U.S.C. § 301 82

35 U.S.C. § 305 83

35 U.S.C. § 311(a) 83

35 U.S.C. § 314(a) 83

RULES

Fed. R. App. P. 4(a)(3) 1

Fed. R. Civ. P. 50(b) 21

Fed. R. Civ. P. 59 21

STATEMENT OF RELATED CASES

No appeal in or from this action was previously before this or any other appellate court. The Court's decision in this appeal may affect *Edwards Lifesciences AG, et al.* v. *Medtronic, Inc., et al.*, Case No. 09-873-GMS (D. Del.).

STATEMENT OF JURISDICTION

The District Court had jurisdiction in this patent case pursuant to 28 U.S.C. §§ 1331 and 1338(a). This Court has exclusive jurisdiction over this appeal pursuant to 28 U.S.C. § 1295(a)(1). On March 8, 2011, after the District Court's February 7, 2011 final order, plaintiffs-cross appellants Edwards Lifesciences AG and Edwards Lifesciences LLC ("Edwards") filed a timely notice of cross-appeal under Rule 4(a)(3) of the Federal Rules of Appellate Procedure.

STATEMENT OF THE ISSUES

1. Did the District Court properly construe the term "cylindrical support means," as used in Claim 1 of Andersen et al. ("Andersen") U.S. Patent 5,411,552 ("'552 Patent"), as "a portion of the stent supporting the valve that has a shape of or relating to a cylinder" and not necessarily having a diameter that is "constant along the longitudinal axis" of the cylindrical support means?

2. Was the jury's verdict of infringement supported by substantial evidence establishing that the accused Generation 3 product contains "a plurality of

commissural supports projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof"?

3. Did substantial evidence support the jury's verdict that defendants-appellants CoreValve, Inc. and its successor-in-interest Medtronic CoreValve LLC (collectively "CoreValve") failed to prove by clear and convincing evidence that Claim 1 of the '552 Patent is invalid because it was not enabled?

4. Was the jury's lost profits award supported by substantial evidence?

5. Did the District Court err in denying Edwards' motion for a permanent injunction?

6. Did the District Court err in denying Edwards' request for clarification that the Protective Order entered in this action does not preclude its trial counsel and technical expert from participating in reexaminations of the '552 Patent and other Edwards patents that were initiated by Medtronic CoreValve LLC's parent corporation, Medtronic, Inc. ("Medtronic")?

STATEMENT OF THE CASE

Edwards and CoreValve are direct competitors. Both companies manufacture and sell prosthetic heart valves implantable by a catheter, commonly

referred to as a "transcatheter heart valve" or "THV". No other competitors have entered the commercial THV market.

Edwards filed this action on February 12, 2008. A00113-53. The case was tried to a jury on Claim 1 of the '552 Patent. Only a single CoreValve device – its commercial Generation 3 THV product – was accused of infringement.

The parties disputed the construction of a number of terms used in Claim 1. A claim construction hearing was held on April 28, 2009 (A00703-97), with a supplemental hearing on February 16, 2010 (A08075-190). The District Court construed all disputed terms in various *Markman* Orders, hearings and related Jury Instructions: Order dated May 27, 2009 (A00044-48); Amended Order dated February 16, 2010 (A00049-53); Order dated February 26, 2010 (A08195-200); and April 1, 2010 Final Jury Instructions (A08858-59).

Trial commenced on March 23, 2010. The evening before, CoreValve abandoned all prior art defenses. A10337. CoreValve's sole attack on the validity of Claim 1 was lack of enablement under 35 U.S.C. § 112. *Id.*

On April 1, 2010, the jury returned its verdict. A00039-43. It found that the Generation 3 product literally infringed Claim 1 of the '552 Patent, and awarded Edwards $72.6 million in lost profits and $1.2 million in reasonable royalties. The jury also found that CoreValve's infringement was willful. These findings and the damage award were based on substantial fact and expert evidence.

The jury also found that CoreValve failed to prove Claim 1 was not enabled. This, too, was based on substantial fact and expert testimony, including the admissions of CoreValve's own witnesses praising the invention and strength of the '552 Patent.

The District Court denied CoreValve's renewed JMOL motion and its motion for a new trial or alternatively to amend the judgment. It upheld the jury's verdict finding CoreValve liable for willful infringement and the amount of the damages award. A0001-32.

The District Court erroneously denied Edwards' motion for a permanent injunction. A00029-30; A00032. [[

CONFIDENTIAL
MATERIAL OMITTED

]] The Court also misapprehended certain factual circumstances relevant to the equitable injunction analysis, which led to an improper application of the *eBay* decision.

Edwards requested clarification that the Protective Order (A00312-30) permits Edwards' trial counsel and technical expert to participate in post-trial reexaminations of the '552 Patent and other Edwards patents initiated by Medtronic. A20044. The District Court's denial of this request was erroneous because participation in patent reexaminations is not barred by the Protective Order. A00054-55.

Upon the entry of the District Court's February 7, 2011 final Order, CoreValve appealed. A20036-38. Thereafter, Edwards timely cross-appealed the denial of the permanent injunction and the Protective Order ruling. A20039-41.

STATEMENT OF FACTS

"Revolutionary" is an overworked word in patent cases. Not here. The Andersen THV invention has proven to be a game changer in cardiac surgery. The invention has saved lives of aged and infirm patients who need heart valve replacements but cannot tolerate traditional open heart surgery. Now, a heart valve can be replaced using a minimally invasive catheterization procedure that eliminates open heart surgery, its risks and the prolonged post-operative recovery time.[1]

The Andersen invention goes back over twenty years. Long before CoreValve appeared on the scene.

A. Invention of THV

The human heart beats millions of times a year and billions of times over an average lifetime. A20081. With each beat, valves open and close to allow

[1] An animation of the Andersen invention being deployed in the human heart appears on Edwards' website: http://www.edwards.com/products/transcathetervalves/pages/transfemoralanimation.aspx?SapienTHV=1

the heart to pump blood to the body. Unfortunately, as people age, their heart valves – particularly the aortic valve – sometimes degenerate. A20081-82.

Prior to the Andersen invention, patients who experienced these problems had to undergo open heart surgery to replace the aortic valve. A00061; A20082-83. Open heart surgery is extremely invasive and expensive. The chest is surgically opened, the patient is placed on a heart-lung bypass machine, the heart is stopped and cut open, the diseased valve is removed, and a replacement valve is sewn into place. The operation takes hours. *Id.* Afterwards, patients undergo lengthy and painful recoveries that last weeks. A10511-12; A20082-83. Many patients who need heart valve replacement are too elderly or infirm to survive this surgery. A00061; A10512; A20250. There was no treatment option available for these patients and their condition worsened until death.

In the late 1980's, Dr. Andersen was training as an interventional cardiologist at Aarhus Medical School in Denmark.[2] A20093. He watched countless patients go through open heart surgery or slowly demise. A20097. He conceived of replacing a patient's native valve without surgery, by using a catheter

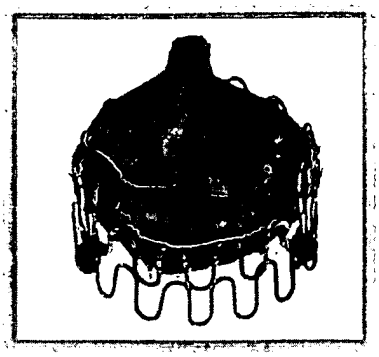
[2] An interventional cardiologist concentrates on closed-chest procedures using catheters, such as angioplasty. A20274; A20209-10; A10777. A cardiac surgeon performs surgery on the heart itself. A10989-90; A10776.

to deliver a collapsible valve mounted on a stent and then expanding and securing the new valve in the native aortic annulus. *Id.*

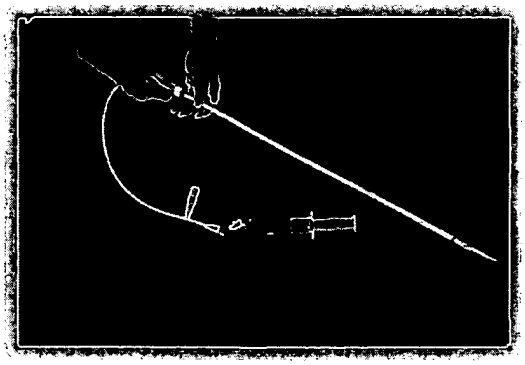
Dr. Andersen recognized this was an ambitious endeavor, so he sought assistance from other doctors. A20216. His colleagues thought his idea was "crazy" and "impossible." A20215-16. Nonetheless, he found the help he needed. Dr. Hasenkam, training in cardiac surgery, provided knowledge of conventional aortic valve replacement, valve design and suturing. A20094. Medical student Knudsen also joined the team. A20095-96. Each contributed to the effort. Each is named as a co-inventor on the '552 Patent. A00056.

The inventors worked in a hospital catheter lab, employing surplus surgical wire, pig valves, used catheters and live pigs to perform their first feasibility experiments.[3] A20099-102; A20106-07. They built handmade prototypes (shown on following page).

[3] Pigs were chosen because their vascular anatomies are very similar to human anatomy. A20118.



Andersen prototype valve mounted in stent
A31196 (PTX 2131)



Andersen prototype catheter delivery system
A31272 (PTX 2132)

Andersen prototype valve and stent collapsed in catheter ready for delivery
A31268 (PTX 2132)

All of this was done on a budget of just $50.00. A20226. The doctors had no financing or technical assistance from medical device engineers. A20106; A20128. Despite these constraints, the pig experiments were successful. Contemporaneous videos showed the deployed valves working properly. A20114-18; A20122.

The inventors' results were viewed with skepticism. Medical journals refused to publish their work. One said the inventors' manuscript drew "outrageous conclusions" and was "gimmicky." A23219. At the time, only one journal published their work. A23134-36; A23120-24.

The doubters were proven wrong. Ultimately, a leading cardiology textbook described the inventors' work as "most exciting" and "pioneering." A23454; A11758-63. Medical journals and textbooks hailed their experiments as proving that transcatheter valve replacement was not merely a "crazy idea" but an impending reality. A23454; A22954; A22957; A20215.

Even CoreValve recognized the importance of the Andersen invention and the '552 Patent. Dr. Seguin, CoreValve's founder, characterized it as a "very strong patent." A11336-37; A22996. Georg Bortlein, CoreValve's CEO, described the inventors' publication of their work as "important." A11159-60. CoreValve's chief product designer, Than Nguyen, expressed a desire to meet Dr. Andersen, stating, "really I admire him very much, based on whatever he's done."

A10755. One of CoreValve's trial experts, Dr. Rothman, characterized Dr. Andersen's work as a "good idea." A11762.

With a small grant from the Danish Technological Institute, the inventors filed a Danish patent application in 1990. A20090; A00056. The '552 Patent was granted, with priority from the Danish Application. A00056; A20219.

Commercializing the invention was beyond the doctors' reach. Recognizing they were "simple doctors" and not "design engineers" (A20128), they knew that they could not produce a commercial product without help from medical device engineers and corporate financing. A20179-80; A20234-35; A20128-29. They sought to partner with a medical device company, but were met only with skepticism. A20138-41. Many companies did not even respond to the inventors' letters for fear that THV technology would alienate cardiac surgeons, who were their most lucrative customers. A11752-53; A23190. Only Palo Alto start-up Stanford Surgical Technologies ("SST") showed interest, and, in 1993, the inventors granted SST an exclusive license. A20141-42; A23137-46. The inventors believed SST would immediately begin the design optimization work necessary to make their invention a commercial reality. A23266.

SST never performed that work. In the seven years SST (later renamed "Heartport") held the exclusive license for the '552 Patent, they did virtually nothing to develop the revolutionary invention it disclosed and claimed.

A20141-46. Dr. Andersen begged them to advance the technology. A23266. As he wrote to Heartport in 1995: "I have the feeling that you ar[e] doing nothing." *Id.* In 1997, Dr. Hasenkam traveled from Denmark to SST and was disheartened to discover that SST had still done nothing. A20144-45.

In 2000, after years of inactivity, SST sold its exclusive license to Percutaneous Valve Technologies, Inc. ("PVT"), a start-up with the sole goal of developing an aortic THV. A23231-59; A20146; A20257. PVT thought so much of the '552 Patent that it spent 20% of its funding to buy the patent rights. A11672-73. Within two years, PVT successfully implanted in a patient an aortic THV covered by the '552 Patent. This "first-in-man" procedure, as it is known in the industry, occurred in 2002. A20257; A11485; A23008-09.

Contemporaneously, Edwards was working to develop its own THV. A20254-56. After PVT's success, Edwards negotiated to purchase PVT. A20257. Central to Edwards' decision was ownership of PVT's license rights. A20259-61. Edwards structured its agreement with PVT so it would retain the rights to the '552 Patent even if the deal fell apart prior to closing. A20259; A27319-38. After it purchased PVT, Edwards commercialized the Andersen invention when it launched its "SAPIEN" THV. A20264. The SAPIEN THV, which has now been implanted in thousands of patients worldwide, is covered by the '552 Patent.

A20287; A10901. By the time of trial, Edwards had spent some $400 million on the SAPIEN THV program. A20249.

CoreValve came on the scene years after the inventors' work. From the start, CoreValve's plan was to capitalize on the Andersen invention, build a company based on an aortic THV, and then cash out by selling to a big medical device company. Both in contemporaneous documents and at trial, CoreValve's executives admitted this was their "exit strategy." A11509-10; A11513-17; A26153-54. The plan worked. In 2009, Medtronic acquired CoreValve for $700 million. A20696; A11303-04.

CoreValve started in France. There, Dr. Seguin, CoreValve's founder, was an interventional cardiologist and an entrepreneur looking for a lucrative opportunity. He had some notion that a prosthetic heart valve could be implanted using a catheter, but until the day he got a copy of the Andersen European patent in 1996, he had no idea how to actually accomplish it. A11319-21. In 1999, he teamed with Georg Bortlein, a former investment banker, to form CoreValve. A11110-12. They studied the inventors' '552 Patent and publication. A11259-60; A11322-23; A11157. They followed the developments at PVT. Bortlein "understood at the time that [it] was an important development for PVT to acquire the rights to [the '552 Patent]." A11331; A11326; A11158. With what they learned from the inventors, Messrs. Seguin and Bortlein enlisted the aid of

Admedes, a German stent manufacturer. A11141. Together, it took them just six months to construct and implant a prototype device (Generation 1). A11140-41; A11153-54.

Dr. Seguin claimed he developed CoreValve's THV independently. But at trial, he admitted he did not have a scrap of paper, a prototype or a photograph to substantiate his claim. A11317. The earliest documentation Dr. Seguin produced was 1996 correspondence with his French patent attorney about the European Andersen patent. A11321.

In 2005, Edwards sent Dr. Seguin a letter notifying him that Edwards suspected that the CoreValve device then in development infringed the '552 Patent and requesting an explanation. A22940-41. Neither Dr. Seguin, nor anyone acting on his behalf, ever responded. A11330.

At trial, no attorney came forward on CoreValve's behalf to testify that the '552 Patent was not infringed and/or invalid. After hearing how CoreValve studied the inventors' patent, and the sequence of events that led to the Generation 3 product, the jury found the infringement was willful. A00036. The Court below denied CoreValve's JMOL motion on willfulness. A00008-10; A00031, which CoreValve has not appealed.

B. Andersen '552 Patent

Claim 1 of the '552 Patent provides:

> A valve prosthesis for implantation in a body channel, the valve prosthesis comprising a collapsible elastical valve which is mounted on an elastical stent, the elastical valve having a plurality of commissural points, wherein the stent comprises:
>
> cylindrical support means which is radially collapsible for introduction within the body channel and which has a plurality of circumferentially-expandable sections such that the cylindrical support means is radially expandable for being secured within the body channel; and
>
> a plurality of commissural supports projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof for supporting the commissural points of the collapsible valve, at least one circumferentially-expandable section of the cylindrical supports means lying between each of the commissural supports, such that the collapsible valve may be collapsed and expanded together with the cylindrical support means for implantation in the body channel by means of a technique of catheterization.

A00064, col.7 l.57-col.8 l.19 (underlined elements are subject of CoreValve's appeal). The validity of Claim 1 was recently confirmed by the PTO.[4]

Claim 1 recites that only the support means is cylindrical, not the entire stent. The preferred embodiment shown in Figure 2 illustrates the

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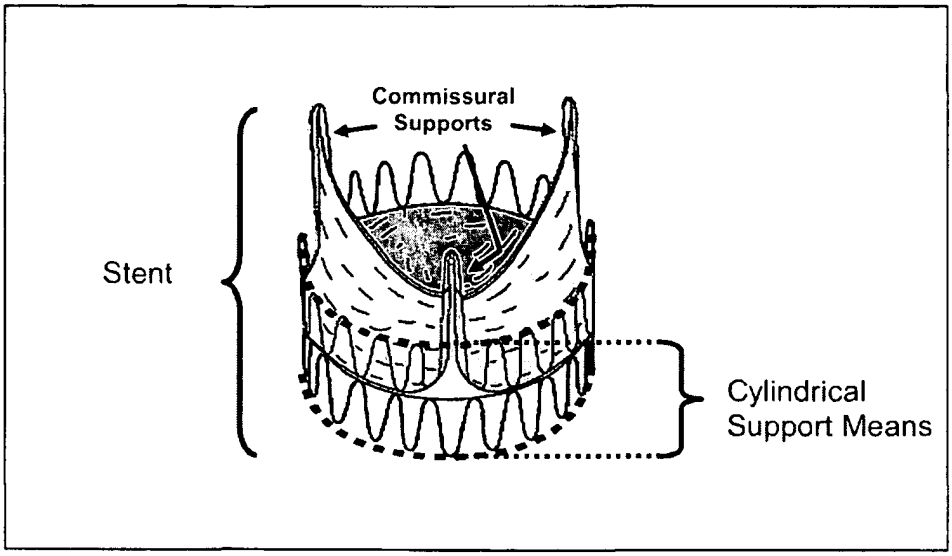
[4] *Notice of Intent to Issue Ex Parte Reexamination Certificate*, USPTO Appl. No. 90/09779, May 20, 2011, http://portal.uspto.gov/external/portal/pair.

cylindrical support means and the commissural supports projecting from one side thereof:

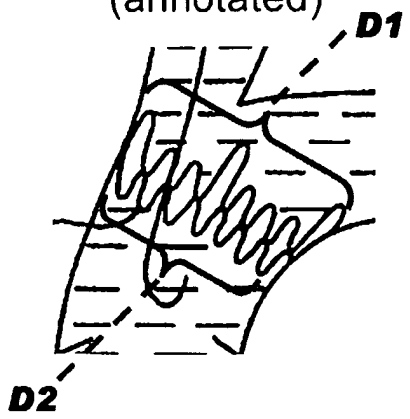


Annotated Figure 2 of '552 Patent (A00057)

Figure 2 is the prototype the inventors used in the pig studies. *See* picture, *supra* p. 8. This drawing, and the related portions of the specification, detailed the way they constructed the device, the materials used and the precise dimensions. A00063, col.5 ll.9-35. The inventors also taught that a "corresponding form" could be implanted in human patients. A00063, col.5 ll.37-39. Proof at trial established that one familiar with interventional cardiology would understand that a device usable in humans would necessarily be smaller and stronger than the inventors' prototypes. A10814-15.

Figure 9 (A00059) warrants special mention. It shows the THV positioned above the aortic annulus, with a varying diameter conforming to the anatomy (diameter D1 is greater than diameter D2):

Portion of Andersen Figure 9
(annotated)



See A10823-24.

The specification also describes various ways to expand the device. In Figures 3-7, the inventors taught using a balloon, the expansion mechanism used in their experiments (A00058-59). They also taught using a self-expandable stent, the method CoreValve uses in its Generation 3 product. A00061, col.2 ll.45-68; A22703.

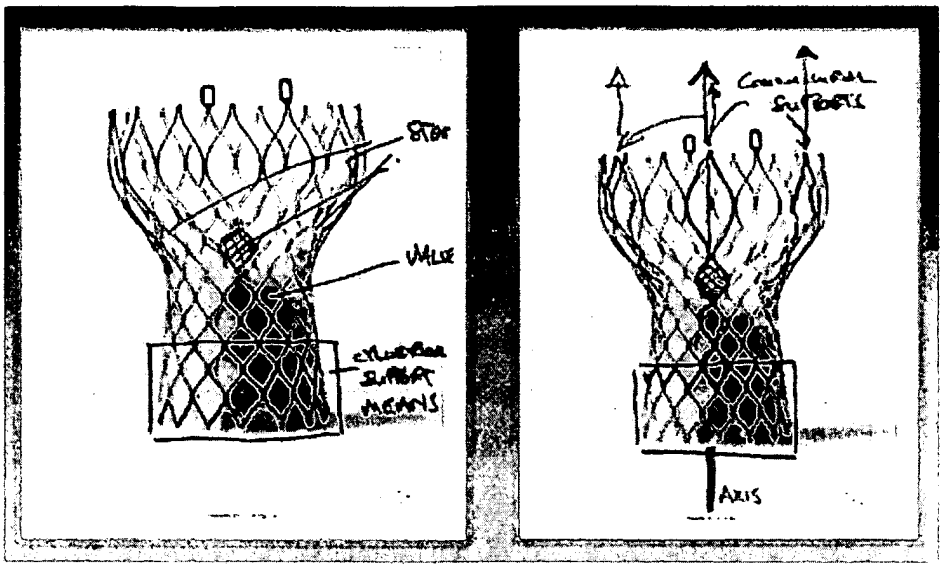
C. CoreValve's Infringing Generation 3 Product

Only CoreValve's Generation 3 product was manufactured and sold commercially.

Generation 1 was designed and constructed in France, using a stent manufactured by Admedes. A11141. It was implanted in a patient in 2004, two years after PVT's first-in-man procedure. A11140-43; A11157; A11485.

Recognizing they needed technical help to develop a commercial product, in 2004, Messrs. Seguin and Bortlein moved the company from France to Irvine, California, where Edwards is located. A11278-80; A11152; A26753. There, they hired former Edwards engineers, who proceeded to design Generation 2 and later, Generation 3. A11338-40. As CoreValve's chief product designer Nguyen testified, the valve used in Generation 3 was a "design by itself." A10749.

At trial, Edwards' technical expert, Dr. Buller, demonstrated how each element of Claim 1 was present in the Generation 3 product. A10849-71. To illustrate his testimony, Dr. Buller annotated photographs of Generation 3 (shown on following page).



Dr. Buller's annotated photographs of Generation 3
(cylindrical support means in blue; commissural supports in green)
A31341; A31342 (PTX 2136 and 2137)

Dr. Buller's annotated photographs were admitted into evidence without objection. A11097; A31341; A31342. With the Court's permission and without any objection, the annotated photographs were included in the jurors' notebooks. A11900.

On the "cylindrical" issue central to CoreValve's appeal, Dr. Buller relied on CoreValve's own documents that described Generation 3 as having a "non-uniform ***cylindrical*** shape." A10843; A30913; A30916; A30922; A30925; A30928; A30931; A30937; A30943; A30946; A30955; A30958; A30961;

A30964; A30967; A30970; A30985; A30994; A30997; A31000; A31003; A31012; A31015; A31021; A31029; A31032 (emphasis added). He also relied on CoreValve's instructional video and a photograph of Generation 3 after implantation. They showed that – both prior to implantation and when deployed in the body – Generation 3 has a cylindrical support means with a shape approaching a geometric cylinder and commissural supports projecting in a direction generally parallel to the cylindrical support means' longitudinal axis. A10837-38; A26782; A10987-88; A24557-58.

CoreValve claims Generation 3 embodies features not disclosed in the '552 Patent. CV.Br. 11-15. Most are disclosed, such as the "integral structure" (A11779; A11781-82), avoiding the coronary ostia (A00063, col.6 ll.56-62, A00063), and varying diameter (A00059, Fig. 9). None of CoreValve's alleged "fundamental device changes" (CV.Br. 11) are directed to elements of Claim 1 of the '552 Patent. *See, e.g.*, A11774-77.

D. District Court *Markman* Orders

On May 27, 2009, the District Court issued its first claim construction Order. A00044-48. It construed "cylindrical support means" to mean "a portion of the stent supporting the valve that has a shape of or relating to a cylinder." A00045. The Court expressly rejected CoreValve's contention that the "diameter be 'constant along the longitudinal axis'" of the cylindrical support means.

A00045 n.4; A00012. The parties agreed that the terms "projecting" and "generally parallel" should be given their ordinary meanings, and no special construction was required. A00004-06.

As the District Court canvassed in its February 7, 2011 Memorandum, time and again CoreValve sought to reargue "cylindrical" based on its rejected "constant diameter" interpretation. A00012-16. In a February 16, 2010 Order, the District Court even amended its claim construction Order to make plain that the term "cylindrical" does not require "a diameter that is constant along the longitudinal axis." A00014; A00052. Undaunted, CoreValve's expert, Dr. Rothman, refused at trial to follow the Court's construction. A00014-15.

With "hope springing eternal," the District Court believed that CoreValve's harassment on the cylindrical construction would end with the trial. A00015. It did not. CoreValve's post-trial motions continued to reargue that a "cylinder" with a "constant diameter" was the proper construction. The Court found that "[s]uch conduct is simply unacceptable in light of trial counsels' duties as officers of the court." A00016. It warned that sanctions may be appropriate in the future. *Id.*

E. Jury Verdict

The jury returned a verdict that CoreValve willfully infringed the '552 Patent by manufacturing the Generation 3 product in Irvine. It awarded Edwards

approximately $74 million in damages. A00039-43. The jury also found that CoreValve had failed to prove that Claim 1 was not enabled. A00042.

F. Post-Trial Decisions

1. CoreValve's JMOL and related motions

CoreValve filed motions under Federal Rules of Civil Procedure 50(b) and 59, to set aside the verdict, for a new trial, or to amend the judgment. The District Court rejected CoreValve's arguments, echoed in this appeal, regarding claim construction and the sufficiency of evidence supporting the jury's verdict. A00003-08; A00010-21; A00031.

2. Permanent Injunction

Edwards moved for a permanent injunction under 35 U.S.C. § 283. A00025-30; A00032. [[

CONFIDENTIAL
MATERIAL OMITTED

]] The harm to Edwards is real and continuing. And the injury will escalate, since CoreValve is gearing up to sell its Generation 3 product in the U.S.

3. Protective Order

Leading up to trial, CoreValve argued that the '552 Patent was invalid in view of the prior art. A08073-74; A05623-24; A06251-53. About twelve hours before jury selection and without prior notice, however, CoreValve abandoned all of its prior art defenses. A10337. After receiving the unfavorable jury verdict, Medtronic then requested *ex parte* reexamination of the '552 Patent. A19929.

Edwards requested clarification that the "patent prosecution bar" in the Protective Order (A000312-30) did not preclude its trial counsel and Dr. Buller from assisting in the '552 and related reexamination proceedings. A19923; A20044; A20046-47. The District Court denied Edwards' request. A00054-55.

On May 20, 2011, the PTO issued its final action in the '552 Patent reexamination, confirming the validity of Claim 1 of the '552 Patent without qualification and rejecting all of Medtronic's arguments. *See supra* p. 14 n.4. Because Medtronic has initiated requests to reexamine three other Andersen patents[5] and is likely to repeat that practice for additional Edwards THV patents, Edwards appeals the Court's Protective Order ruling.

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[5] App. No. 90/009791, App. No. 95/001615 and App. No. 95/001616.

SUMMARY OF ARGUMENT

Claim 1 of the '552 Patent literally covers CoreValve's Generation 3 product. The District Court's *Markman* construction was correct. As of its effective filing date in May 1990, the specification and drawings of the '552 Patent enabled one skilled in the art to practice the invention. The jury verdict on literal infringement, willfulness, enablement and damages was supported by substantial evidence. Misled by CoreValve, the District Court erred in denying a permanent injunction. It also erred in declining to allow Edwards' trial counsel and expert to participate in the reexamination proceedings Medtronic provoked.

I. "Cylindrical Support Means" Construction

The District Court properly construed the term "cylindrical support means" to mean "a portion of the stent supporting the valve that has a shape of or relating to a cylinder." That construction is supported by the specification and drawings. Nothing in the specification, claims or prosecution history supports importing CoreValve's limitation that the diameter be "constant along the longitudinal axis." Indeed, the '552 Patent discloses an embodiment (Figure 9) that is not in the shape of a perfect geometric cylinder having a constant diameter, and specifically references as the "nearest" prior art a shape that is not a perfect cylinder.

Nothing in the prosecution history evidences a clear disavowal of structures other than a perfect geometric cylinder. The term "cylindrical support means" was used in the claims as originally filed, and was never limited – indeed, never even addressed – during prosecution.

Claim 1 recites a valve "for introduction within [a] body channel." A00064, col.8 l.4. In this environment, and as this Court has observed, "a perfect cylinder, ...of course, is an abstraction that cannot be achieved by any real world device." *Cordis Corp.* v. *Medtronic AVE, Inc.*, 511 F.3d 1157, 1176 (Fed. Cir. 2008). Another District Court – also tasked with construing "cylindrical" – construed it exactly the same way the District Court did here and rejected a perfect geometric cylinder. *John Mezzalingua Assocs., Inc.* v. *Arris Int'l, Inc.*, No. 03-C-353-C, 2003 WL 23282752, at *9-10 (W.D. Wis. Nov. 14, 2003).

Edwards recognizes that a *Markman* construction is reviewed *de novo* in this Court. Where, as here, however, the District Court repeatedly reviewed and revisited the meaning of "cylindrical" at CoreValve's request and persistence, the trial court's view should carry weight. *Randall May Int'l, Inc.* v. *DEG Music Prods., Inc.*, 378 Fed. App'x. 989, 996 (Fed. Cir. 2010).

The jury properly rejected CoreValve's attempt to limit Claim 1 to the preferred embodiment shown in Figure 2 of the '552 Patent. Its verdict that Generation 3 literally infringed because it included a "cylindrical support means"

was based on a proper claim construction and substantial evidence. The District Court's denial of CoreValve's post-trial motions on that ground should be affirmed.

II. Generation 3 Meets the "Projecting ... in a Direction Generally Parallel" Limitation

Ample evidence also supported the jury's finding that Generation 3 possesses "a plurality of commissural supports projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof." The jury applied the ordinary meaning of the term "projecting ... in a direction generally parallel" because both parties agreed, and the District Court ruled, that no special construction was necessary. The jury properly found that, just like the inventors' preferred embodiment, the Generation 3 stent is an integral structure that includes upper portions (commissural supports) projecting from one side of the lower portion (cylindrical support means) in a direction generally parallel to its longitudinal axis.

CoreValve improperly conflates the valve's "commissural points" and the stent's "commissural supports" to argue that the Generation 3 commissural *supports* are not oriented in a direction generally parallel to the longitudinal axis because the commissural *points* of the valve are anchored on slopes. Neither the

jury nor the District Court was swayed by this argument. This Court should affirm.

III. Enablement

Claim 1 is fully enabled by the specification. It claims a valve prosthesis for implantation in a body channel. The inventors successfully implanted their device in the body channels of pigs, whose anatomy is very similar to human anatomy. The specification fully disclosed their successful design and experimental results, and extensively discussed human implantation. Moreover, promptly after doctors began working with medical device engineers – the collaboration defined by CoreValve's expert as possessing ordinary skill in the art – two different teams implanted devices based on the '552 Patent in human patients. Measured by this Court's *Wands* factors, Claim 1 was enabled.

A patent need not disclose a perfected commercial embodiment. *Transocean Offshore Deepwater Drilling, Inc.* v. *Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1306-07 (Fed. Cir. 2010). Section 112 requires enablement of Claim 1, not a commercial product.

Additionally, refinement of an invention does not establish nonenablement when it is done to meet commercial standards and is routine in the relevant art. *CFMT, Inc.* v. *YieldUp Int'l Corp.*, 349 F.3d 1333, 1339 (Fed. Cir. 2003). As acknowledged by multiple witnesses for both parties, developmental

work undertaken by doctors working with medical device engineers is typical in the cardiovascular field.

CoreValve failed to provide clear and convincing evidence that Claim 1 was not enabled, and the jury's finding was supported by substantial evidence. The District Court properly denied CoreValve's post-trial motions on enablement. That decision should be affirmed.

IV. Lost Profits

Lost profits were appropriately awarded to Edwards. CoreValve's Generation 3 design was frozen in January 2006. That was the date of first infringement argued by Edwards, adopted by the jury, and upheld by the District Court. A00016-17. Based on the manufacture of one part of Generation 2 (the stent[6]), CoreValve asserts that the date of first infringement was August/September 2004. Using that earlier date, CoreValve argues the alleged existence of an acceptable noninfringing substitute. Substantial evidence supports the rejection of CoreValve's argument. Moreover, although Generation 2, which CoreValve never commercialized, may also infringe the '552 Patent, it is a different device. The manufacture of Generation 3 was a separate act of infringement, and therefore

[6] CoreValve's brief sometimes refers to the stent as a "frame." *See* CV.Br. 66.

requires a separate damages analysis as a matter of law. *See Applied Med. Res. Corp.* v. *U.S. Surgical Corp.*, 435 F.3d 1356, 1361-62 (Fed. Cir. 2006).

The jury's award of lost profits was proper, and the District Court correctly denied CoreValve's motions. That decision should be affirmed.

V. Permanent Injunction

The District Court's denial of a permanent injunction turned in large part on a single "fact" – that CoreValve would imminently move its manufacturing operations to Mexico. Having no discovery on this issue, Edwards, like the Court, was forced to assume this "fact" in its motion for a permanent injunction based on CoreValve's representation. [[CONFIDENTIAL MATERIAL OMITTED]] Making matters worse, CoreValve is preparing to sell that product in the U.S. The District Court's invitation that Edwards should simply sue again violates both Edwards' *res judicata* rights and settled public policy of finality.

Furthermore, the District Court erred in its findings on irreparable harm and the sufficiency of monetary damages by failing to assign any value to the loss of Edwards' right of exclusivity, or to the on-going harm caused by CoreValve's first-mover advantage. The District Court also did not credit that

Edwards was being forced to enter into a compulsory license with its only THV competitor. This was contrary to a proper *eBay* analysis.

The District Court's denial of a permanent injunction should be reversed and an injunction ordered.

VI. Protective Order

The Protective Order is limited to persons "working on patent prosecution." Reexamination is fundamentally different, and not included in the patent prosecution bar. Numerous courts have recognized this important distinction.

Prompted by CoreValve's claim that its confidential information *might* be used, the District Court erred on the side of caution. Because CoreValve's confidential information is not involved in, and is irrelevant to, the reexamination proceedings, this Court should reverse and allow Edwards' trial counsel and expert to participate in the reexaminations.

ARGUMENT

I. THE DISTRICT COURT CORRECTLY CONSTRUED "CYLINDRICAL SUPPORT MEANS"

CoreValve raises a single claim construction issue: the meaning of "cylindrical support means."[7] Although the District Court's claim construction is reviewed *de novo*, "common sense dictates that the trial judge's view will carry weight." *Nazomi Commc'ns, Inc.* v. *Arm Holdings, PLC*, 403 F.3d 1364, 1371 (Fed. Cir. 2005); *Randall May*, 378 Fed. App'x. at 996.

The District Court's construction is particularly entitled to weight here. Prompted by CoreValve's unrelenting persistence, the District Court was forced to revisit its construction over and over. The long, unfortunate history is chronicled in the Court's post-trial decision. A00012-16. Over the course of a year, the Court held a *Markman* hearing and a supplemental hearing. A00703-97; A08075-190. It issued three *Markman* Orders. A00044-48; A00049-53; A08195-200. CoreValve continued to argue "cylindrical" at trial. A11743. When CoreValve's expert, Dr. Rothman, refused to follow the Court's construction, the Court drafted its Final Jury Instructions to make plain that it rejected CoreValve's

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[7] CoreValve does not contest that only a portion of the stent – the support means – is cylindrical. That is how Claim 1 is constructed, as the District Court correctly ruled. A00045; A00050; CV.Br. 32.

The parties agreed that "cylindrical support means" does not render Claim 1 a means-plus-function claim. A00723.

construction that cylindrical meant a perfect geometric cylinder having "a diameter that is constant along the longitudinal axis." A08858-59. As the Court instructed the jury, "[t]he term cylindrical does not mean that the object described must be a cylinder." A08858-59.

The District Court properly construed "cylindrical support means" to mean "a portion of the stent supporting the valve that has a shape of or relating to a cylinder." A00045, A00050. It rightly rejected CoreValve's attempt to import into Claim 1 "the limitation that the diameter be 'constant along the longitudinal axis'" because that limitation is nowhere in the specification. A00045 n.4; A00050 n.4; *see Sanders* v. *Mosaic Co.*, No. 2010-1418, 2011 WL 1491248, at *3 (Fed. Cir. Apr. 20, 2011); *Arlington Indus., Inc.* v. *Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1256 (Fed. Cir. 2011).

The District Court faithfully followed the instructions in *Phillips* v. *AWH Corp.*, 415 F.3d 1303, 1312-19 (Fed. Cir. 2005). Its claim construction was compelled by both the ordinary meaning of "cylindrical" and the intrinsic evidence.

A. Ordinary Meaning of "Cylindrical" is "A Shape of or Relating to a Cylinder"

Claim 1 uses the term "cylindrical," not "cylinder." "Cylindrical" is a different word than "cylinder," and its meaning is related, but distinct. This is

apparent from everyday use. For example, a soda can, having bevels at the top and bottom, is "cylindrical," though it lacks a constant diameter along its entire length to qualify as a perfect geometric cylinder.

CoreValve would limit Claim 1's support means to the shape of a perfect geometric cylinder. This Court, however, rejected a similar attempt to limit a claim covering cardiovascular stent technology, because "a perfect cylinder, ...of course, is an abstraction that cannot be achieved by any real world device." *Medtronic AVE*, 511 F.3d at 1176. As another District Court observed, "cylindrical" is an adjective that refers to the geometric concept of the noun "cylinder," but is not restricted to the noun's precise meaning. *See John Mezzalingua Assocs.*, 2003 WL 23282752, at *9-10 ("Nothing in th[e ordinary] definition [of cylindrical] ... requires 'cylindrical' objects to be perfect circular cylinders. A tapered object can still be 'cylindrical.'").

CoreValve insists Generation 3 is "noncylindrical." CV.Br. 28. But in its own documents, CoreValve repeatedly used "cylindrical" in its ordinary sense to describe its product as having a "non-uniform ***cylindrical*** shape." *See, supra* p. 18-19.

Recognizing that the terms "cylindrical" and "cylinder" are related but distinct, the District Court properly construed "cylindrical," the term which actually appears in Claim 1, as "a shape of or relating to a cylinder." As set forth

below, the intrinsic evidence confirms that the inventors used that ordinary meaning.

B. Intrinsic Evidence Confirms "Cylindrical" Refers to Shapes Broader than a Perfect Geometric Cylinder

The '552 Patent demonstrates that the inventors used the term "cylindrical" in Claim 1 to refer to shapes related to a cylinder, not just perfect geometric cylinders having a constant diameter. They even illustrated an embodiment that does not have a constant diameter.

The specification describes an invention designed for "implantation in a body channel" and its ultimate "outer dimension [] is slightly larger than the channel in which it is placed." A00064, col.7 ll.57-58; A00061, col.2 ll.59-60. Anatomical channels are never perfect cylinders in the geometric sense. A10817-18; A10830-31. The invention, then, must conform to the shape of the body channel in which it is deployed. A00061, col.2 ll.59-60; A10823-24. Therefore, Claim 1 cannot be limited to devices with a constant diameter.

Figure 9 proves the point. It illustrates how the invention conforms to the shape of the ascending aorta, which does not have a constant diameter. A10823-24. *See* annotated Figure 9, *supra* p. 16.

Even the prior art referenced in the '552 Patent demonstrates the inventors did not confine themselves to perfect geometric cylinders. The

specification refers to Ross et al. published British patent application GB-A-2,056,023 as the "nearest prior art." A00061, col. 2 ll.10-18. In the Andersen inventors' own words, Ross discloses "an elastic collapsible valve mounted on the cylinder surface of a *cylindrical* stent." *Id.* at ll.13-14 (emphasis supplied). Reference to Ross shows why the Andersen inventors described it as "cylindrical," not a cylinder:

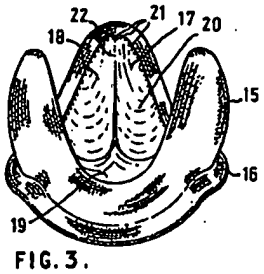


FIG. 3.

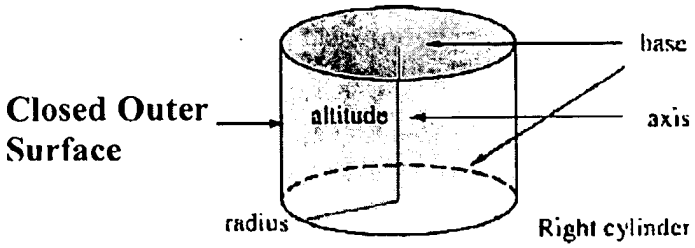
Ross published application (A00559)

Indeed, Ross described its device as "barrel-like in form," and thus not a cylinder in the strict geometric sense. A00561, p.2, ll.118-27.

Nothing in the '552 prosecution supports the conclusion that the inventors intended to deviate from the ordinary meaning of "cylindrical" adopted by the District Court. The phrase "cylindrical support means" was present in application Claim 1 as originally filed. A20458. As CoreValve acknowledges, throughout the entire prosecution history, this element was never addressed, let alone limited. CV.Br. 33. There was no disavowal of structures other than a perfect geometric cylinder, which this Court requires to be clear and unambiguous.

See Cordis Corp. v. *Boston Sci. Corp.*, 561 F.3d 1319, 1329 (Fed. Cir. 2009); *Inverness Med. Switz. GmbH* v. *Warner Lambert Co.*, 309 F.3d 1373, 1382 (Fed. Cir. 2002).

The intrinsic evidence provides another reason why CoreValve's "cylinder" construction should be rejected: it excludes the inventors' preferred embodiment. Specifically, CoreValve defines "cylinder" as the shape resulting from "moving a straight line in a circular path around another parallel line." CV.Br. 33. This means the cylinder has a closed outer surface, as shown in the following annotated version of CoreValve's cylinder graphic (CV.Br. 34):



See also CV.Br. 33 (citing dictionary at A00635, defining cylinder as "[a] solid bounded by two parallel planes and such a *surface having a closed curve*, esp. a circle") (emphasis added).

CoreValve's construction would exclude the preferred embodiment of Figures 1-10, because they have *open* outer surfaces. For example, in Figures 1-2, the stent is formed by two wires (2, 3) folded into loops, subsequently bent to form rings and then welded at the ends. A00063, col.5 ll.9-19. Fabricating the

cylindrical support means in this manner forms a shape that has open space between each loop of wire, and thus is not a cylinder under CoreValve's construction.

This Court has consistently rejected constructions, like CoreValve's, that exclude the preferred embodiment. "A claim construction that excludes the preferred embodiment 'is rarely, if ever, correct.'" *Adams Respiratory Therapeutics, Inc.* v. *Perrigo Co.*, 616 F.3d 1283, 1290 (Fed. Cir. 2010).

Because it contravenes the specification and would exclude the inventors' preferred embodiment, CoreValve's construction of "cylindrical support means" as requiring a constant diameter and a closed outer surface should be rejected.

C. CoreValve's Intrinsic Evidence Arguments Are Without Merit

CoreValve opens its intrinsic evidence discussion with citations to several dictionaries and textbooks. CV.Br. 33. This is odd, since CoreValve assails the District Court for "elevating [a] dictionary definition over the intrinsic record." CV.Br. 39. Even after *Phillips*, dictionaries are still useful tools to determine the meaning of words used in patent claims. *Phillips*, 415 F.3d at 1318.

CoreValve next contends that the lack of an adjective qualifying "cylindrical" means that the term must be given the geometric definition of "cylinder." CV.Br. 33-35. CoreValve points to the phrase "substantially

cylindrical" in one sentence of the specification to argue that the inventors would have used a modifier in Claim 1 if they sought to depart from a perfect geometric cylinder. *Id.* at 35. However, CoreValve only quotes half of the sentence. The full sentence makes plain that those modifiers were merely used to contrast different embodiments of the invention: "By using a *substantially cylindrical* thread structure ... a reduction in weight is obtained as compared to a stent which is *exclusively cylindrical* ..." *Id.* (emphasis applied). A00063, col.5 ll.25-28.

CoreValve's grammatical argument misses the essential point: "cylindrical," not "cylinder," is used in Claim 1. Had "cylinder" been intended, the inventors would have said so. *See, e.g., i4i, Ltd. P'ship* v. *Microsoft Corp.*, 598 F.3d 831, 843 (Fed. Cir. 2010) *aff'd*, 564 U.S. ___, 2011 WL 2224428 (June 9, 2011).

CoreValve's reliance on "generally parallel" is misplaced. CV.Br.34-35. "Parallel" is a strict, mathematical concept requiring a modifier if deviations are contemplated. *See Anchor Wall Sys., Inc.* v. *Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1311 (Fed. Cir. 2003). "Cylindrical" is a shape and requires no modifier since one is built into the word itself (cylindrical).

CoreValve also argues that the preferred embodiment shown in Figures 1-2 is a perfect cylinder. CV.Br. 35. Even if true,[8] a preferred embodiment cannot be read into the claims. *Am. Piledriving Equip., Inc.* v. *Geoquip, Inc.*, 637 F.3d 1324, 1337 (Fed. Cir. 2011). All the experts from both sides acknowledged a patent is not limited to its preferred embodiment. A10979; A11548; A11777-78.

CoreValve offers specification "context" to justify its "cylinder" construction. CV.Br. 36. It argues that the specification's use of the terms "diameter" and "rings" demonstrates that the device described must have a constant diameter. *Id.* CoreValve is wrong on the law and the facts. On the law, it is improper to import these terms into Claim 1. *Arlington Indus.*, 632 F.3d at 1254; *MBO Labs., Inc.* v. *Becton, Dickinson & Co.*, 474 F.3d 1323, 1333 (Fed. Cir. 2007). On the facts, the Andersen invention expands to fit the body channel, and necessarily may have different diameters along the length. Figure 9 illustrates just that.

CoreValve concludes its "intrinsic evidence" argument with a discussion of foreign decisions on a European Andersen patent. CV.Br. 36-37; *see also id.* 15-16. However, foreign decisions cannot control a U.S. court's

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[8] As noted *supra* p. 35-36, under CoreValve's "closed outer surface" construction, Figures 1-2 are not cylinders.

evaluation of a U.S. patent. *Medtronic, Inc.* v. *Daig Corp.*, 789 F.2d 903, 907-08 (Fed. Cir. 1986). Moreover, the Andersen European claim (quoted in CV.Br. 15 n.1) is materially different. In the European claim, the entire stent – not just the support means – is cylindrical. A05357-58 ("not the case that the *stent* is generally cylindrical" (U.K. decision, emphasis added)); A05362 ("[I]t is critical for the *stent* holding the valve prosthesis to be cylindrical." (German decision, emphasis added)).

CoreValve also contends that *Anchor Wall*, and *International Rectifier Corp.* v. *IXYS Corp.*, 361 F.3d 1363 (Fed. Cir. 2004), announced a blanket rule that a "geometric term without a modifier" must be construed strictly and be limited to its precise mathematical meaning. CV.Br. 34-35. This argument is meritless for several reasons.

First, *Anchor Wall* does not stand for that proposition. *Anchor Wall* simply noted that the term "generally parallel" must include "some amount of deviation from exactly parallel." 340 F.3d at 1311. *Anchor Wall* did not create a categorical rule that all "geometric" terms used without modifiers must be limited to a strict geometric definition. Moreover, "parallel" is a mathematical concept and requires a modifier for deviation. "Cylindrical" does not, since a modifier is contained in the word itself. *See supra* p. 37.

CoreValve's reliance upon *International Rectifier* is even more misplaced. The *Markman* analysis in that case was conducted before *Phillips* was decided and was driven by a dictionary definition. *See Int'l Rectifier*, 361 F.3d at 1370-71. *Phillips* rendered *International Rectifier* obsolete. *Phillips*, 415 F.3d at 1321 ("The main problem with elevating the dictionary to such prominence is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent."); *Alltech, Inc.* v. *Cenzone Tech., Inc.*, No. 06 CV0153 JM, 2007 WL 5793393, at *8 n.3 (S.D. Cal. Jan. 4, 2007) ("*International Rectifier's* reasoning has been superseded by *Phillips* ...") (citations omitted).

Applying that now-obsolete framework, *International Rectifier* focused on the dictionary definition of a geometric term (polygon) related to, but not used in, the claim language at issue (polygonal). 361 F.3d 1370-71. Here, the intrinsic evidence provided a clear meaning of the actual term used in Claim 1 ("cylindrical"). A00045 n.5; *see supra* p. 33-36. Also, the District Court in this case correctly looked to dictionary definitions of that precise term at issue to confirm that ordinary meaning drawn from the specification. A00433; A00472.

The District Court properly rejected the "jumble of arguments stemming from CoreValve's insistence that 'cylindrical' should be construed as referring to [CoreValve's] 'ordinary meaning' of cylinder." A00013.

D. The District Court Did Not Err in Declining to Further Define "Relating to a Cylinder"

CoreValve contends the phrase "relating to a cylinder" is ambiguous. CV.Br. 40. It argues the Court erred by not providing "any guidance" on the meaning of the phrase. *Id.* This criticism is unwarranted. Absent a clear limitation in the prosecution history, and there was none here, the District Court should not have imposed a more exact construction on a term of degree. *Playtex Prods., Inc.* v. *Procter & Gamble Co.*, 400 F.3d 901, 907 (Fed. Cir. 2005). Whether Generation 3 has a shape "relating to" that of a cylinder was a classic factual decision for the jury. *See Power-One, Inc.* v. *Artesyn Techs., Inc.*, 599 F.3d 1343, 1349 (Fed. Cir. 2010).

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A reasonable jury could find that the CoreValve Generation 3 product employed a "cylindrical support means." *See* annotated photographs, *supra* p. 18. As this Court has recognized, no medical device intended for use in the body can achieve the dimensions of a perfect cylinder, and Claim 1 does not require that abstraction. *Medtronic AVE*, 511 F.3d at 1176. CoreValve itself, after all, has repeatedly referred to its product as "cylindrical" in over forty internal documents. A10843-44.

Because the District Court's construction of the term "cylindrical" represents the ordinary meaning of the term as used in the '552 Patent, that

construction, and the District Court's denial of post-trial motions attacking that construction, should be affirmed.

II. SUBSTANTIAL EVIDENCE SUPPORTED THE JURY'S DETERMINATION THAT GENERATION 3 MEETS THE "PROJECTING ... IN A DIRECTION GENERALLY PARALLEL" LIMITATION

The Claim 1 invention and Generation 3 both employ stents in which the valve's commissural points are supported by portions of the stent (commissural supports) projecting from one side of the stent's cylindrical support means in a direction generally parallel to the longitudinal axis of the cylindrical support means. The jury reached that conclusion after weighing conflicting expert testimony.

At the initial *Markman* hearing, the parties agreed that Claim 1 uses the ordinary meaning of "projecting." A00776. There was also no dispute that "generally parallel" should be given its ordinary meaning. A00396. When the District Court denied CoreValve's post-trial motion on these issues, it noted that CoreValve was simply trying to reopen claim construction. A00006. Now, CoreValve asks this Court for a new claim construction and to set aside the jury verdict based on the testimony of its experts, which the jury rejected. This improper request should be denied.

CoreValve advances two arguments regarding the "projecting" and "generally parallel" language in Claim 1. First, CoreValve tries to reopen the construction of "projecting" to mean "protruding from" or "sticking out of," because its experts say so. Under its new construction, it argues nothing "protrudes from" or "sticks out of" Generation 3. CV.Br. 42-50.[9] Second, because the Generation 3 valve commissural *points* are attached to the stent on slopes that form an angle of 30° with the longitudinal axis, CoreValve maintains that the commissural *supports* cannot be "generally parallel" to the longitudinal axis. CV.Br. 50-54. Each argument is incorrect.

This Court reviews a jury verdict of infringement for substantial evidence. *Finisar Corp.* v. *DirecTV Grp., Inc.*, 523 F.3d 1323, 1333 (Fed. Cir. 2008). An infringement verdict will be upheld unless no reasonable jury, viewing the entire record before it, could have arrived at the conclusion it did. *Id.* at 1334. There is ample evidence in the record to support the jury's conclusion that Generation 3 possesses a plurality of commissural supports projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof. A00064.

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[9] CoreValve even offers alternative new constructions: "jutting out" or "extending forward or out." CV.Br. 42.

A. Generation 3 Employs Commissural Supports Projecting from One Side of Its Cylindrical Support Means

1. "Projecting" is not limited to physically "sticking out" or "protruding"

CoreValve argues that the jury's verdict was unsupported by substantial evidence because the Generation 3 commissural supports are not "projecting" as required by Claim 1. Using its new construction, CoreValve argues that no portion of its product "sticks out" or "protrudes," and therefore, no portion "projects" from any other portion. CV.Br. 42-43.

The '552 Patent expressly discloses commissural supports "projecting" from one side of the cylindrical support means, and yet are part of the stent structure. The inventors' preferred embodiment, depicted in Figures 1-10, employs commissural supports that overlap with the cylindrical support means. This is best seen in Figures 1-2, where a single wire (2) is used to form lower loops (25) of the cylindrical support means, as well as three higher commissural supports (4). A00063, col.5 ll.9-17. The valve commissural points (5) are secured to the three higher loops (4). *Id.* A single continuous wire thus forms both the higher loops of the commissural supports and the lower loops of the cylindrical support means.

The '552 Patent discloses other embodiments that contradict CoreValve's new definition of "projecting." Figures 11-12 depict embodiments

with a constant height. A00060. The figures show a support means "made of an elongated tubular means" (24), which encompasses both the cylindrical support means and commissural supports. A00064, col.7 ll.19-20. No portion of these embodiments "protrudes from" or "sticks out" of any other portion.

CoreValve's experts also claimed that an infringing device must have "projections," "posts," "protrusions," or "towers." A10585-86; A10596-97. The jury properly rejected their testimony. As the experts admitted, these were *their* words used to describe the inventors' preferred embodiment. None of these terms is found in Claim 1 or the specification at all. *E.g.*, A11551; A11556-57.

There was conflicting expert testimony on infringement. The jury rejected the testimony of CoreValve's experts and credited Dr. Buller's testimony. This resolution was entirely within the jury's province. *Litecubes, LLC* v. *N. Light Prods., Inc.*, 523 F.3d 1353, 1374 (Fed. Cir. 2008).

CoreValve denigrates Dr. Buller's testimony as "conclusory" and therefore inadequate to support the jury's verdict. CV.Br. 47. However, where an expert analyzes an accused product and explains how it infringes in design and function, there is "more than adequate evidence" to support a reasonable jury verdict. *Broadcom Corp.* v. *Qualcomm Inc.*, 543 F.3d 683, 696-97 (Fed. Cir. 2008).

CoreValve's authorities are not on point. In *Kim*, the expert "simply assumed" that the same ingredients in the accused product had the same function as in the patented compound and failed to even examine the accused product. *Kim* v. *ConAgra Foods, Inc.*, 465 F.3d 1312, 1319-20 (Fed. Cir. 2006). Dr. Buller, by contrast, spent several years analyzing Generation 3 and forming the basis of his carefully considered opinion. A10800; A10843-44; A10848. A jury is entitled to believe the infringement opinion of a qualified, independent and prepared expert. *See Litecubes*, 523 F.3d at 1374.

Texas Instruments, Inc. v. *Cypress Semiconductor Corp.*, is even further afield. The language cited by CoreValve refers to "particularized testimony" about infringement under the doctrine of equivalents. 90 F.3d 1558, 1567 (Fed. Cir. 1996). Here, the jury never reached the doctrine of equivalents (A00035; A00040), and infringement under the doctrine of equivalents is not before this Court.[10] CoreValve's reliance on *Hewlett-Packard Co.* v. *Mustek Systems, Inc.*, is similarly unwarranted. The decision there was also based on the "long-standing evidentiary requirements for proof of infringement under the doctrine of equivalents." 340 F.3d 1314, 1322-23 (Fed. Cir. 2003).

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[10] CoreValve improperly raises a doctrine of equivalents argument. CV.Br. 53-54. The jury verdict was based only on literal infringement, and the District Court did not render a final judgment based on equivalents. As such,

(continued)

2. Claim 1 covers an integral structure

CoreValve advances a wholly new argument on appeal: Claim 1 should be construed to require that the cylindrical support means and commissural supports be entirely separate and independent structural elements. CV.Br. 49-50. This new "two separate structural elements" argument contravenes the disclosure of the '552 Patent, the parties' agreed claim construction and the expert testimony at trial. The argument is untimely and wrong.

The '552 specification includes several figures showing the cylindrical support means and the commissural supports where they are not "two separate structural elements." Rather, they are portions of the same integral stent structure. This is clearly shown in Figures 1-2, where a single, continuous wire is used to fabricate both a portion of the cylindrical support means and the commissural supports. Moreover, both overlap one another. *See supra* p. 44.

The District Court's claim construction explains that the cylindrical support means and the commissural supports are part of the same stent structure. Its definition of "cylindrical support means" refers to "*a portion* of the stent supporting the valve." A00050 (emphasis added). The District Court accepted the parties' agreed construction of "commissural supports" as "*portions* of the stent

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CoreValve's prosecution history argument is not before this Court. *See TiVo, Inc.* v. *EchoStar Commc'ns Corp.*, 516 F.3d 1290, 1305 (Fed. Cir. 2008).

that support the commissural points of the valve." A00051 n.8 (emphasis added). The agreed claim construction does not require the commissural supports to be the only means of supporting the valve commissural points. Stated another way, they are not defined as "*the* portions of the stent that support the commissural points." Thus, CoreValve's new argument that Claim 1 "requires two separate structural elements" ignores the very claim construction to which it previously agreed.

The record demonstrates CoreValve's about-face. At the *Markman* hearing, CoreValve's counsel stated that, "[t]he cylindrical support means includes the commissural supports." A00777. Now, CoreValve takes the exact opposite position.

Additionally, at the parties' request, the Court did not further construe the words "projecting from one side of the cylindrical support means." A00046; A00051. At trial, when asked why, CoreValve replied: "From our perspective, the term projecting was sort of clear to us and we didn't think it needed to be explained." A11359. Nor did CoreValve object to the Court reading its "projecting" construction to the jury at the end of the evidence. A08684-87; A08725. Only after the unfavorable verdict did CoreValve seek a special meaning for "projecting." The District Court properly rejected this. A00004-07. *See, e.g.*, *Abbott Labs.* v. *Syntron Bioresearch, Inc.*, 334 F.3d 1343, 1352 (Fed. Cir. 2003).

On appeal, CoreValve goes one step farther and proposes yet another new construction. This is manifestly improper. *Cf. Sage Prods., Inc.* v. *Devon Indus., Inc.*, 126 F.3d 1420, 1426 (Fed. Cir. 1997) (refusing to consider "new infringement arguments raised for the first time on appeal").

CoreValve alleges that "both sides' experts agreed that Claim 1 requires the commissural supports to project from another separate component of the stent – the cylindrical support means." CV.Br. 43. However, nothing in CoreValve's transcript excerpts supports the assertion that the commissural supports are a "separate component." Rather, that expert testimony merely recounts that the Claim 1 stent structure includes both the commissural supports and the cylindrical support means. In the words of the claim, "the stent comprises cylindrical support means ... and a plurality of commissural supports." A00064, col.8 ll.2-3, 9.

CoreValve's new "two separate structural elements" theory is flatly contradicted by its own experts. CoreValve's expert, Dr. Rothman, admitted that Figure 1 of the '552 Patent, like Generation 3, is an integral structure. A11781-82. CoreValve's other expert, Dr. Pinchuk, testified similarly. A11557-58. In Dr. Buller's words, "[a]ll of the structure of both Andersen's preferred embodiment and this infringing device, in my opinion, supports the valve." A10968. Generation 3 is "an integral structure, just like Andersen is teaching." *Id.*

Because the language of Claim 1 – on its face, as interpreted by the District Court, as agreed to by the parties and as explained by the experts – makes clear that the claim covers an integral stent structure and each portion of that stent performs the common function of supporting the valve, CoreValve's new "two separate structural elements" construction must be rejected. *See Cannon Rubber Ltd.* v. *The First Years, Inc.*, 163 Fed. App'x. 870, 876 (Fed. Cir. 2005) (rejecting similar argument). CoreValve's cases are inapposite. Each addressed patents that expressly called for separate structural elements. *See, e.g.*, *Gaus* v. *Conair Corp.*, 363 F.3d 1284, 1288 (Fed. Cir. 2004) (two separate elements required because "[n]othing in the descriptions of those two components suggests that their structures or functions overlap"); *Becton, Dickinson & Co.* v. *Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) ("There is nothing in the asserted claims to suggest that the hinged arm and the spring means can be the same structure.").[11]

[11] *Playtex Prods.*, 400 F.3d 901, is also irrelevant. There, the Court noted that when a patent uses a comparative term to describe a claim element, there must be some other element to draw the comparison. *Id.* at 908-09. In no sense is "projecting" a comparative term.

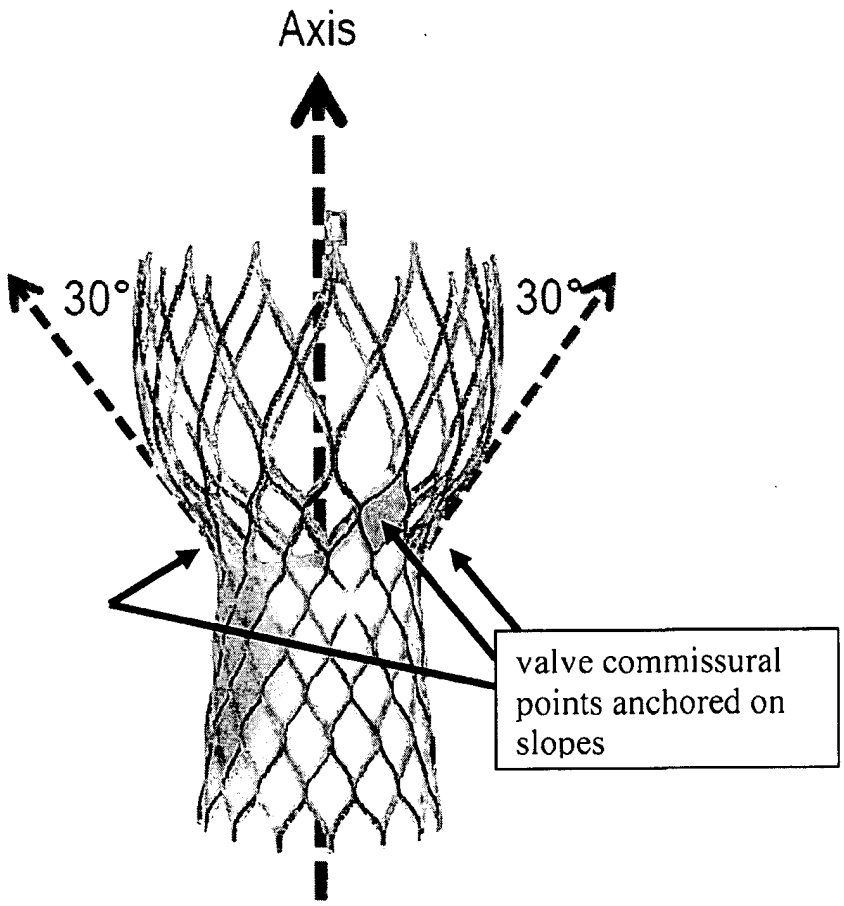
B. Generation 3's Commissural Supports Are Projecting "in a Direction Generally Parallel" to the Longitudinal Axis of Its Cylindrical Support Means

CoreValve's "in a direction generally parallel" argument is based on two basic errors. CoreValve neglects that the stent "commissural supports" are different than the valve "commissural points." It also ignores that "generally parallel" does not describe the shape of the "commissural supports" but rather the *direction* in which they are oriented.

The "commissural points" are the "points or locations where the leaflets of the valve are joined." A00050. The "commissural supports" are "portions of the stent that support" those valve points. A00051. Claim 1 requires that the "commissural supports" – not the valve "commissural points" – project "in a direction generally parallel to the longitudinal axis" of the cylindrical support means. A00064.

Despite this clear claim language, CoreValve's experts based their analyses of "in a direction generally parallel" on the 30° slopes where the valve commissural points are anchored, not the orientation of the commissural

supports. A11718; A11462-63. On appeal, CoreValve continues to focus on the 30° slopes. CV.Br. 51, 53. Illustrated below are CoreValve's 30° slopes:



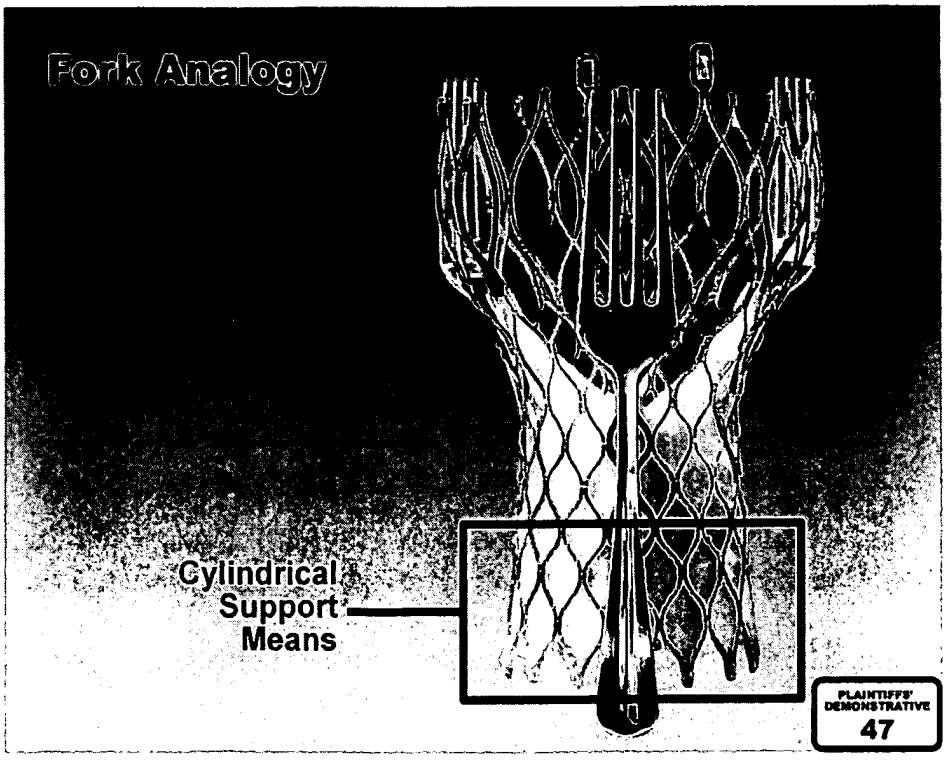
Annotated CoreValve Trial Graphic

Dr. Buller, by contrast, focused on the actual language of Claim 1. Using a table fork as an analogy, he testified that the "portions of the stent that support the commissural points" project "in a direction generally parallel," because

they have a shape, albeit with some curvature, that is oriented in the same general direction as the longitudinal axis of the cylindrical support means:

> [Y]ou can see that this fork has a shape which curves, it's not a straight line. But in the way I can point it and direct it in a direction, ... and if it's pointing upwards, it's in a direction generally parallel to the longitudinal axis. Being generally parallel to the longitudinal axis doesn't mean it has to be a completely straight structure. It means, in my opinion, that the whole structure, looked at from top to bottom, has to be orientated in a direction generally in line with the longitudinal axis.

A10867. *See also* A10966-68; A10971-72. The trial graphic showing the fork analogy appears below (commissural supports in green):



The jury reasonably determined, based on substantial evidence, that the Generation 3 commissural supports are projecting "in a direction generally

parallel to the longitudinal axis" of its cylindrical support means. The District Court denied CoreValve's post-trial motions on that ground. A00008. This Court should affirm.

III. SUBSTANTIAL EVIDENCE SUPPORTED THE JURY'S VERDICT THAT COREVALVE FAILED TO PROVE NONENABLEMENT BY CLEAR AND CONVINCING EVIDENCE

Nonenablement is an invalidity defense that must be proven by clear and convincing evidence. *Microsoft Corp.* v. *i4i Ltd. P'ship*, 564 U.S. ___, 2011 WL 2224428, at *1 (June 9, 2011). This Court reviews a determination of enablement *de novo*, though underlying factual findings in the District Court are reviewed for clear error. *ALZA Corp.* v. *Andrx Pharm., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010). The *Wands* factors are employed to guide the factual inquiries that provide the basis for an enablement determination. *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988).

CoreValve's nonenablement argument has three fundamental errors. First, CoreValve asserts that the '552 specification is not enabled for human use. However, the inventors disclosed the THV they successfully implanted in pigs, whose relevant anatomy is quite similar to human anatomy, and the specification extensively discussed the invention's use in humans. Second, CoreValve wrongly states that "[i]t took many years before a valve prosthesis ... was percutaneously implanted in a human heart." The proof is otherwise. Finally, CoreValve is

incorrect that no device suitable for human use has been developed pursuant to the teachings in the '552 Patent.

A. The Successful Pig Tests Correlated to Tests in Humans

Pig and human vascular anatomies are very similar. A20118. Both have a heart with an aortic valve and an arterial system. A10820-22. For years, porcine valves have been used to fabricate replacement valves for use in humans. A10691-95. Researchers have long used pigs to simulate the human anatomy. A20118.

The Andersen inventors took advantage of this anatomical similarity to build and test their invention in pigs. A20118. They used pig valves in their prototypes. A20099; A20102; A00063, col.5 ll. 29-30. After they successfully tested their preferred embodiment in pigs, the inventors disclosed its structure, materials and dimensions in the specification. *See supra* p. 15. The inventors' pig studies were lauded as successes. A22954; A22957; A23454; A10814-15; A11369; A11375; A11385-86. Both CoreValve's founder and expert witness conceded that the pig studies successfully demonstrated that the device covered by Claim 1 was feasible and functioned in the beating heart. A11326; A11757-58.

B. The '552 Patent Discloses Embodiments for Use in Humans

The full scope of Claim 1 is only limited to "a valve prosthesis for implantation in a body channel." A00064, col.7 ll.57-58. "The enablement

requirement is met if the description enables *any mode* of making and using the invention." *Johns Hopkins Univ.* v. *CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998) (emphasis added, citation omitted); *accord Invitrogen Corp.* v. *Clontech Labs., Inc.*, 429 F.3d 1052, 1071 (Fed. Cir. 2005); *Durel Corp.* v. *Osram Sylvania Inc.*, 256 F.3d 1298, 1308 (Fed. Cir. 2001). Put another way, to be enabling, the specification need not "describe how to make and use every possible variant of the claimed invention." *AK Steel Corp.* v. *Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003); *accord Invitrogen Corp.*, 429 F.3d at 1071 (Fed. Cir. 2005); *Chiron Corp.* v. *Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004).

Even if Claim 1 is required to enable implantation in a human, it meets that standard. Most of the specification is dedicated to describing embodiments for use in human body channels. A00061, col.1 ll.13-50; A00061, col.2 l.21-A00062, col.4 l.17. CoreValve claims the Andersen preferred embodiment is too large for use in humans. CV.Br. 59. It minimizes the specification's direction that "the cardiac valve prosthesis for use in human beings has a corresponding form." CV.Br. 56; A00063, col.5 ll.38-39. However, this teaching is sufficient for one skilled in the art to create a working embodiment of the device for use in human patients. The proof at trial established this. A10814-15; A10978-79. Even CoreValve's expert, Dr. Pinchuk, conceded that making stents smaller was routine engineering. A11562-63.

C. The Length of Time it Took to Commercialize the Andersen Invention Was Due to Skepticism, Inattention and Routine Development Work

A patent is not invalid for lack of enablement simply because work was required to manufacture a commercial product. This Court has rejected any requirement that a patent must be a blueprint for a commercial product. *See, e.g.*, *Transocean Offshore*, 617 F.3d at 1306-07. This is particularly the case when testing is common in the art. *Wands*, 858 F.2d at 737.

The jury was presented with substantial evidence that development is routinely necessary to bring heart valve technology to market. A11370-71; A20246-49; A20256-57; A20281-82. Witness after witness, from both sides, confirmed this was the case here. Larry Wood, Edwards Vice President for THV, described the commercial development of the '552 Patent as the very pattern on which Edwards' business model was based: doctors have an idea to meet a patient need, and engineers invest time and resources to bring that idea to market. A20246-49; A20264. CoreValve's engineering expert, Dr. Pinchuk, defined the level of ordinary skill in the art as a qualified doctor working with medical device engineers. A11561. He further testified that, in 1990, when the original Andersen patent application was filed, it was within the reach of routine engineering to reduce the diameter of a cardiovascular stent. A11562-63. Stanton Rowe, one of PVT's founders, whom CoreValve selectively quotes, described the steps

necessary to commercialize the '552 Patent as design "optimization." A10993-94. Dr. Buller elaborated on this point, and testified that metal strength and device diameter were precisely the sort of details that medical device engineers routinely refine after a concept is demonstrated by pioneering doctors. A10994. This was routine development work for a heart valve, not undue experimentation.

The inventors' limited resources, industry resistance and skepticism all slowed development of the Andersen invention. *See supra* p. 9-11. Once PVT acquired the rights to the '552 Patent, however, with its financing, engineers and doctors, it accomplished its first-in-man THV implant in two years. A11762; A26737-39. CoreValve's successful implantation was even more rapid. Spurred on by PVT's first-in-man success, and with the '552 Patent in hand, in just six months CoreValve constructed Generation 1 and successfully implanted it in a human patient. A11153-54.

When viewed in the proper context of the entire record, it is remarkable how quickly the Andersen invention was brought to market once those of ordinary skill in the art focused upon it. Under these circumstances and measured by the *Wands* factors, the jury's determination that CoreValve failed to show nonenablement by clear and convincing evidence was fully supported by the evidence.

D. Both CoreValve's Generation 3 and Edwards' SAPIEN Products Are Based on the '552 Patent

CoreValve asserts that "empirical evidence" shows nonenablement because "no one, including Edwards, has been able to develop a human heart valve prosthesis according to [its] teachings." CV.Br. 61. CoreValve ignores the proof that the '552 Patent was the basis for both CoreValve's infringing Generation 3 product and Edwards' SAPIEN THV.

CoreValve's position is untenable in the face of the jury's verdict of willful infringement, which was based on evidence that CoreValve studied the '552 Patent. CoreValve's founder Dr. Seguin testified that he did not know how to accomplish transcatheter aortic valve replacement until he reviewed the '552 Patent. A11319-21. Mr. Bortlein testified he studied the inventors' work. A11159-60. Despite a lack of any proof that he had conceived of transcatheter valve replacement prior to reviewing the '552 Patent, Dr. Seguin maintained that he arrived at the idea independently. The District Court rejected CoreValve's JMOL motion on willfulness, observing, "this jury could disbelieve Dr. Seguin and his entire testimony and conclude that CoreValve copied." A11364. In its decision rejecting CoreValve's renewed JMOL motion on willfulness, the District Court reiterated this point: "The jury was under no obligation ... to accept the testimony of CoreValve's witnesses." A00009.

There was undisputed testimony that Edwards' SAPIEN THV was based on the '552 Patent. Edwards marks the '552 Patent on its SAPIEN packaging. A20287. Edwards paid the inventors royalties on the SAPIEN THV before it purchased the '552 Patent. *Id.* Dr. Buller, whose infringement analysis the jury accepted, testified that the SAPIEN THV was an embodiment of the '552 Patent. A10901. His testimony was not challenged.

Despite this evidence, CoreValve claims that the '552 Patent has never been embodied in a working device. CoreValve spends two pages stringing together selected statements describing how the device in the '552 Patent needed to be made smaller and stronger to be commercially used in human patients with regulatory approval. CV.Br. 62-64. This argument is wrong as a matter of law because commercial viability is not the standard for enablement. *See* authorities collected *supra* p. 26; *Princo Corp.* v. *ITC*, 563 F.3d 1301, 1318 (Fed. Cir. 2009).

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To succeed in its nonenablement defense at trial, CoreValve had the burden to show, by clear and convincing evidence, that the '552 Patent did not enable those of ordinary skill in the art to practice the invention described in Claim 1. Based on substantial evidence, the jury found that CoreValve failed. A00042. The District Court concluded CoreValve's post-trial motions did not

"even raise a colorable non-enablement defense." A00011. That determination should be affirmed.

IV. THE JURY'S LOST PROFITS AWARD WAS SUPPORTED BY SUBSTANTIAL EVIDENCE

A jury's award of damages must be sustained unless "the amount is grossly excessive or monstrous, clearly not supported by the evidence, or based only on speculation or guesswork." *Biotec Biologische Naturverpackungen GmbH* v. *Biocorp, Inc.*, 249 F.3d 1341, 1355 (Fed. Cir. 2001) (quotation omitted). The availability of lost profits is a question of law. However, the jury determines the factual underpinnings of an award of lost profits and those findings are reviewed for substantial evidence. *See Depuy Spine, Inc.* v. *Medtronic Sofamer Danek, Inc.*, 567 F.3d 1314, 1332 (Fed. Cir. 2009).

There are four well-established factors a patentee must prove to recover lost profits. *Siemens Med. Solutions USA, Inc.* v. *Saint-Groban Ceramics & Plastics*, 637 F.3d 1269, 1287 (Fed. Cir. 2011); *Panduit Corp.* v. *Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978). CoreValve's appeal addresses only one: the jury's determination that there was no acceptable noninfringing substitute available to CoreValve during the relevant time. CV.Br. 65. CoreValve's argument fails because there is substantial evidence to

support the jury's findings that January 2006 was the date of first infringement, and that CoreValve had no acceptable noninfringing alternative.

As an initial matter, where, as here, the alleged acceptable noninfringing alternative was not on the market, but is a hypothetical product alleged by the defendant as a possible alternative, the burden is on the defendant to overcome the inference of unavailability. *Depuy Spine*, 567 F.3d at 1331-32; *Grain Processing Corp.* v. *Am. Maize-Prods. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1991).

Lost profits must be addressed in the but-for world. *Am. Seating Co.* v. *USSC Group, Inc.*, 514 F.3d 1262, 1269 (Fed. Cir. 2008); *Grain Processing*, 185 F.3d at 1349. In an attempt to push back the clock to create an acceptable noninfringing alternative (a move off-shore [[CONFIDENTIAL MATERIAL OMITTED]]), CoreValve challenges the date of first infringement found by the jury and confirmed by the District Court. CoreValve contends that the date of first infringement is August/September 2004, not January 2006, because that is when the Generation 2 stent (or frame) was manufactured. CV.Br. 66-68. CoreValve asserts the Generation 2 and Generation 3 stents are the same. *Id.* The jury rejected this argument. A05621-22 n.2; A08760. Even though Generation 2 may also infringe the '552 patent, the jury correctly found that the commercial Generation 3 product was different. Its infringement was separate and therefore,

requires a separate damages analysis as a matter of law. *See Applied Med.*, 435 F.3d at 1361-62.

There was substantial evidence for the jury to determine that the date of first infringement was January 2006, when the Generation 3 design was finalized and frozen. A11496; A11615-16; A11633. First, Generation 3 was the only device accused at trial and CoreValve's only commercial product. A11642-43. Second, Generation 2 and Generation 3 had a number of important differences. In Generation 3 the skirt was "cut ... in three pieces" and the commissural point locations were moved higher. A11451-54. Third, CoreValve executive Robrecht Michiels testified that the "secret idea" for Generation 3 was not even conceived by CoreValve's chief product designer, Than Nguyen, until September 2005. A11495-96; A11643-44. Mr. Nguyen admitted that Generation 3 contained a valve that was a "design by itself." A10749. As a result, that both Generation 2 and Generation 3 use the same stent is not relevant. Generation 3 as a whole was not even conceived until September 2005 and the design not frozen until January 2006. The jury was entitled to rely on this substantial evidence to make the factual determination that the date of first infringement was January 2006.

The only acceptable noninfringing alternative argued by CoreValve was the hypothetical manufacture of its commercial product overseas to avoid infringement. Overwhelming proof at trial demonstrated why CoreValve could not

move off-shore. Irvine, California held the key for CoreValve to bring a commercial product to market. A11494-95. CoreValve told investors that it moved from France to Irvine to be "where most of the experts are available in valve design and valve testing," including Mr. Nguyen. A11019-21; A22982; A22990-91. Mr. Nguyen designed Generation 3 – in Irvine. A10744-46; A11452-53; A11495-97. He and other CoreValve employees based in Irvine were necessary to design Generation 3. A11341; A11497-98. Moreover, Mr. Nguyen was in ill health and likely could not have moved overseas. A11429-30.

There was further proof why CoreValve was cemented in Irvine. CoreValve had just leased a specialized facility in Irvine in January 2006 and had limited available cash. A11011; A11038; A11041; A11340-41. Rather than move abroad, CoreValve "doubled down" in Irvine and expanded its production there. A11091.

Edwards' damages expert, Dr. Leonard, presented substantial evidence that it would take CoreValve at least two and a half years to move facilities abroad even if it began moving in January 2006. A11042-43; A11045-46. Dr. Leonard used CoreValve's own internal estimates of the time it would take to move overseas, receive European approval (CE Mark), obtain funding and ramp up production in a new facility. A11044-47.

On this record, CoreValve failed to prove the availability of an acceptable noninfringing alternative, which was its burden. The jury had substantial evidence to find that CoreValve could not have moved abroad. A11037-43. And, had CoreValve tried to move, it would have taken substantial time to move, scale up and commercialize abroad. A11025-27. CoreValve essentially is challenging the admissions of its own witnesses (Nguyen and Michiels), and Dr. Leonard's testimony, which the jury alone is entitled to credit. *See i4i*, 598 F.3d at 855-56.

CoreValve's arguments relating to lost profits simply rehash those it made at trial. A11615-18. The jury did not agree with CoreValve regarding the date of the first infringement or the availability of an acceptable noninfringing alternative. Substantial trial evidence supports the jury verdict. The District Court denied CoreValve's post-trial motions on damages. A00016-17. That decision should be affirmed.

V. THE DISTRICT COURT ERRED IN DENYING A PERMANENT INJUNCTION

This case calls out for a permanent injunction. Edwards and CoreValve compete head-to-head. CoreValve chose to manufacture its infringing product in the U.S. It moved from France to Irvine (where Edwards is located) specifically for the purpose of tapping the local specialized labor pool. Although

its commercial sales to date are only made abroad, CoreValve is now preparing to commercially sell its Generation 3 product in the U.S.

Immediately after it was found to be a willful infringer, CoreValve was in the press announcing that an injunction was not an issue, because it was moving its manufacturing facility to Mexico. It cited its Mexico move as a reason why it should not be enjoined. If this were legally sufficient to defeat an injunction, every infringing manufacturer could simply argue it could move abroad to avoid being enjoined. Although *eBay* changed the rules for granting an injunction, it never contemplated such an inequitable result.

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]] The District Court's proposed resolution is that Edwards should sue again for infringement. A00028. This is wrong as a matter of law. Edwards already proved that Generation 3 infringes the '552 Patent. Neither Edwards nor the judicial system should be subjected to such serial litigation.

The District Court erroneously denied the injunction in large part because of the "fact" that CoreValve was moving abroad. [[

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A. Standard of Review

eBay established the now familiar four-part test for issuing a permanent injunction: (1) irreparable harm, (2) inadequacy of remedies at law, (3) balance of hardships, and (4) the public interest. *eBay Inc.* v. *MercExchange, LLC*, 547 U.S. 388, 391-92 (2006). This Court reviews the denial of a permanent injunction for an abuse of discretion. *Ecolab, Inc.* v. *FMC Corp.*, 569 F.3d 1335, 1352 (Fed. Cir. 2009). An abuse of discretion occurs when a district court makes a "clear error of judgment in weighing relevant factors or exercise[s] its discretion based upon an error of law or clearly erroneous factual findings." *Innogenetics, N.V.* v. *Abbott Labs.*, 512 F.3d 1363, 1379 (Fed. Cir. 2008) (citation omitted). A district court's conclusions regarding issues of law are reviewed *de novo* by this Court. *Sanofi-Synthelabo* v. *Apotex, Inc.*, 470 F.3d 1368, 1374 (Fed. Cir. 2006).

B. [[CONFIDENTIAL MATERIAL OMITTED]]

CoreValve [[ ]] said it was moving Generation 3 manufacturing to Mexico: "CoreValve has undertaken steps to ensure that its Gen 3 THV will be available ... by setting up alternative manufacturing facilities in Mexico." A18042. In its public statements, CoreValve was similarly explicit: "In the event of a U.S. injunction, Medtronic has manufacturing capabilities for CoreValve products outside the United States ... ."

A15139. The business community heard this message loud and clear (A15142; A15183), as did the District Court (A00027).

In denying the injunction, the District Court referred repeatedly to CoreValve's ability and/or plans to move to Mexico. *See* A00027 ("CoreValve would be able to move its remaining manufacturing operations to Mexico almost immediately if the court enjoined it from continuing to manufacture its products in the United States."); A00028-29. Even if true, an infringer's avowed cessation of infringement is no reason to withhold an injunction. *W.L. Gore & Assocs., Inc.* v. *Garlock, Inc.*, 842 F.2d 1275, 1281-82 (Fed. Cir. 1988) ("The fact that the defendant has stopped infringing is generally not a reason for denying an injunction against future infringement ... .").

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The unique advantages of producing Generation 3 in Irvine were discussed exhaustively at trial. *See supra* p. 64. A11010-11; A11026-27; A11424; A11506-08. Irvine offers a highly specialized labor pool unavailable in other locations. A11025-27. As CoreValve readily admits, these skilled workers are rare even in Irvine, and it takes six to nine months to find and train such employees. A18493. [[

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C. Irreparable Harm

1. Patentee's right to exclude

A patentee's right to exclude is a fundamental tenet of patent law. *Richardson* v. *Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1247 (Fed. Cir. 1989); *Smith Int'l, Inc.* v. *Hughes Tool Co.*, 718 F.2d 1573, 1578 (Fed. Cir. 1983). Though *eBay* held that injunctions should not issue upon a finding of infringement as a matter of course, it did not abandon the patentee's basic right to exclude. When warranted, as here, injunctions are issued post-*eBay*. And in medical device patent cases such as this one. *See, e.g.*, *Spectralytics, Inc.* v. *Cordis Corp.*, Nos. 2009-1564, 2010-1004, 2011 WL 2307402, at *1 (Fed. Cir. June 13, 2011) (affirming grant of permanent injunction involving coronary stent technology); *Acumed LLC* v.

Stryker Corp., 551 F.3d 1323, 1327-28 (Fed. Cir. 2008) (affirming grant of permanent injunction related to orthopedic nail technology).

2. Infringement itself can constitute irreparable harm

"The essential attribute of a patent grant is that it provides a right to exclude competitors from infringing the patent. In view of that right, infringement may cause a patentee irreparable harm not remediable by" money damages. *Acumed*, 551 F.3d at 1328 (internal citation omitted).

Here, [[

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]] This explains why the District Court required that Edwards "establish that CoreValve's *manufacturing* operations *in the United States* are continuing and will continue to cause irreparable harm if not enjoined." A00027. This unwitting erroneous factual finding requires reversal.

3. Prospective irreparable harm

The District Court concluded that Edwards failed to prove prospective irreparable harm. A00026-27. It committed a clear error of law by requiring prospective irreparable harm and failing to consider Edwards' past irreparable harm. And, even if required, Edwards did establish prospective irreparable harm.

Past irreparable harm cannot be ignored. "Although injunctions are tools for prospective relief designed to alleviate future harm, by its terms the first *eBay* factor looks, in part, at what has already occurred." *i4i*, 598 F. 3d at 862. *eBay* itself only requires that a patentee's past harm be irreparable. Nowhere does it mandate that the irreparable harm must be yet to come: "A plaintiff must demonstrate that it *has suffered* an irreparable injury." *eBay*, 547 U.S. at 391 (emphasis added). This Court has also unmistakably observed that "[p]ast harm to a patentee's market share, revenues, and brand recognition is relevant for determining whether the patentee '*has suffered* an irreparable injury.'" *i4i*, 598 F.3d at 861-62 (alteration in original) (quoting *eBay*).

The record here established past irreparable harm. Edwards lost a substantial share of the THV market because of CoreValve's willful infringement. It also lost the opportunity to establish relationships and train medical centers that it otherwise would have if CoreValve had not been on the market. A10608-16; A11058-59; A11070-71; A19295; A26441-42 (Edwards business plan showing importance of "[l]ock[ing] up key accounts" and building relationships with customers); A26124 (demonstrating Edwards' manufacturing capacity). Edwards' reputation as the global leader in the science of heart valves has been tarnished by CoreValve's early unauthorized entry into the market and continued willful infringement. A26436; A26438; A15127 (CoreValve press release touting its

"novel" product); A19296; A15129 (CNBC interview of Medtronic CEO using Generation 3 as example of "innovation").

(a) [[CONFIDENTIAL MATERIAL OMITTED]]

As noted, the District Court premised its ruling on the mistaken belief that "CoreValve would be able to move its remaining manufacturing operations to Mexico almost immediately," and "the parties' ability to sell their products would remain substantially the same regardless of whether an injunction issued." A00027; A00029. The District Court concluded "CoreValve would remain in the market with little or no interruption even if the court were to enjoin its infringing manufacturing in the United States." A00028. The District Court drew the conclusion that "Edwards' market position and the parties' ability to sell their products would remain substantially the same regardless of whether an injunction issued." A00029.

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(b) First-mover advantage harm continues

Undisputed evidence established that the first-mover advantage was repeated with each new customer and would continue into the future. A11048-49;

A19295-26. Expert testimony demonstrated that "[a]llowing CoreValve to continue to expand its business by manufacturing in Irvine will only serve to allow CoreValve to expand its reach in the marketplace thereby perpetuating the harm to Edwards." A19297.

The market for THV technology is in its infancy, and future market share will be driven by factors beyond price and product specifications. In fact, one of the most important factors in determining which THV product – CoreValve's or Edwards' – a particular customer purchases in the future is which THV product that customer purchases first. A11056; A10666. The extensive device-specific training and investment of staff time and hospital resources required to begin a THV program, coupled with doctors' preference to use products they are familiar with, all tend to make hospitals and treatments centers "sticky" customers. They are unlikely to switch products once they begin using a particular company's THV product. A10668; A11049; A19408. Through its aggressive and willful infringement in Irvine, CoreValve reached many hospitals and treatment centers before Edwards had a product on the market. A10609. Edwards continues to be unable to make sales to many hospitals CoreValve reached first. A10680. Edwards and CoreValve also compete to make initial sales to hospitals that have yet to adopt either product. A10681-83. Infringement constitutes irreparable harm in a market where the first producer to reach a

customer has an ongoing and potentially insurmountable advantage in making sales to that customer. *Broadcom*, 543 F.3d at 702-03.

Although an injunction cannot undo the past harm CoreValve caused, it will stop CoreValve from signing up more doctors, supplying them with a domestically made product and shutting out Edwards. In a non-traditional consumer goods market that involves competition for customers that will integrate the patented device into their own business going forward, this Court has found irreparable harm even where, unlike here, the patent holder did not yet practice the patent. *Broadcom*, 543 F.3d at 702-03.

Courts have encountered this "sticky" customer problem before, and have granted injunctions to address the irreparable harm involved. *See, e.g.*, *TiVo Inc.* v. *EchoStar Commc'ns. Corp.*, 446 F. Supp. 2d 664, 669-70 (E.D. Tex. 2006) *aff'd in part, rev'd in part, remanded in part* 516 F.3d 1290 (Fed. Cir. 2008);[13] *Atlanta Attachment Co.* v. *Leggett & Platt, Inc.*, No. 1:05-CV-1071-ODE, 2007 WL 5011980, at * 7 (N.D. Ga. Feb. 23, 2007); *see also Acumed*, 551 F.3d at 1328-29 (approving district court's reliance on *TiVo* in determining that lost market share caused irreparable injury with no adequate remedy at law).

[13] This Court has recently affirmed a finding of contempt for violation of the *TiVo* permanent injunction based on the presence of "sticky" customers. *See TiVo Inc.* v. *EchoStar Corp.*, No. 2009-1374, 2011 WL 1486162 (Fed. Cir. Apr. 20, 2011) (*en banc*).

(c) Reputational harm to Edwards continues

The District Court assumed that because CoreValve was "first ... to market," the reputational damage caused by CoreValve and endured by Edwards could not be ameliorated through a permanent injunction. A00027. But being first to market does not exempt an infringer from injunctive relief. In *Broadcom*, this Court affirmed an injunction where the patent owner had yet to enter the market. 543 F.3d at 703.

It was CoreValve's willful infringement that allowed it to become the first company to commercialize THV technology, and to garner accolades and market respect. A19296. Even after the jury verdict, CoreValve continued to hold itself out as the innovator of THV technology. A15127; A15129. Edwards – the owner of the patent that made the entire THV revolution possible – is the rightful recipient of the medical community's recognition. Only an injunction can return credit to where credit is due.

In contesting Edwards' motion for a permanent injunction, CoreValve repeatedly complained that, if forbidden from continuing its willful infringement, it would be subjected to reputational harm. A18047. Ironically, CoreValve's protestations prove the necessity of an injunction. As Dr. Leonard explained, "If an injunction caused CoreValve to lose some of its goodwill ... [that] goodwill

would return to Edwards, where it would have been in the absence of infringement." A19296.

D. Inadequate Remedies at Law

The District Court also concluded that "any harm that Edwards does continue to suffer as a result of CoreValve continuing its U.S. manufacturing operations can be redressed by a monetary remedy." A00028. First, the District Court concluded that monetary damages were not necessarily insufficient simply because CoreValve was Edwards' only competitor in the market. *Id.* Second, the District Court found that past "licensing activity is further evidence that monetary damages would be adequate to compensate Edwards." *Id.* The District Court committed clear error in arriving at each of these conclusions.

1. A compulsory license to Edwards' only THV competitor does not afford adequate compensation for infringement

This Court has recognized that monetary damages are inadequate where a patent holder will be forced to grant a compulsory license to its much larger direct competitor:

> In this case, a small company was practicing its patent, only to suffer a loss of market share, brand recognition, and customer goodwill as the result of the defendant's infringing acts. Such losses may frequently defy attempts at valuation, particularly when the infringing acts significantly change the relevant market, as occurred here.

i4i, 598 F.3d at 862.

This is the case here. At the time of trial, Medtronic was almost ten times the size of Edwards, with a market capitalization of $50 billion as compared to Edwards' $5.7 billion. A15035. When it acquired CoreValve, Medtronic boasted that its "scale and expertise" would "accelerate the use" of CoreValve's infringing product. A15137. As discussed above, CoreValve's continued presence in the U.S. dilutes Edwards' rightful goodwill and market recognition as the innovator of the revolutionary THV technology. Thus, Edwards is in the same position as the patent owner in *i4i*.

Neither Edwards nor CoreValve currently offers THV products for commercial sale in the U.S. However, following FDA approval, both companies plan to sell in the U.S. A15004 n.10; A19229 n.14. Because the U.S. THV market is entirely untapped, allowing CoreValve to enter the U.S. commercial market – which would surely occur if no injunction is entered – will dilute Edwards' first-mover advantage in the U.S. or potentially vitiate that rightful advantage entirely. The damage caused by CoreValve's entrance into the U.S. market will be incalculable, irreparable and not compensable by monetary damages. *Broadcom*, 543 F.3d at 703-04 (difficulty estimating monetary damages associated with compulsory license to direct competitor supports conclusion that remedies at law are inadequate).

2. The District Court misinterpreted the 3F license

Though past licensing of the patent may show money damages to be adequate compensation, a court must carefully consider the factual circumstances surrounding such licensing decisions in performing the *eBay* analysis. *Acumed*, 551 F.3d at 1328. The District Court found monetary damages sufficient compensation on the basis of clear errors in evaluating the history of the '552 Patent rights. A00028.

The District Court simply misread a 2005 agreement between Edwards and 3F Therapeutics ("3F") as "evidence that monetary damages would be adequate to compensate for any future infringing manufacturing operations by CoreValve." A00028. The agreement to which the District Court referred is a rider to a larger agreement between Edwards and 3F, by which Edwards actually *regained* rights to the '552 Patent. A20262; A19417-20.

Moreover, this Court has held that past licenses "ha[ve] little bearing on the effect of a compulsory license to a direct competitor" where "market realities" dictate that the competitor's ability to practice the patent will disadvantage the patentee in a dynamic market. *Broadcom*, 543 F.3d at 703. In *Acumed*, an injunction was affirmed even where the patentee had previously granted licenses to two other competitors. 551 F.3d at 1328-29. The District Court erred here by forcing Edwards to issue a compulsory license to Medtronic, one of

the largest medical device companies in the world. A15035; A15137. In fact, the compulsory license will be contrary to Edwards' past refusal to grant Medtronic a '552 Patent license. A15104-17.

E. Balance of Hardships

The District Court stated that its analysis was not affected by the balance of hardships factor. A00029. [[CONFIDENTIAL MATERIAL OMITTED]], the District Court assumed that any harms associated with that infringement were moot. A00027-28. If CoreValve were to infringe again in the U.S., the District Court offered Edwards cold comfort: "Edwards can bring suit against CoreValve and seek damages." A00028.

This cannot be correct. [[CONFIDENTIAL MATERIAL OMITTED]], absent an injunction its infringement will start again when it commences commercial Generation 3 sales in the U.S. Thus, under the District Court's analysis, Edwards would have to sue the same defendant, on the same patent, for infringement by the same Generation 3 product. Edwards has already vindicated its rights in the '552 Patent. No more is required.

The prospect of CoreValve's entry into the U.S. commercial market tips the balance of hardships decidedly in favor of a permanent injunction.

F. Public Interest

The public interest factor of the *eBay* analysis also favors an injunction. An injunction will spare the judicial system the burden of entertaining another patent case involving CoreValve's Generation 3 product. Notions of finality and *res judicata*, central to our judicial system, also require an injunction, because without a prohibition against future infringement, the binding and final nature of the judgment in this case is eviscerated. *See Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 100 (1993) ("[O]ur prior cases have identified a strong public interest in the finality of judgments in patent litigation."). As observed over a century ago, "[e]ven patent litigation must end somewhere." *Am. Gramophone Co.* v. *Leeds & Catlin Co.*, 170 F. 327, 329 (2d Cir. 1909).

There is also the public's keen interest in the integrity of intellectual property rights. *Sanofi-Synthelabo*, 470 F.3d at 1383-84. As repeatedly presented to the District Court, from a business perspective, it is impossible to undertake the investments required to bring revolutionary medical technologies to market in the absence of meaningful patent protection. A20248-49; A19048.

Moreover, an injunction will not endanger lives. Edwards can treat the entire CoreValve patient population. A19409-10; A20315; A20339 (Dr. Leonard's calculations for post-verdict damages in Europe, showing that, as of February 2011, the SAPIEN and Generation 3 products could service the same

patient population). CoreValve did not challenge Dr. Leonard's calculations. Because Edwards can service the entire universe of THV customers, the District Court's conclusion that an injunction would not "seriously affect[ ] the supply of the product available," is still accurate. A00029.

The efficiency and integrity of the judicial system, intellectual property laws and innovation-based industries are all at stake in this litigation. Without an injunction, each will be severely damaged.

***

The District Court denied a permanent injunction based on CoreValve's misrepresentations about its intentions. Now that the true facts surrounding CoreValve's continued willful infringement in the U.S. have become clear, the District Court's erroneous analysis should be corrected. This Court should reverse the denial of the permanent injunction and remand with instructions that an injunction be entered.

VI. THE PROTECTIVE ORDER RULING SHOULD BE REVERSED

The Protective Order in this case (A00032-330) contains what is commonly known as a "patent prosecution bar." With exceptions not relevant here, the Protective Order precludes persons who are "working on patent prosecution" for one side from having access to the opponent's Confidential and Highly Confidential Information. A00317; A00320.

Because both Edwards' trial counsel and its expert, Dr. Buller, had access to CoreValve's confidential information (A00317; A00320), Edwards requested that the District Court clarify that the Protective Order does not preclude them from participating in Medtronic-initiated patent *reexamination* proceedings. A19977.

In a brief Order (A00054-55), the District Court denied Edwards' request. It summarily found "that permitting Dr. Buller and Paul Weiss attorneys to participate in the reexamination would create a high risk that confidential CoreValve/Medtronic information would be used or disclosed." A00054.

This Court reviews a district court order concerning the scope of a protective order for an abuse of discretion. *In re Deutsche Bank Trust Co. Ams.*, 605 F.3d 1373, 1377 (Fed. Cir. 2010) ("*Deutsche Bank*"). Measured by that standard, the decision below should be reversed.

The Protective Order is plain. Those with access to confidential information are only precluded from "working on patent prosecution." Reexamination is not mentioned and is fundamentally different. During patent prosecution, claims can be broadened. Hence, there is a risk confidential information might be used to craft new, broader claims to capture a competitor's product. There is no such risk in reexamination. In both *ex parte* and *inter partes* reexaminations, only the patent and the prior art are involved. 35 U.S.C. §§ 301,

311(a). In both, the patentholder can only *narrow* the scope of the patent. 35 U.S.C. §§ 305, 314(a).

Thus, numerous decisions, including decisions by other judges in the District of Delaware, have recognized that a patent prosecution bar does not include reexamination. *See, e.g., Vasudevan Software, Inc.* v. *Int'l Bus. Machs. Corp.*, No. C09-05897, 2010 WL 3629830, at *3-4 (N.D. Cal. Sept. 14, 2010); *Xerox Corp.* v. *Google, Inc.*, 270 F.R.D. 182, 184-85 (D. Del. 2010); *Document Generation Corp.* v. *Allscripts, LLC*, No. 6:08-CV-479, 2009 WL 1766096, at *2 (E.D. Tex. June 23, 2009); *Kenexa Brassring Inc.* v. *Taleo Corp.*, Civ. No. 07-521-SLR, 2009 WL 393782, at *2 (D. Del. Feb. 18, 2009). These courts have uniformly found there is no risk of inadvertent disclosure during reexamination proceedings. "Because reexamination involves only the patent and the prior art, defendant's confidential information is basically irrelevant to the reexamination." *Id.* (internal quotation omitted).

Under *Deutsche Bank*, the burden was on CoreValve to demonstrate "the risk presented by the disclosure of proprietary competitive information." 605 F.3d at 1381. CoreValve failed. It offered speculation, but no evidence that there is any actual risk, since none of the CoreValve documents it cited is eligible for submission in a reexamination. A19983; A20032.

The facts are aggravated here. Without notice and on the eve of trial, CoreValve abandoned its prior art defenses, only to reassert them in reexamination proceedings initiated by its parent company, Medtronic. A19977. Medtronic has compounded the hardship on Edwards by filing serial reexamination requests on the Andersen patent portfolio. *See supra* p. 22 n.5. Such gamesmanship is fundamentally unfair to Edwards, which now faces the loss of the counsel and expert it chose to litigate the Andersen patents, and in whom it has made a substantial investment. In the words of *Deutsche Bank*, "the potential injury to the moving party from restrictions imposed on its choice of litigation and prosecution counsel outweighs the potential injury to the opposing party caused by such inadvertent use." 605 F.3d at 1381.

The District Court order should be reversed.

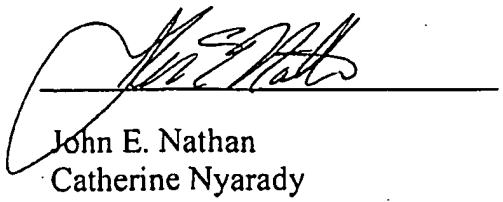
CONCLUSION

The District Court's construction of "cylindrical support means" should be affirmed. The Court's denial of CoreValve's motions for JMOL, for a new trial or to amend the judgment on infringement, enablement and damages should also be affirmed.

The District Court's denial of a permanent injunction and its ruling on the Protective Order should be reversed.

Edwards Lifesciences AG and Edwards Lifesciences LLC

By its attorneys,



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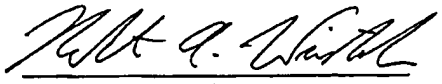

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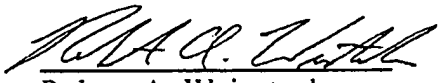

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2011-1215, -1257

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

EDWARDS LIFESCIENCES AG and
EDWARDS LIFESCIENCES LLC,

Plaintiffs-Cross Appellants,

v.

COREVALVE, INC. and
MEDTRONIC COREVALVE, LLC,

Defendants-Appellants.

Appeals from the United States District Court for the District of Delaware
in Case No. 08-CV-0091, Chief Judge Gregory M. Sleet.

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TABLE OF CONTENTS

PAGE

TABLE OF AUTHORITIES iii

INTRODUCTION 1

ARGUMENT 4

I. THE DISTRICT COURT IMPROPERLY CONSTRUED "CYLINDRICAL SUPPORT MEANS" TO COVER NON-CYLINDRICAL STRUCTURES 4

A. Edwards Offers No Meaningful Defense Of The District Court's "Relating To" Construction Of "Cylindrical" 4

B. The Claim Language Requires That The Support Means Be A Cylinder 6

C. The Specification Confirms That The Support Means Must Be A Cylinder 11

D. Edwards Offers No Intrinsic Evidence That Supports The District Court's Construction 14

E. Edwards Offers No Extrinsic Evidence That Supports The District Court's Construction 16

II. THE COREVALVE DEVICE DOES NOT INCLUDE COMMISSURAL SUPPORTS THAT MEET THE LIMITATIONS OF CLAIM 1 17

A. The CoreValve Device Does Not Have Commissural Supports "Projecting From" The Cylindrical Support Means 17

1. Dr. Buller's conclusory testimony cannot support the infringement judgment 18

2. Dr. Buller's testimony showed that the CoreValve device does not meet the "projecting from" limitation 19

B. The CoreValve Device Does Not Have Commissural Supports That Project In A Direction "Generally Parallel" To The Longitudinal Axis 26

III. CLAIM 1 OF THE '552 PATENT WAS NOT ENABLED FOR HUMAN USE 30

A. The Inventors' Pig Experiments Do Not Prove That The '552 Patent Was Enabled For Human Use 30

TABLE OF CONTENTS
(CONTINUED)

PAGE

B. Claim 1 Of The '552 Patent Could Not Be Developed For Human Use Despite Years Of Experimentation 32

C. The SAPIEN Valve Is Not An Embodiment Of The '552 Patent 35

IV. THE LOST PROFITS DAMAGES AWARD SHOULD BE VACATED 36

A. Edwards Did Not Present Sufficient Evidence To Establish That January 2006 Was The Date Of First Infringement 37

B. The Undisputed Evidence Shows That CoreValve Could Have Begun Non-Infringing Production Overseas Before August 2007 40

V. EDWARDS' CROSS-APPEAL ARGUMENTS ARE WITHOUT MERIT 43

A. The District Court Properly Rejected Edwards' Request For A Permanent Injunction 43

1. Edwards will not be irreparably harmed absent an injunction 44

2. Edwards' pecuniary remedies are adequate 47

3. The balance of harms weighs against an injunction 49

4. The public interest disfavors an injunction 50

B. This Court Should Not Disturb The District Court's Prosecution Bar Ruling 54

CONCLUSION 57

CONFIDENTIAL MATERIAL OMITTED

The material omitted on pages 43 and 46 contains information regarding CoreValve's ongoing manufacturing activities from the Parties' Statement Regarding Accounting of Monetary Damages and Interest for the Period March 16, 2010 – February 7, 2011, which was filed under seal. (Dkt. No. 439, A20305-64). The material omitted on pages 49 and 53 contains information containing CoreValve's and Edwards' manufacturing capabilities, and information comparing market research data on CoreValve's and Edwards' devices.

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603 F.3d 935 (Fed. Cir. 2010) 33

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170 F. 327 (2d Cir. 1909) 50

American Piledriving Equip. Inc. v. Geoquip, Inc.,
637 F.3d 1324 (Fed. Cir. 2011) 13, 14

Applied Med. Resources Corp. v. U.S. Surgical Corp.,
435 F.3d 1356 (Fed. Cir. 2006) 38, 39

Arlington Indus., Inc. v. Bridgeport Fittings, Inc.,
632 F.3d 1246 (Fed. Cir. 2011) 13

Becton, Dickinson v. Tyco Healthcare Group,
616 F.3d 1249 (Fed. Cir. 2010) 21, 22, 23, 25

Cardinal Chem. Co. v. Morton Int'l, Inc.,
508 U.S. 83 (1993) 50

Cook Biotech, Inc. v. Acell, Inc.,
460 F.3d 1365 (Fed. Cir. 2006) 29

Cordis Corp. v. Boston Scientific Corp.,
99 F. App'x 928 (Fed. Cir. 2004) 51

Cordis Corp. v. Boston Scientific Corp.,
561 F.3d 1319 (Fed. Cir. 2009) 5

Cordis Corp. v. Medtronic AVE, Inc.,
511 F.3d 1157 (Fed. Cir. 2008) 7, 9

Datascope Corp. v. Kontron Inc.,
786 F.2d 398 (Fed. Cir. 1986) 53

Durel Corp. v. Osram Sylvania Inc.,
256 F.3d 1298 (Fed. Cir. 2001) 31

eBay Inc. v. MercExchange, LLC,
547 U.S. 388 (2006) 43, 44

First Fed. Lincoln Bank v. United States,
518 F.3d 1308 (Fed. Cir. 2008) 37, 40

Free Motion Fitness, Inc. v. Cybex Int'l, Inc.,
423 F.3d 1343 (Fed. Cir. 2005) 8

Genentech, Inc. v. Novo Nordisk, A/S,
108 F.3d 1361 (Fed. Cir. 1997) 32, 34

Grayzel v. St. Jude Med., Inc.,
162 F. App'x 954 (Fed. Cir. 2005) 56

Harris Corp. v. IXYS Corp.,
114 F.3d 1149 (Fed. Cir. 1997) 33

Hewlett-Packard v.Mustek Sys. Inc.,
340 F.3d 1314 (Fed. Cir. 2003) 18

Housey Pharms., Inc. v. Astrazeneca UK Ltd.,
366 F.3d 1348 (Fed. Cir. 2004) 5

i4i L.P. v. Microsoft Corp.,
598 F.3d 831 (Fed. Cir. 2010) 9, 45, 48

In re Buchner,
929 F.2d 660 (Fed. Cir. 1991) 32, 36

In re Deutsche Bank Trust Co. Americas,
605 F.3d 1373 (Fed. Cir. 2010) 56, 57

International Rectifier Corp. v. IXYS Corp.,
361 F.3d 1363 (Fed. Cir. 2004) ..... *passim*

Inverness Medical Switzerland GmbH v. Warner Lambert Co.,
309 F.3d 1373 (Fed. Cir. 2002) 5

Invitrogen Corp. v. Clontech Labs., Inc.,
429 F.3d 1052 (Fed. Cir. 2005) 31

John Hopkins Univ. v. CellPro, Inc.,
152 F.3d 1342 (Fed. Cir. 1998) 31

John Mezzalingua Assocs. v. Arris Int'l, Inc.,
2003 WL 23282752 (W.D. Wis. Nov. 14, 2003) 10

Kim v. ConAgra Foods, Inc.,
465 F.3d 1312 (Fed. Cir. 2006) 18, 19

Laryngeal Mask Co. Ltd. v. Ambu,
618 F.3d 1367 (Fed. Cir. 2010) 14

Lucent Techs., Inc. v. Gateway, Inc.,
580 F.3d 1301 (Fed. Cir. 2009) 42

Mangosoft, Inc. v. Oracle Corp.,
525 F.3d 1327 (Fed. Cir. 2008) 7

Martek Biosciences Corp. v. Nutrinova, Inc.,
579 F.3d 1363 (Fed. Cir. 2009) 6

MBO Laboratories, Inc. v. Becton, Dickinson & Co.,
474 F.3d 1323 (Fed. Cir. 2007) 13

Methode Elecs., Inc. v. Delphi Auto. Sys. LLC,
2009 WL 3875980 (E.D. Mich. Nov. 17, 2009) 55

Monsanto Co. v. Geertson Seed Farms,
130 S. Ct. 2743 (2010) 44

Nasatka v. Delta Sci. Corp.,
58 F.3d 1578 (Fed. Cir. 1995) 54

Nazomi Commc'ns, Inc. v. Arm Holdings, PLC,
403 F.3d 1364 (Fed. Cir. 2005) 6

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88 F.3d 1025 (Fed. Cir. 1996) 36, 37, 39, 40

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415 F.3d 1303 (Fed. Cir. 2005) (en banc) ..... *passim*

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594 F.3d 860 (Fed. Cir. 2010) 42

Retractable Techs., Inc. v. Becton, Dickinson & Co.,
___ F.3d ___, 2011 WL 2652448 (Fed. Cir. July 8, 2011) 29

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418 F. App'x 914 (Fed. Cir. 2011) 13

Sanofi-Synthelabo v. Apotex, Inc.,
470 F.3d 1368 (Fed. Cir. 2006) 50

Scripps Clinic & Research Found. v. Genentech, Inc.,
666 F. Supp. 1379 (N.D. Cal. 1987), *aff'd in part, rev'd in part on other grounds*, 927 F.2d 1565 (Fed. Cir. 1991) 53

Silicon Graphics, Inc. v. ATI Techs., Inc.,
2007 WL 5433478 (W.D. Wis. Aug. 8, 2007) 56

Smith & Nephew, Inc. v. Arthrex, Inc.,
2011 WL 2438633 (Fed. Cir. June 20, 2011) 26

Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.,
620 F.3d 1305 (Fed. Cir. 2010) 45

Steel Co. v. Citizens for a Better Environment,
523 U.S. 83 (1998) 55

Teleflex, Inc. v. Ficosa N. Am. Corp.,
299 F.3d 1313 (Fed. Cir. 2002) 15

Texas Instruments, Inc. v. Cypress Semiconductor Corp.,
90 F.3d 1558 (Fed. Cir. 1996) 18, 27

Visto Corp. v. Seven Networks, Inc.,
2006 WL 3741891 (E.D. Tex. Dec. 19, 2006) 55

Weinberger v. Romero-Barcelo,
456 U.S. 305 (1982) 50

STATUTES

35 U.S.C. § 112 32

35 U.S.C. § 271(a) 37

35 U.S.C. § 283 ..... 43, 44

35 U.S.C. § 284 46

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INTRODUCTION

In its effort to preserve a judgment it never should have received, Edwards distorts the plain meaning of geometric claim terms, disregards controlling decisions of this Court, asserts that one portion of a stent can somehow "project from" itself, and ignores the critical role played by the innovative features of CoreValve's prosthetic heart valve. The CoreValve design succeeded because the inventors varied the diameter of their device to optimize anchoring by mirroring the anatomical features of the site of implantation. They also designed their device to withstand stress fatigue by using an angled network of interlocking "diamonds" to support the valve attachment points. Because of these innovations, the CoreValve device was the first artificial aortic valve to be approved for human use, and it now has been implanted in more than 10,000 patients. By contrast, the device claimed in the '552 patent has not been implanted in a single patient because of its fundamental structural defects, including its "cylindrical" support means and "projecting" commissural supports.

Edwards nevertheless asserts that the CoreValve device infringes the '552 patent and that Edwards is entitled to more than $72 million in damages. But Edwards fails to rebut CoreValve's showing that:

- The district court's construction of "cylindrical" as any shape "relating to" a cylinder is inconsistent with the plain meaning of the claim language, unsupported by the specification or the prosecution history,

and contrary to this Court's construction of the geometric claim term "polygonal" in *International Rectifier*.

- No substantial evidence supports the jury's finding that the CoreValve commissural supports are "projecting from" its support means or run "generally parallel" to it, and Edwards' alternative theory that the "whole structure" of the stent comprises the commissural supports would require the commissural supports to project from themselves, a physical impossibility and thus wrong as a matter of law.
- No substantial evidence supports the jury's finding that the full scope of Claim 1 was enabled when the '552 patent application was filed. The evidence is undisputed that the claimed invention could not then be implanted in a human body channel and that developers failed to achieve that objective despite years of trying.
- And no substantial evidence supports the first infringement date on which the jury based its calculation of damages.

Edwards argues—without factual or legal support—that the CoreValve device infringes Claim 1 because the '552 patent's "cylindrical" support means need not be a cylinder; insists that "projecting" commissural supports can project from themselves and that supports angling away from a vertical line run "generally parallel" to it; asserts that the SAPIEN device implements the '552 patent without rebutting the abundant evidence that the SAPIEN inventors could develop an implantable valve only by discarding the '552 patent's key limitations; and relies on immaterial differences between two versions of the CoreValve device to defend

the date of first infringement and the lost profits damages award. Because Edwards offers no support for its assertions from the evidence of record or this Court's precedents, the judgment below should be reversed.

On its cross-appeal, Edwards has not shown that the district court abused its discretion by denying Edwards' request for an injunction. As the court found based on the evidentiary record, CoreValve would respond to an injunction by moving its manufacturing operations to Mexico so that it could maintain its non-infringing sales abroad, making the requested injunction futile. Moreover, if an injunction were effective, it would adversely affect public health by preventing the many patients whom Edwards admittedly is unable to serve from obtaining the CoreValve device. Finally, Edwards' challenge to the district court's prosecution bar ruling is moot because the reexamination proceeding has terminated, and in any event that ruling was well within the court's broad discretion to protect confidential information from inappropriate disclosure. Accordingly, Edwards' cross-appeal arguments should be rejected.

ARGUMENT

I. THE DISTRICT COURT IMPROPERLY CONSTRUED "CYLINDRICAL SUPPORT MEANS" TO COVER NON-CYLINDRICAL STRUCTURES.

A. Edwards Offers No Meaningful Defense Of The District Court's "Relating To" Construction Of "Cylindrical."

The district court's construction of "cylindrical" as any shape "relating to a cylinder," as well as its instruction that the claimed "cylindrical support means" need not be a cylinder, provided no meaningful public notice and no guidance to the jury as to the scope of this central claim term. See Blue Br. 37-40. By failing to give any geometric meaning to the term "cylindrical," the court effectively read the limitation out of the claim.

Edwards offers no response to CoreValve's showing that such non-cylindrical shapes as triangular prisms and spheres could be covered by the district court's "relating to" construction of "cylindrical." See Blue Br. 40. A construction of such boundless scope cannot be reconciled with the '552 patent or with the fundamental public notice function of patent claims. A skilled artisan would know how to build support means having the shape of a cylinder, but could experiment endlessly with the infinite set of shapes "relating to a cylinder."

The *only* defense offered by Edwards for the court's construction is that it was right to reject "a more exact construction" in the absence of "a clear limitation in the prosecution history." Red Br. 41. This argument flips on its head the most

basic principle of claim construction—that claims terms are generally given their plain and ordinary meaning "unless the patentee has explicitly disclaimed or clearly disavowed this meaning in the specification or prosecution history." *Housey Pharms., Inc. v. Astrazeneca UK Ltd.*, 366 F.3d 1348, 1352 (Fed. Cir. 2004); see *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (en banc). Here, CoreValve seeks only to give a well-understood geometric term its plain and ordinary meaning. The prosecution history contains no disavowal of this plain and ordinary meaning, and in fact says nothing at all about the meaning of "cylindrical." Thus, far from supporting the district court's "relating to" construction, the absence of any relevant prosecution history *supports* the plain geometric meaning of "cylindrical."

Edwards' cited cases do not support its view that the absence of prosecution history authorizes inexact and unbounded claim constructions. Red Br. 35-36. In *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319, 1329 (Fed. Cir. 2009), the Court held that a patent claim's "plain language" could not be "overcome" by "unclear prosecution history," and the Court said the same thing about "ambiguous" prosecution history in *Inverness Medical Switzerland GmbH v. Warner Lambert Co.*, 309 F.3d 1373, 1382 (Fed. Cir. 2002). Here, the prosecution history is neither "unclear" nor "ambiguous" but rather silent, and CoreValve seeks to give effect to Claim 1's plain language, not to "overcome" it.

Edwards suggests that the district court's claim construction should "carry weight" on appeal. Red Br. 30. But claim construction is reviewed "without deference," *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1379-80 (Fed. Cir. 2009), especially where, as here, the district court provided no basis for its construction. See A00050. The court's claim construction opinion nowhere cites any intrinsic or extrinsic evidence—or provides any reasoning or findings—to support its "relating to" construction. It rejects CoreValve's proposed construction but offers nothing at all (including any "plain and ordinary meaning" analysis) to support the court's own construction. *Id.* This failure deprives the district court's construction of any "weight," as in Edwards' cited case, *Nazomi Commc'ns, Inc. v. Arm Holdings, PLC*, 403 F.3d 1364, 1371 (Fed. Cir. 2005), where this Court gave no weight to the district court's construction because it did "not supply the basis for its reasoning sufficient for a meaningful review."

B. The Claim Language Requires That The Support Means Be A Cylinder.

A geometric claim term without words of "modification or qualification" must be given its plain geometric meaning. Just as this Court construed "polygonal" in *International Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363 (Fed. Cir. 2004), in accordance with the plain geometric meaning of "polygon," so too should "cylindrical" be construed in accordance with the plain geometric meaning of "cylinder." "Cylindrical" is not modified by any limiting term like "generally"

or "substantially," in contrast to the claim term "substantially uniform" in *Cordis Corp. v. Medtronic AVE, Inc.*, 511 F.3d 1157, 1167 (Fed. Cir. 2008) (Red Br. 32), where this Court held that "substantially" made "uniform" less precise.

Moreover, Claim 1 modifies the term "parallel" with "generally," showing that the inventors knew how to broaden a geometric term with modifying language. See Blue Br. 34-35. Edwards responds that "[p]arallel" is a "strict, mathematical concept," whereas "cylindrical" is "a shape and requires no modifier since one is built into the word itself (cylindrical)." Red Br. 37. But just as this Court did not view the adjectival term "polygonal" to signify a modification from a mathematical polygon, there is no reason to view the adjectival term "cylindrical" to do so.

There is nothing "odd" about supporting CoreValve's plain geometric construction of "cylindrical" with citations to contemporaneous dictionaries and textbooks. Red Br. 36. See *Mangosoft, Inc. v. Oracle Corp.*, 525 F.3d 1327, 1333 (Fed. Cir. 2008) (finding construction of claim language to be "consistent with the technical dictionary definition"). Edwards improperly relies on the broadest available dictionary definition to bring non-cylindrical devices within the scope of "cylindrical" because they are allegedly "related to" a cylinder in some unspecified fashion. Red Br. 40.

Edwards also contends that *International Rectifier* is "obsolete" in light of *Phillips*. Red Br. 40. But *Phillips* nowhere suggests that a geometric shape

claimed without qualification should be construed to cover different shapes with different geometric properties. Edwards argues that *International Rectifier* erroneously relied on dictionary definitions of "polygonal." *Id.* In fact, both parties in *International Rectifier* "agree[d] that the ordinary and customary meaning of the term 'polygon' is 'a closed plane figure bounded by straight lines.'" 361 F.3d at 1370. This Court confirmed that mutual understanding by noting that it was "consistent with dictionary definitions contemporaneous with the patents at issue," looking to "the written description for context and guidance," and finding nothing in the prosecution history bearing on the "scope of any of the disputed claim terms." *Id.* at 1370-71. That approach was fully consistent with *Phillips*, which explained that "dictionaries, and especially technical dictionaries, ... can assist the court." 415 F.3d at 1318. Edwards deviates from *Phillips* by asserting that the district court in this case "correctly looked to dictionary definitions" (Red Br. 40) where the court accepted the broadest possible definition with no citation to the source and without regard for the plain meaning of the claim language or the context provided by the specification. See *Phillips*, 415 F.3d at 1321 (rejecting claim construction that "starts with the broad dictionary definition"); *Free Motion Fitness, Inc. v. Cybex Int'l, Inc.*, 423 F.3d 1343, 1348-49 (Fed. Cir. 2005); Blue Br. 39.

As in *International Rectifier*, the parties here do not dispute the plain geometric meaning of "cylinder." Edwards instead argues that "cylindrical," not "cylinder," is the "claim language at issue." Red Br. 40; see *id.* at 31. But that was true in *International Rectifier* as well, where the claim language was not "polygon" but "polygonal." 361 F.3d at 1370. Edwards adds that if the '552 inventors meant "cylinder" rather than "cylindrical," they would have said so. Red Br. 37 (citing *i4i L.P. v. Microsoft Corp.*, 598 F.3d 831 (Fed. Cir. 2010)). Yet in *International Rectifier*, this Court recognized that "polygonal" is simply the adjectival form of "polygon," and it criticized the district court for "relaxing" the geometric requirements of a polygon, "attribut[ing] new meaning to the term," and "excus[ing] the patentee from the consequences of its own word choice." *Id.* at 1371-72. *i4i* is not to the contrary. There, this Court refused to construe claims to require "independent manipulation" where the claims did not mention it. *i4i*, 598 F.3d at 843. Here, by contrast, Claim 1 *expressly* asserts a "cylindrical" support means, thereby requiring a support means shaped as a cylinder.

Edwards further argues that "cylindrical" cannot mean a "perfect geometric cylinder" because real world items, such as "a soda can," may not have a constant diameter due to "bevels." Red Br. 32. The example is inapposite—a soda can has a constant diameter over almost its entire length. Edwards cites this Court's observation in *Medtronic AVE*, 511 F.3d at 1176 (Red Br. 32), that a perfect

cylinder "cannot be achieved by any real-world device." But in that case, neither "cylindrical" nor "cylinder" was a claim term, and the quoted comment was made with respect to infringement, not claim construction. Moreover, the fact that manufactured items may contain imperfections says nothing about the intended scope of the claim. This Court explained in *International Rectifier* that even if the manufacturing process "will naturally cause some blurring of the corners and sides of the polygonal regions," that does not warrant "the re-definition" of the geometric term chosen by the inventor. 361 F.3d at 1371. In other words, the issue for purposes of claim construction is the inventor's intent as expressed in the patent, not tolerance ranges in the manufacture of commercial embodiments.

Edwards also relies on a district court opinion stating that "[a] tapered object can still be 'cylindrical.'" Red Br. 32. In that case, *John Mezzalingua Assocs. v. Arris Int'l, Inc.*, 2003 WL 23282752, at *9 (W.D. Wis. Nov. 14, 2003), the court rejected a proposed construction of "cylindrical sleeve" to mean a "non-tapered cylinder" where a preferred embodiment expressly stated that the "cylindrical body member wall tapers." Here, there is no preferred embodiment expressly describing a tapered cylindrical support means and thus *John Mezzalingua* is off-point.

Finally, Edwards takes issue with CoreValve's citations to decisions of foreign tribunals that construed "cylindrical support means" in the European version of the '552 patent to require a uniform diameter or circular cross-section.

See Blue Br. 15-16, 36-37; Red Br. 34-36. CoreValve does not contend that those decisions "control" this appeal, as Edwards states. Blue Br. 38-39. This Court should know, however, that appellate courts of two countries with developed patent law jurisprudence rejected arguments similar to those made by Edwards here with respect to the same claim term. Although Edwards asserts that the European and U.S. patent claims are "materially different," it identifies only one difference which is not material at all for purposes here. Edwards says that in the European claims the entire stent and not just the support means is "cylindrical." Red Br. 39; see European claim at Blue Br. 15 n.1. Edwards does not explain why that difference would affect the construction of "cylindrical," especially where it is undisputed that Claim 1 of the '552 patent states that the stent "comprises" the "cylindrical support means." A00064 (Col. 8, lns. 2-3).

C. The Specification Confirms That The Support Means Must Be A Cylinder.

The '552 specification supports construing "cylindrical" in accordance with its plain geometric meaning. For example, the specification's use of modifying language supports giving the unmodified "cylindrical" in Claim 1 its plain geometric meaning. Blue Br. 35. The specification describes Figure 1 as "using a *substantially* cylindrical thread structure with projecting apices" because the projections prevent it from being "*exclusively* cylindrical." A00063 (Col. 5 lns. 25-28) (emphasis added).

Edwards argues that this description suggests that the inventors "sought to depart from a perfect geometric cylinder." Red. Br. 37. In fact, by distinguishing a "substantially cylindrical" stent with "projecting apices" from an "exclusively cylindrical" stent without such projections, the inventors showed that they knew how to qualify "cylindrical" when there was reason to do so. They distinguished a shape with a constant diameter along its entire length from one with a constant diameter along only part of its length (the part without the projecting apices). They had no need to make that distinction in Claim 1 because it claims a stent comprising two separate elements—the "cylindrical support means" and the "commissural supports projecting from one side of the cylindrical support means." A00064 (Col. 8, lns. 3-10). The fact that the inventors did not qualify "cylindrical" in Claim 1 as they did when describing Figure 1 refutes Edwards' attempt to broaden the claim term to reach non-cylinders.

Edwards accuses CoreValve of importing into the claim preferred embodiments with a constant diameter that are "nowhere in the specification." Red Br. 31, 38. In particular, Edwards complains that CoreValve cannot rely on the apparent illustration of "a perfect cylinder" in Figure 1 or the specification's use of the terms "diameter" and "rings" to support its construction of "cylindrical" according to its plain geometric meaning. *Id.* at 38; see Blue Br. 35-36. CoreValve has not imported anything and has no need to do so. As noted above,

Edwards does not contest the mathematical fact that a cylinder has a constant diameter, and Claim 1 itself calls for a "cylindrical" support means without any qualifying modifier. Pointing to the specification and preferred embodiments to support that plain meaning is simply a straightforward application of *Phillips*, 415 F.3d at 1315 (patent claims "must be read in view of the specification").

Edwards relies on inapposite cases for its "import" argument. Red Br. 31, 38. In *Sanders v. Mosaic Co.*, 418 F. App'x 914, 917 (Fed. Cir. 2011), this Court addressed whether disclaimers in "the parent prosecution clearly and unambiguously limit[ed] the scope of the claims at issue." There is no disclaimer issue here. In *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1256 (Fed. Cir. 2011), the Court held that the intrinsic evidence revealed no intent to exclude particular types of spring metal adaptors from the claim term "spring metal adaptor." Here, CoreValve does not seek to exclude any types of cylinders from the scope of "cylindrical." In *MBO Laboratories, Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323 (Fed. Cir. 2007), and *American Piledriving Equip. Inc. v. Geoquip, Inc.*, 637 F.3d 1324, 1337 (Fed. Cir. 2011), this Court refused to limit the meaning of claim terms based on preferred embodiments. Here, CoreValve does not seek to limit a disputed claim term but rather to give "cylindrical" its plain geometric meaning, a meaning that the preferred embodiments confirm. Nothing in this Court's precedents bars the use of preferred embodiments for such a

confirmatory purpose. In fact, as this Court explained in *American Piledriving*, the specification is usually "the single best guide to the meaning of a disputed term." *Id.* at 1333.

D. Edwards Offers No Intrinsic Evidence That Supports The District Court's Construction.

Nothing in the specification shows that the inventors sought to act as their "own lexicographer"; no "special definition" of "cylindrical" is "clearly stated in the patent specification or file history." *Laryngeal Mask Co. Ltd. v. Ambu*, 618 F.3d 1367, 1372 (Fed. Cir. 2010). Edwards fails in its hunt for obscure clues in the intrinsic evidence to support its view that a "*cylindrical* support means" need not be a cylinder.

First, Edwards contends that the claimed support means cannot have a constant diameter because the claimed device "must conform to the shape of the body channel," and body channels "are never perfect cylinders." Red Br. 33. But the patent nowhere says that the device mirrors the shape of a body channel, and the full specification passage cited by Edwards describes how the stent's support means is collapsed for insertion and then expanded to secure it in the body channel. See A00061 (Col. 2, lns. 38-64). Indeed, Claim 1 itself requires that the "cylindrical support means" be "radially collapsible for introduction" into the body channel and "radially expandable for being secured within the body channel." A00064 (Col. 8, lns. 3-8). Nothing in the claim or specification suggests that the

support means lacks a constant diameter prior to undergoing this process of collapse and expansion. Edwards points to a newly-"annotated" version of Figure 9, on which Edwards' counsel has added "annotations" to show alleged differences in the stent's diameter. Red Br. 16, 33. But that figure shows the valve secured in a body channel *after* implantation and thus is irrelevant to the meaning of "cylindrical" in Claim 1. See A00064 (Claim 1 stating that valve prosthesis is "for implantation" and cylindrical support means is "for introduction" in body channel). It is no surprise, then, that the '552 patent does not describe Figure 9 as having a "cylindrical support means." See A00063 (Col. 6, lns. 62-65).[1]

Next, Edwards points to the specification's reference to the prior-art Ross patent application, which described a stent as having a "barrel-like" form. Red Br. 34 (citing A00561, p.2, lns. 118-27). However, the Ross application nowhere describes its claimed stent as "cylindrical" (see A22522-29), and thus the shape of its embodiments is immaterial to the question at issue here. In any event, a single reference to a preferred embodiment of even *the invention at issue*, much less to a *prior art* embodiment, is presumptively insufficient to overcome the ordinary meaning of a claim term. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002).

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[1] By contrast with the '552 patent, CoreValve's patents stress the importance of a stent with varying diameters. See, *e.g.*, A34074-81 (Col. 3, lns. 26-37; Col. 4, lns. 27-34; Figs. 1, 9; Claims 8-9, 13).

Finally, Edwards contends that construing "cylindrical" to require a cylinder would exclude the preferred embodiments in Figures 1-10 because they have open rather than closed outer surfaces due to their wire mesh framework. Red. Br. 35-36. The issue here, however, is not whether the outer surface is solid or open but whether the inventors required that the support means be shaped like a geometric cylinder (and thus have a constant diameter) or instead authorized a non-cylinder to serve as the "cylindrical support means." All the figures in the '552 patent specification that depict the invention prior to implantation (Figures 1-2 and 11-12) show a cylinder with a common diameter or uniform cross-section. Figures 11 and 12 depict a closed surface, unlike Figures 1 and 2, because Figures 11 and 12 are embodiments of dependent Claim 8 (as originally filed before "projecting commissural supports" were added to Claim 1, see *infra* pp. 24-25), and Claim 8 expressly asserts a "closed" surface. See A00064 (Col. 8, ln. 57). Giving "cylindrical" in Claim 1 its plain geometric meaning does not exclude any preferred embodiment.

E. Edwards Offers No Extrinsic Evidence That Supports The District Court's Construction.

Edwards tries to support its attempt to broaden "cylindrical" to cover non-cylinders by asserting that CoreValve "has repeatedly referred to its product as 'cylindrical' in over forty internal documents." Red Br. 41; see also *id.* at 18-19, 32. In fact, those documents refute Edwards' argument.

Every document cited by Edwards states that the CoreValve device's frame has different strut lengths and widths to "accommodate expansion" to a "*non-uniform* cylindrical shape." See A30913 and all other documents cited at Red Br. 18. CoreValve's modification of "cylindrical" by the term "non-uniform" shows its understanding that "cylindrical" without modification would describe a geometric cylinder (one with a *uniform* diameter). That modification contrasts sharply with the absence of any modifier before "cylindrical" in Claim 1.

Finally, Edwards complains that CoreValve's trial attorneys were unduly persistent in asking the district court to revisit its construction of "cylindrical" as meaning any shape "relating to" a cylinder. Red Br. 30-31. But as shown in this and CoreValve's opening brief, CoreValve had a strong basis for challenging the court's construction, and the jury verdict shows that CoreValve was prescient in predicting the consequences of construing "cylindrical" to cover non-cylinders.

II. THE COREVALVE DEVICE DOES NOT INCLUDE COMMISSURAL SUPPORTS THAT MEET THE LIMITATIONS OF CLAIM 1.

A. The CoreValve Device Does Not Have Commissural Supports "Projecting From" The Cylindrical Support Means.

Edwards does not rebut either of CoreValve's alternative showings that the infringement judgment must be reversed because (1) Edwards presented no evidence—other than Dr. Buller's conclusory assertions—that the CoreValve device has commissural supports "projecting from" its support means; and (2) even

if Buller's testimony could be credited, it would establish only that the CoreValve device does not meet the "projecting from" limitation because the "whole structure" of the stent cannot possibly "project from" itself. See Blue Br. 48-49.

1. Dr. Buller's conclusory testimony cannot support the infringement judgment.

Edwards points to no factual support for Dr. Buller's "green outline" testimony or otherwise suggests that it consisted of anything other than conclusory assertions. Edwards does not identify any tests or other analyses that Buller performed, or cite any "particularized testimony" for his conclusions—including his conclusion that all of the "diamonds" in his three green outlines (and no others) constitute the commissural supports in the CoreValve device. See Red Br. 45-46.

Instead, Edwards challenges the cases cited by CoreValve that preclude such testimony from supporting an infringement judgment. *Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312, 1320 (Fed. Cir. 2006); *Hewlett-Packard v.Mustek Sys. Inc.*, 340 F.3d 1314, 1323 (Fed. Cir. 2003); *Texas Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567-68 (Fed. Cir. 1996). Edwards claims that these cases are "not on point" because they involved the doctrine of equivalents or arose in a different factual context. Red. Br. 46. But Edwards does not explain the relevance of these distinctions or dispute the basic principle—affirmed in each of the cited cases—that an infringement judgment cannot stand

when based solely on conclusory expert testimony. See, *e.g.*, *Kim*, 465 F.3d at 1320. This principle controls here.

Edwards claims that the jury could nevertheless credit Dr. Buller's *ipse dixits* because he was "qualified" and "prepared" and purportedly spent "several years" analyzing the CoreValve device. Red Br. 45-46. Edwards cites no case holding that an expert's "qualifications" or "preparation" can justify his failure to provide a factual basis for his conclusions. Nor does Edwards provide any factual support for its claim that Buller spent "several years" analyzing the CoreValve device. Two of the three transcript pages cited by Edwards make no mention of the length of Buller's alleged preparation, and the third page reveals only that he spent a "few days" reviewing a "huge batch of CoreValve documents." A10800, A10843-44, A10848. That "few days" of review cannot justify his failure to provide any factual support for his assertions.

2. Dr. Buller's testimony showed that the CoreValve device does not meet the "projecting from" limitation.

Edwards also provides no plausible answer to CoreValve's alternative showing that even if Dr. Buller's testimony were accepted, it would establish only that the CoreValve device does not meet the "projecting from" limitation. Blue Br. 48-49. At trial, Buller abandoned his initial claims by conceding on cross-examination that the "whole structure" of the CoreValve stent (and not just the "diamonds" in his three green outlines) supports the commissural points. A10968,

A10971. His changed theory followed from his admission that the CoreValve stent would "fail" if the portions of the structure *between* the diamonds outlined in green were removed. A10950.

Under Dr. Buller's revised theory, the "whole structure" of the CoreValve device functions as the "commissural supports"—*i.e.*, the "portions of the stent that support the commissural points." Blue Br. 48-49. Consequently, to meet the "projecting from" limitation, the "whole structure" of the stent would have to be "projecting from" one of its own constituent parts (the cylindrical support means), a physical impossibility.

Edwards does not deny that Dr. Buller changed his theory on cross-examination, instead insisting that the "whole structure" of the stent *can* be "projecting from" one of its own constituent parts. Red Br. 49-50. In particular, according to Edwards, the limitations of Claim 1 can be met by a single "integral" stent in which "each portion of that stent performs the common function of supporting the valve." *Id.* at 50. Under this theory (which Edwards presents for the first time on appeal), the "projecting from" limitation does not require two separate structural elements because the entire "integral" stent can serve as both the "commissural supports" and the "cylindrical support means." *Id.*

Edwards' "integral stent" theory cannot be squared with the plain language of Claim 1, which requires a "plurality of commissural supports projecting from

one side of the cylindrical support means." A00064. First, the requirement of a "*plurality* of commissural supports" clearly contemplates a stent with *multiple* structural elements that are each separately identifiable as a "commissural support." For this reason, the district court construed "commissural supports" to mean the "portions" of the stent that support the commissural points. A00051. This requirement of multiple commissural supports cannot be met if the "whole structure" of the stent constitutes the alleged supports.

Second, the limitation that the commissural supports be "projecting from" one side of the cylindrical support means requires the presence of two separate structural elements (the commissural supports and the cylindrical support means) because one component cannot be "projecting from" itself.

This argument draws support from *Becton, Dickinson v. Tyco Healthcare Group*, 616 F.3d 1249 (Fed. Cir. 2010), a case that Edwards virtually ignores despite CoreValve's repeated citations to it. See Blue Br. 43, 49-50. In *Becton Dickinson*, the Court rejected the patentee's claim that the "hinged arm" and the "spring means" in a surgical needle could be "one and the same" element, when the patent required the hinged arm to be "connected to" the spring means. *Id.* at 1254. The Court reasoned that "[i]f the hinged arm and the spring means are one and the same, then the hinged arm must be 'connected to' itself and 'extend between' itself and a mounting means, a physical impossibility." *Id.* at 1255. The

same logic applies here: If the *entire* stent functions as both the "commissural supports" and the "cylindrical support means" (as Edwards now claims), then the entire stent must "project from" itself, a physical impossibility.

Edwards mentions *Becton Dickinson* only in a string cite suggesting that *Becton* can be distinguished because it involved a patent "that expressly called for separate structural elements." Red Br. 50. This is no distinction at all because the '552 patent also calls for separate structural elements—a "plurality of commissural supports" and a "cylindrical support means."

To be sure, as Edwards notes, the district court described both the commissural supports and the cylindrical support means as "portions" of the "same integral stent structure." Red Br. 47. But to say that the two components are part of the "same integral stent structure" is not to say that they are a *single* structural element. The district court's claim construction expressly requires multiple "portions" of the stent (the "commissural supports") to be "projecting from" another "portion" of the stent (the "cylindrical support means"). A00050-51. As *Becton Dickinson* makes clear, this construction requires two separate structural elements.

This is precisely why Dr. Buller's theory that the *entire* CoreValve stent supports the commissural points is fatal to Edwards' infringement claim. Under the district court's claim construction, Buller's theory established that the "whole

structure" of the CoreValve stent constitutes the commissural supports and must therefore be "projecting from" the cylindrical support means. This is a physical impossibility for the same reasons that the hinged arm in *Becton Dickinson* could not be "connected to" itself. 616 F.3d at 1254.

Edwards also contends that CoreValve's argument depends on a "new construction" of "projecting" to mean "sticking out" or "protruding." Red Br. 44-45. This argument also fails. First, CoreValve's opening brief did not advance a new construction of "projecting," but simply recited the experts' undisputed testimony concerning how a skilled artisan would understand the term at the time of the invention. Blue Br. 42-43; see A11538, A11707, A11709. Edwards' own experts never challenged this understanding or advanced a different meaning of the term. A10929-30. This approach is fully consistent with the parties' agreement, adopted by the trial court, that the term should be given its ordinary and customary meaning, as understood by a skilled artisan at the time of the invention. A00051, A08858; see *Phillips*, 415 F.3d at 1313. Edwards simply wants the term "projecting" to have no meaning at all.

Edwards further contends that preferred embodiments of the '552 patent demonstrate that the term "projecting" cannot mean "protruding" or "sticking out." Red Br. 44. Edwards notes that in Figures 1 and 2, a single wire is used to form both the three commissural supports and the "lower loops" of the cylindrical

support means. *Id.* But as explained above, the mere fact that discrete structural components are part of the overall stent structure does not mean that one component cannot "protrude from" another. Figures 1 and 2 clearly illustrate this point by depicting the commissural supports as "protruding" from the cylindrical support means, even though they are all part of the "same stent structure"—and even though they are formed in part through use of the same wire:

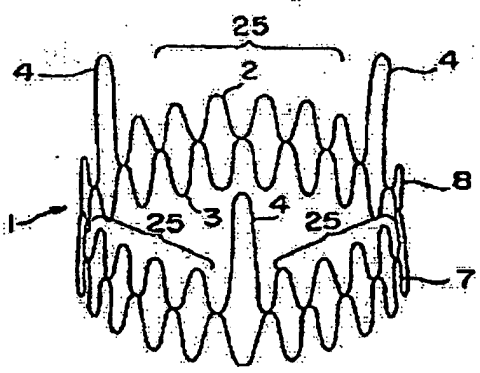


FIG. 1

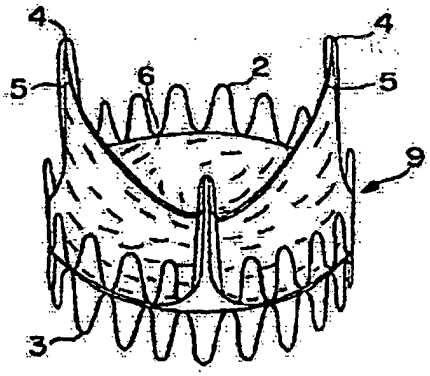


FIG. 2

A00057.

Edwards also argues that Figures 11 and 12 depict embodiments in which the commissural supports do not "protrude" from the rest of the stent. Red Br. 45. This argument ignores the prosecution history of the '552 patent. The patentees included Figures 11 and 12 in their original application, which set forth claims that did *not* contain a limitation requiring the commissural supports to project from the cylindrical support means. The patentees subsequently added the "projecting

from" limitation to overcome the Examiner's obviousness objections. However, in doing so, the patentees neglected to amend Figures 11 and 12, which continued to depict an embodiment of the stent without the "projecting from" limitation. See Blue Br. 10; compare A20467 (drawing in original application) and A20445-60 (original specification and claims), with A20571-74 (adding "projecting from one side" and related limitations) and A20412 (same drawings in issued patent). In light of the prosecution history, Figures 11 and 12 do not undermine the unrebutted trial testimony establishing that a skilled artisan would understand "projecting" to mean "protruding" or "sticking out."

Furthermore, even if Edwards could plausibly show that the term "projecting" has some different meaning—a showing that Edwards nowhere makes—CoreValve's argument does *not* depend on whether the term means "protruding" or "sticking out." Rather, it depends on the plain meaning of the phrase "projecting *from*," which requires the stent to have two separate structural elements in which one component is "projecting from" another. Under any definition of "projecting," this limitation cannot be met if the entire stent is deemed to constitute one of the two structural elements. *Becton Dickinson*, 616 F.3d at 1254.

Finally, Edwards argues that CoreValve's "two separate structural elements" argument is inconsistent with the description of the claimed invention by

CoreValve's experts as an "integral" structure. Red Br. 49. This argument ignores the actual testimony of the CoreValve experts, which made clear that the claimed invention is an "integral structure" only in the sense that it consists of discrete parts that are "joined permanently together"—not in the sense that the "whole structure" serves as both the commissural supports and the cylindrical support means. A11557-59, A11779-81. As shown above, the plain meaning of the "projecting from" limitation in Claim 1 requires two discrete structural elements, even though both are "portions" of the overall structure of the stent.

In sum, Edwards can point to no evidence that the CoreValve device has commissural supports that are "projecting from" the device's support means, as required by Claim 1. For this reason, the infringement judgment below must be reversed. See, *e.g.*, *Smith & Nephew, Inc. v. Arthrex, Inc.*, 2011 WL 2438633 (Fed. Cir. June 20, 2011) (reversing infringement judgment "[b]ecause there is no evidence of record supporting the jury's verdict").

B. The CoreValve Device Does Not Have Commissural Supports That Project In A Direction "Generally Parallel" To The Longitudinal Axis.

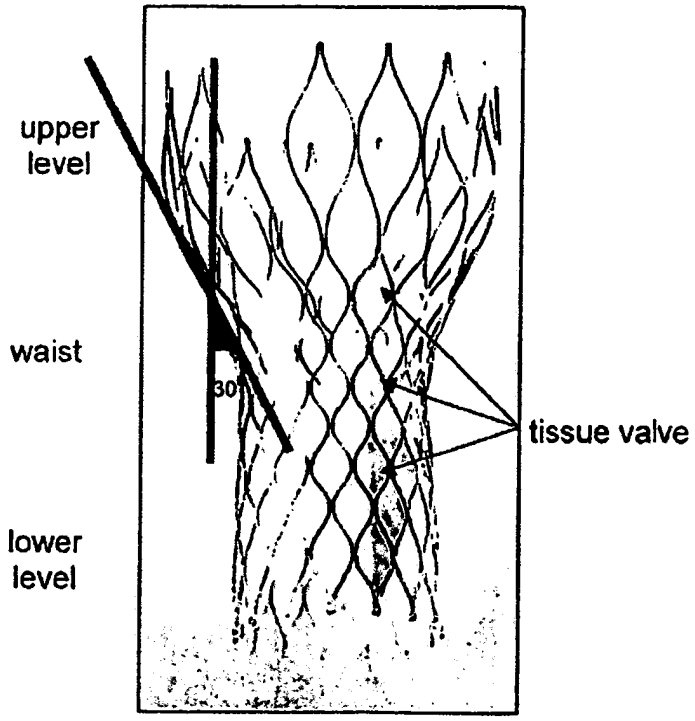
Edwards also fails to rebut CoreValve's showing that (1) Edwards presented no competent evidence that the CoreValve commissural supports project in a direction "generally parallel" to the longitudinal axis; and (2) as a matter of law, the CoreValve commissural supports do not meet the "generally parallel"

limitation because they end at commissural points on a 30° angle in the middle of the stent. Blue Br. 50-54.

As with the "projecting from" limitation, Edwards makes no attempt to show that Dr. Buller's testimony on the "generally parallel" limitation of Claim 1 was anything other than conclusory. Red. Br. 51-54. Edwards cites no testimony by Buller pointing to any evidence—or providing any "particularized explanation"—to support his conclusion that the CoreValve commissural supports meet the "generally parallel" limitation. *Id.* Instead, Edwards simply quotes Buller's pronouncements—made with no factual basis whatsoever—that the CoreValve commissural supports can be analogized to a fork because the "whole structure" of the CoreValve stent purportedly constitutes the commissural supports. Red Br. 53. Such highly "generalized" assertions cannot support an infringement verdict. *Texas Instruments*, 90 F.3d at 1567-68.

Edwards asserts that CoreValve's argument "neglects that the stent 'commissural supports' are different than the valve 'commissural points.'" Red Br. 51. Edward bases this assertion on CoreValve's "focus" on the location of the commissural points on the slopes of a 30° angle that circles the middle of the stent. *Id.* at 52. This argument misses the point. To determine if the CoreValve commissural supports are "generally parallel" to the longitudinal axis, the first step is to determine what portions of the stent constitute the "commissural supports"—

i.e., the "portions of the stent that support the commissural points." A00051. As CoreValve showed in its opening brief, Dr. Buller's "fork" analogy depends entirely on his claim that the commissural supports extend above the commissural points and encompass the top half of the stent. Blue Br. 52-53. If the commissural supports encompass only the portion of the stent that ends with the 30° angle containing the commissural points, then the supports clearly cannot be deemed to be "generally parallel" to the longitudinal axis.



A02589 (annotated photo of the CoreValve device illustrating the 30° angle).

Dr. Buller provided no factual or evidentiary support—or even a reasonable explanation—for his counterintuitive claim that the portion of the stent lying *above*

the commissural points could somehow be involved in supporting the same commissural points. Instead, he simply pronounced as a self-authenticating proposition that the "generally parallel" limitation means that the "whole structure" of the stent, "*looked at from top to bottom*," has to be oriented in a direction generally parallel to the longitudinal axis. A10867 (emphasis added).

That testimony is not only devoid of factual support but also contrary to the plain language of the claim, which requires a "*plurality* of commissural supports" to be oriented in a direction "generally parallel to the longitudinal axis." A00064 (Col. 8, lns. 9-11). This language plainly requires *more than one* "commissural support" to be projecting in a direction generally parallel to the longitudinal axis. Such a requirement cannot be met if the "projecting" commissural supports consist simply of the "whole structure" of the stent. For this reason as well, the CoreValve device does not meet the "generally parallel" limitation as a matter of law.[2]

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[2] Edwards contends that if this Court reverses the literal infringement judgment, a new trial is required on Edwards' alternative doctrine of equivalents claim. Red Br. 46 n.10. But this Court often holds, after reversing a literal infringement verdict, that a new trial on a doctrine of equivalents theory would be futile. *E.g.*, *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, ___ F.3d ___, 2011 WL 2652448, at *9 (Fed. Cir. July 8, 2011); *Cook Biotech, Inc. v. Acell, Inc.*, 460 F.3d 1365, 1368 (Fed. Cir. 2006). As CoreValve's opening brief explained, Edwards' doctrine of equivalents theory fails as a matter of law because Edwards disclaimed any equivalents to claim elements added during prosecution. Blue Br. 53-54.

III. CLAIM 1 OF THE '552 PATENT WAS NOT ENABLED FOR HUMAN USE.

The full scope of Claim 1 was not enabled for human use without undue experimentation. The patent did not indicate how the claimed invention could overcome the substantial obstacles to human implantation, and developers proved unable to do so despite many years of experimentation. See Blue Br. 57-63. Edwards responds that the '552 inventors' pig experiments were sufficient to show enablement, the patent was implemented for human use with "remarkable" speed, and Edwards' SAPIEN device is a commercial embodiment of the '552 patent. As demonstrated below, Edwards is wrong on all points.

A. The Inventors' Pig Experiments Do Not Prove That The '552 Patent Was Enabled For Human Use.

The pig experiments do not establish enablement of the claimed invention for human use. Edwards does not seriously contest the fact that the scope of Claim 1 includes human implantation, and it concedes that "most of the specification" is directed to that purpose. Red Br. 56. Hence, to enable one skilled in the art to make and use *the full scope* of the claimed invention without undue experimentation, the patent must teach how to make and implant it in a human body channel. See Blue Br. 55-57 (citing cases).

Noting that the patent need not enable more than one *mode* of making and using the invention, Edwards argues that enabling the invention for implantation in

pigs is sufficient. Red. Br. 55-56. Edwards confuses the scope of the invention with the means of implementing it. If A and B are both within the scope of the claimed invention, the specification must teach how to make and use *both* A and B to enable the full scope of the invention, but it need not disclose more than one mode (or means) of doing so for each of A and B. The issue here is whether the claimed invention is enabled for its full scope, including human implantation, not whether the patent teaches more than one means of doing so.

Edwards does not address the "full scope" cases cited in CoreValve's opening brief (at 56-57). But Edwards' cited cases confirm that principle, and they do not support Edwards' conflation of "full scope" with "any mode." Red Br. 56. In each case, the Court explained that the "full scope of the claimed invention" must be enabled "without undue experimentation," a requirement that it found satisfied before proceeding to reject objections for failure to disclose alternative modes. *John Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1359 (Fed. Cir. 1998); *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1070 (Fed. Cir. 2005); *Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1306 (Fed. Cir. 2001).

Edwards also argues that the vascular anatomies of pigs and humans are sufficiently "similar" for enablement purposes. Red Br. 55. However, pigs are not humans. Edwards cannot explain why, if the vascular anatomies of pigs and

humans are so similar, no one could replicate even the very modest pig implantations in humans in 1990 or anytime reasonably thereafter.

Edwards argues that the patent's single assertion that "the cardiac valve prosthesis for use in human beings has a corresponding form" was sufficient to allow one skilled in the art to develop a valve for human use. Red Br. 56 (citing A00063). Nothing in the patent, however, suggests what the "form" for humans might be or how it would "correspond" to the structure disclosed for pigs. The specification must provide "reasonable detail" to "enable members of the public to understand and carry out the invention." *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997). Edwards points to no such detail in the '552 patent, relying solely on an unsupported assertion by Dr. Buller. Red Br. 56. But "an expert's opinion on the ultimate legal issue [of enablement] must be supported by something more than a conclusory statement." *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). Edwards' failure to offer even a whit of evidence that the patent enabled a device for human use requires that Claim 1 be invalidated as non-enabled.

B. Claim 1 Of The '552 Patent Could Not Be Developed For Human Use Despite Years Of Experimentation.

Edwards notes that an invention need not be commercially viable for the claim to be enabled. Red Br. 60. That is true, but the invention must be implementable without undue experimentation. 35 U.S.C. §112, ¶1. Edwards

contends that designing a device for human use based on the '552 patent involved only "routine development work." Red. Br. 58. However, the '552 inventors admitted that they had achieved only "a preliminary technical investigation" and that "much more work had to be done before anybody ever even *contemplated* using this for a human." A11663 (emphasis added); see A20184.

The inventors further admitted that their prototype could not be used in humans (A20227-28, A20167); was not intended to have "direct clinical applicability" where "clinical" meant "for human use" (A20194); was too bulky for human arteries (A20169); could not stay fixed in the aortic annulus (A20184); and had to overcome numerous other problems (A11663). As in *Harris Corp. v. IXYS Corp.*, 114 F.3d 1149, 1156 (Fed. Cir. 1997), "the most we can credit them with is having predicted—rather than invented—such a device." Even if engineers could have found a way to reduce the size of the Andersen prototypes, as Edwards contends (Red Br. 57), that does not mean they could have overcome the immense difficulties in designing a device sufficiently compressible to fit into human arteries and with enough stability to withstand aortic blood pressure without undue experimentation. See A11528-31, A11674, A31544.

Inability to develop a claimed invention is powerful evidence of non-enablement. *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 942 (Fed. Cir. 2010). The '552 inventors admittedly had no idea how to develop their claimed

invention and therefore licensed the patent to Stanford Surgical (later Heartport), which could not implement the patent for human use despite *seven years of trying*. See Red Br. 10. Edwards tries to blame Stanford Surgical for this failure, claiming that it "did virtually nothing" to develop the invention. *Id.* However, as '552 inventor John Hasenkam admitted, Stanford Surgical had strong financial incentives to develop the patent and hired an additional engineer to make that happen, and Dr. Andersen held several meetings with the company and provided it with technical literature about aorta implantation. A20199-A20103. Despite financial incentives, collaboration with the inventors, and dedicated resources, Stanford Surgical came up empty.

Edwards calls it "remarkable" that the next licensee, PVT, was able to develop a transcatheter heart valve just two years after obtaining the license. Red Br. 58. But in *Genentech*, this Court found an inability to implement the claimed invention "for *nearly a year*" evidence of non-enablement. 108 F.3d at 1367 (emphasis added). Of course, the amount of time sufficient to make experimentation "undue" is not set in stone. But here, where Stanford Surgical could not implement the claimed design in seven years, any success by PVT two years later would fall far short of showing that Claim 1 was enabled nine years earlier when the patent application was filed. In any event, as explained in the next subsection, although PVT did develop a valve implantable in humans, that valve

was not based on the '552 patent, and it succeeded only because it departed from the structure claimed in the patent.

In sum, there was nothing "routine" about developing a valve for implantation in a human body channel based on the '552 patent.

C. The SAPIEN Valve Is Not An Embodiment Of The '552 Patent.

No one has been able to develop a human heart valve prosthesis according to the teachings of the '552 patent. Blue Br. 61-63. Edwards' assertion that its SAPIEN valve is a commercial embodiment of the '552 patent is flatly wrong.

The uncontroverted evidence was that PVT abandoned its attempt to develop a prosthetic valve based on the '552 patent after Dr. Cribier concluded that the '552 patent provided an "impossible" design for a valve implantable in humans. A11379-80, A20264; see Blue Br. 24, 62. At trial, the SAPIEN valve designers confirmed that the SAPIEN valve was not based on the '552 patent. Dr. Cribier, the principal designer, testified that "the Andersen valve model has never been used in an aortic stenosis" and that limitations in the '552 design likely *precluded* "any possible human application." A31392-93, A11378-79. And PVT developer Natanel Benichou testified that the '552 patent contributed nothing to the development of the SAPIEN valve. A11386-87, A11398.

Edwards disregards this evidence, instead relying on the fact that it paid royalties to the '552 inventors. Red Br. 60. There are many business reasons for

paying royalties, however, and Edwards' decision to do so says nothing about whether the SAPIEN valve is based on the '552 patent. Edwards also relies on Dr. Buller's "belief" that the SAPIEN embodies the '552 patent, a belief for which Buller provided no support and thus which is not evidence of enablement. *Id.* (citing A10901); see *Buchner*, 929 F.2d at 661.

In short, Edwards offered no evidence by which a jury could reasonably find that the SAPIEN valve implemented Claim 1 of the '552 patent, and there was abundant evidence, including from Edwards' own witnesses, that it did not.

IV. THE LOST PROFITS DAMAGES AWARD SHOULD BE VACATED.

Edwards cannot paper over the fundamental flaws in the award of lost profits damages. That award should be vacated because it is "'grossly excessive' [and] not supported by evidence." *Oiness v. Walgreen Co.*, 88 F.3d 1025, 1031 (Fed. Cir. 1996).

The parties agree that the critical question is when CoreValve could have manufactured its transcatheter heart valve overseas, and that the availability of that non-infringing substitute must be determined by working forward from the date of first infringement. Thus, no award of lost profits damages can be sustained absent sufficient evidence that (1) the date of first infringement was January 2006, and (2) CoreValve could not have begun non-infringing production overseas before August 2007. In addition, CoreValve is entitled to a new trial absent substantial

evidence that CoreValve could not have begun overseas production even at the time of trial.

Edwards proceeds as if each statement by its damages expert, Dr. Leonard, is substantial evidence *ipso facto*. To the contrary, "[i]t is well established that '[a]n expert's testimony will not support a verdict if it lacks an adequate foundation in the facts of the case.'" *First Fed. Lincoln Bank v. United States*, 518 F.3d 1308, 1319 (Fed. Cir. 2008). When the expert's "entire premise is flawed" so that his conclusions rest on "faulty assumptions," his testimony is insufficient to support a damages award. *Oiness*, 88 F.3d at 1031-32. That is the case here.

A. Edwards Did Not Present Sufficient Evidence To Establish That January 2006 Was The Date Of First Infringement.

Now as at trial, Edwards identifies no evidence or legal principle that could fix the date of first infringement in January 2006, when CoreValve "froze" the design of the Generation 3 device. Freezing a design is not infringing conduct; the relevant infringement began when CoreValve *made* a device that infringed the same way. See 35 U.S.C. § 271(a). Edwards does not dispute that an infringing design could be "frozen" only if the design had been made (and thus infringed) earlier. See Blue Br. 67. Edwards simply asserts that the Generation 3 device was not "conceived" until September 2005 (Red Br. 63)—when prototypes were already being manufactured and thus infringed. See A11615. Because no evidence supported a delay in marketing the CoreValve product if the date of first

infringement was September 2005, the premise of the lost-profits award lacks evidentiary support and should be vacated on that ground alone.

If there was infringement at all, however, the date of first infringement came much earlier because the Generation 2 device infringed the '552 patent when CoreValve made prototypes in fall 2004, when CoreValve produced clinical grade devices in March 2005, and when Edwards sent a letter warning CoreValve about infringement the following month. A22940-41.

Edwards identifies no evidence that the Generation 2 device differed from the Generation 3 device in any way meaningful to infringement. Edwards does not dispute that the stents were identical, but asserts that they infringed differently because the Generation 3 device had a different valve. Red Br. 63. Beyond claiming "a collapsible elastical valve ... having a plurality of commissural points" (A00064), however, Claim 1 addresses only stent structure. *Any* valve that could be mounted on the claimed stent would be collapsible and elastical, and would have more than one commissural point.

Edwards invokes an invalid legal principle to support its contention that any change in an infringing product triggers a new date of first infringement. Red Br. 62-63 (citing *Applied Med. Resources Corp. v. U.S. Surgical Corp.*, 435 F.3d 1356, 1361-62 (Fed. Cir. 2006)). *Applied Medical* addressed a very different question: the date of a hypothetical negotiation for a reasonable royalty. A later negotiation

addressing a different device might well produce a different royalty rate because of changed design or "market conditions." See *id.* at 1363. Indeed, by contrast with the Generation 2 and Generation 3 devices, the successive products in *Applied Medical* were "*vastly different*" by the infringer's own admission. *Id.* at 1362.

Here the question is not whether product changes would trigger successive hypothetical royalty negotiations, but when knowledge of infringement would have prompted the infringer to manufacture its products overseas. That date—when the infringer would have secured a substitute, noninfringing manufacturing source—does not change when one version of the infringing product is superseded by another version that infringed the same way. Although an old royalty agreement might not cover a new product, a non-infringing substitute production facility would still provide a non-infringing substitute after a design change that did not affect infringement. That is one of the "instances" ***not*** addressed in *Applied Medical*, "in which two products, even if not identical, may present the same damages analysis." *Id.* If CoreValve had known that the Generation 2 device infringed, the only evidence indicates that CoreValve would have shifted all "making" of the device overseas, and stayed there after it chose a different valve for the Generation 3 device. Because the "entire premise" of the lost profits award is the "flawed" and unsupported assumption that January 2006 was the date of first infringement, the award should be vacated. *Oiness*, 88 F.3d at 1031.

B. The Undisputed Evidence Shows That CoreValve Could Have Begun Non-Infringing Production Overseas Before August 2007.

If the pertinent date of first infringement preceded CoreValve's significant commitment in Irvine, the undisputed evidence showed that CoreValve could have continued and expanded its development overseas and would have begun full, non-infringing production there. CoreValve lacked a significant commitment until long after the January 2006 design "freeze." It is undisputed that, as late as mid-July 2005, CoreValve had fewer than 15 employees, and expected that number only to double within the following year. A22991.

Edwards identifies no evidence that a move undertaken in August 2004 (when the Generation 2 was first made) or September 2005 (when the Generation 3 was first made) would have delayed initial production by the 2½ years Edwards' expert, Dr. Leonard, claimed would have been consumed by a move undertaken in January 2006. To the contrary, the **only** evidence addressing a hypothetical shift in operations at any time between August 2004 through January 2006 showed that a move so early in the development stage would not have delayed CoreValve's commercial production beyond the actual May 2007 date. A11480, A11496.

The only contrary evidence consisted of expert opinion testimony that rested on transparently "faulty assumptions," *Oiness*, 88 F.3d at 1032, and lacked "foundation in the facts of the case." *First Federal*, 503 F.3d at 1319. Leonard premised his calculations of delay and expense of a shift overseas on CoreValve

documents discussing the time and expense needed to move the mass-production manufacturing operations in place in Irvine **in late 2008.** Red Br. 65 (citing A11025-27, A11037-43); see also A11024 (describing 2008 document). Between August 2004 and January 2006, however, CoreValve required only 100-150 devices per year for clinical trials; it did not have (or need to move) its 2008 manufacturing facility with a 20,000-valve annual capacity. A11480, A11519-20. Rather than the "7.5 to ten million dollars" Leonard speculated would be necessary to move the 20,000-valve facility—and would have stretched company resources in 2006 (A11038-39)—undisputed evidence showed that moving the smaller facility (and 15-employee company) during the developmental phase in 2004-2006 would have cost only $1-2 million (A11481).

Although CoreValve publicly touted Irvine's benefits, the site was chosen when infringement was not a consideration (Red. Br. 63-64 (citing A11494-95)), and unrebutted evidence showed that adequate facilities and expertise were available in Italy, Scotland, Canada, Ireland, Singapore, and Switzerland (where CoreValve's early prototypes were made). A11423, A11479-80. Edwards claims a move might have been impossible because researcher Than Nguyen might not have been able to move overseas in 2004 or 2005, citing only evidence of Nguyen's health in March 2010 (A11429-30). Yet Nguyen did travel to Paris to meet with CoreValve executives in August 2004. A11144, A33363. And because

he did only design work (see A10731, A10739-46), there was no evidence that Nguyen would have had to move at all so long as CoreValve *made* its devices overseas. Indeed, the stent frames that Nguyen designed were fabricated in Germany and then imported to the U.S., where the valve tissue was sewn onto the frame. A10700-01, A10709-12. In exactly the same way, Nguyen could have formulated his designs in Irvine and telecommunicated them across the globe, and used teleconferences and collaboration software to work with distant engineers, just as CoreValve inventors Séguin and Bortlein participated in Irvine design meetings by teleconference from France. A11429.

* * * * *

The lost profits award gave Edwards a windfall amounting to a 55% royalty, even though Edwards had earlier agreed that 25% provided enough compensation for infringement of the '552 patent by the holder of a field-limited license. See A25737 (the within-field royalty was 4%). Because it is "not supported by substantial evidence, but is based mainly on speculation or guesswork," *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1335 (Fed. Cir. 2009), the award of lost profits here is "inconsistent with sound damages jurisprudence," *ResQNet.com v. Lansa, Inc.*, 594 F.3d 860, 868 (Fed. Cir. 2010), and should be vacated.

V. EDWARDS' CROSS-APPEAL ARGUMENTS ARE WITHOUT MERIT.

A. The District Court Properly Rejected Edwards' Request For A Permanent Injunction.

Edwards asks this Court to reverse the district court's denial of Edwards' request for a permanent injunction barring CoreValve from making, importing, selling, or offering to sell the CoreValve device in the United States. A00025-29.

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]] Thus, the court's ruling that an injunction would be futile in these circumstances was consistent with both CoreValve's representations and the evidence.

"[T]he decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts." *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 394 (2006). This equitable discretion derives directly from the Patent Act, which provides that a court "*may* grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent." 35

U.S.C. § 283 (emphasis added). Edwards has not shown that the district court abused its equitable discretion, especially in light of the supply disruption to patients (which likely would cause some to die) and the deadweight economic loss resulting from an enforced relocation of facilities to comply with an injunction that would expire when the patent does, in May 2012.

"An injunction is a drastic and extraordinary remedy, which should not be granted as a matter of course." *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2761 (2010). The proponent must prove that (1) it will suffer irreparable injury absent an injunction; (2) legal remedies such as monetary damages are inadequate; (3) the balance of hardships weigh in favor of an injunction; and (4) an injunction will not disserve the public interest. *eBay*, 547 U.S. at 391. The district court fully considered each of these factors in light of the evidentiary record and properly found that Edwards had not met its burden on any of them.

1. Edwards will not be irreparably harmed absent an injunction.

The district court found that Edwards would not suffer irreparable harm absent an injunction because the only harm it identified—loss of first-mover advantage—had occurred long before trial. A00026. Edwards did not prove (or even allege) that it faced any prospective loss of customers or sales prior to expiration of the patent in May 2012. A00027-28.

The court also noted that Edwards' infringement claim rested on CoreValve's *manufacture* of the accused product in the United States, not on *sales* of the product, all of which occurred abroad. The court found that if CoreValve were enjoined from manufacturing at its current site in Irvine, California, it could move its manufacturing operations to its alternative site in Tijuana, Mexico. Thus, an injunction "would not affect the alleged harm." A00027-28.

Those findings were plainly within the court's discretion and are consistent with the evidence. Edwards seeks an injunction based on "past irreparable harm." Red Br. 71. However, "[a]n injunction is only proper to prevent future infringement of a patent, not to remedy past infringement." *Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305, 1320 (Fed. Cir. 2010). While courts may consider past irreparable harm in determining the prospect of future harm, they must keep in mind that "injunctions are tools for prospective relief designed to alleviate future harm." *i4i*, 598 F.3d at 862. In *i4i*, there was "strong" evidence that i4i's business was "comprised 'almost exclusively' of products" based on the infringed patent and that the infringement rendered those products "obsolete." *Id.* Edwards has offered no such evidence here, and Edwards has been fully compensated for any past harm by the court's entry of judgment on the jury verdict and accounting decision. See *Spine Solutions*, 620 F.3d at 1320 ("a

patentee must seek compensation for past infringement under 35 U.S.C. § 284; the purpose of an injunction is to prevent future violations of the patent").

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]] As CoreValve told the district court, it "has undertaken steps to ensure that its Gen 3 THV will be available ... by setting up *alternative* manufacturing facilities in Mexico." A18755 (emphasis added). CoreValve's public statements similarly announced that "*[i]n the event of a U.S. injunction*, Medtronic has manufacturing capabilities for CoreValve products outside the United States." A15416 (emphasis added). [[

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Edwards' speculation about "sticky" customers and "reputational harm" (Red Br. 73-75) is simply irrelevant given the futility of an injunction in these circumstances. An injunction will not prevent CoreValve from "signing up more doctors" who prefer the CoreValve device (*id.* at 74) because that device will be available to those doctors whether it is manufactured in the United States or Mexico. It is undisputed that CoreValve's sales to those doctors are legal and non-infringing outside the United States, a fact that would not be affected by moving the location of CoreValve's manufacturing operations. Thus, the cases cited by Edwards (*id.* at 74) are inapposite because they all involve infringing sales.

In short, Edwards has not identified—and certainly has not met its burden to prove—that it would be irreparably harmed absent an injunction. Manufacture of the CoreValve device would shift to Mexico, and sales would continue in Europe and other foreign locations just as they would without an injunction.

2. Edwards' pecuniary remedies are adequate.

The district court found that Edwards had offered "no evidence or testimony"—but only "attorney argument"—to show that monetary damages would be an inadequate remedy for any continuing infringement by CoreValve. A00028. The court explained that Edwards can sue for damages if CoreValve continues to infringe and that Edwards' licensing activity indicates that such monetary damages would be adequate. *Id.*

Edwards contends that it is "in the same position as the patent owner in *i4i*." Red Br. 77. *i4i* involved infringing sales, however, and in that case the district court found, based on the evidence, that Microsoft's infringement forced i4i to change its business strategy, a harm that was "particularly difficult to quantify." 598 F.3d at 862. There is no such evidence here, and the jury and district court had no difficulty in quantifying Edwards' alleged harm.

Edwards also suggests that the district court's rejection of an injunction will allow CoreValve to enter the U.S. commercial market and "dilute Edwards' first-mover advantage." Red Br. 77. As Edwards itself has acknowledged, however, FDA approval of the CoreValve device is not expected until at least 2014—long after the May 2012 expiration of the '552 patent. A19229. CoreValve cannot sell its product in the U.S. without such approval, and thus CoreValve's future plans to sell in the U.S. after the '552 patent has expired are irrelevant.

Finally, Edwards argues that the district court misinterpreted a license agreement and made "errors in evaluating the history of the '552 Patent rights." Red Br. 78. Edwards' quibbles about the meaning of a particular license cannot overcome its failure to offer *any* evidence to show that monetary damages would be inadequate. A00028. The district court reviewed the license agreement, considered the parties' arguments about it, and reached a reasoned conclusion

about its impact on the adequacy factor. The court thereby properly exercised its discretion.

3. The balance of harms weighs against an injunction.

The district court properly found that the balance of harms does not weigh in favor of an injunction. Because the "only practical effect" of an injunction would be CoreValve's manufacturing move to Mexico, the court found that Edwards' ability to sell its product "would remain substantially the same." A00029.

Edwards again argues that absent an injunction, CoreValve will re-start its infringement by selling its product in the United States. Red Br. 79. As described above, however, there has been no finding of infringing *sales*, CoreValve can avoid any infringement by moving its manufacturing operations to Mexico, and CoreValve will not obtain approval to sell in the United States until after the '552 patent has expired. Thus, Edwards will suffer no hardship from lack of an injunction because it would face the same degree of competition should an injunction issue.

By contrast, CoreValve would suffer substantial harm from issuance of an injunction. [[

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In short, the only impact of an injunction would be to inflict the costs of moving to Mexico on CoreValve. This Court should not allow Edwards to enlist its assistance for such an anticompetitive purpose.

4. The public interest disfavors an injunction.

"[C]ourts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982). The district court found that an injunction would not advance the public interest because, as explained above, CoreValve could move its manufacturing operations abroad and the supply of its heart valve would remain "substantially the same." A00029.

Edwards responds that an injunction is required to bring "finality" and protect "the integrity of intellectual property rights." Red Br. 80. It does not explain how a move of CoreValve's manufacturing operations to Mexico would make any difference with respect to those abstract goals. The cases cited by Edwards (Red Br. 80) offer it no support. Two of them say nothing at all about injunctions (*Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83 (1993); *Am. Graphophone Co. v. Leeds & Catlin Co.*, 170 F. 327 (2d Cir. 1909)), and the third addresses only preliminary injunctions in a very different context (*Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368 (Fed. Cir. 2006)).

If an injunction *were* effective, it would create serious public health risks. If CoreValve were enjoined from manufacturing in the United States and could not move its manufacturing operations to Mexico, the consequences to patients would be devastating. Over 10,000 patients have received the CoreValve device, which is being sold in Europe, South America, Australia, and New Zealand. A11289. An injunction that stopped manufacture of the CoreValve device would result in a shortage of transcatheter heart valves and force many patients to undergo the rigors and risks of open heart surgery and thereby lead to unnecessary deaths. See Blue Br. 6. This dire consequence is more than sufficient to make an injunction contrary to the public interest. See *Cordis Corp. v. Boston Scientific Corp.*, 99 F. App'x 928, 935 (Fed. Cir. 2004) ("for good reason, courts have refused to permanently enjoin activities that would injure the public health"; "a strong public interest supports a broad choice of drug eluting stents").

Edwards asserts that an injunction "will not endanger lives" because "Edwards can treat the entire CoreValve patient population." Red Br. 80. That assertion conflicts with Edwards' admission below that it cannot treat large annulus patients, which led Edwards to "carve out" such patients from its proposed injunction. A19696-97. Moreover, Edwards' assertion is flatly wrong. Edwards cites only to calculations by its *damages* expert for damages purposes, which is not

competent evidence of the actual patient coverage provided by the parties' respective products.

The competent evidence showed incontrovertibly that Edwards' SAPIEN device could not serve many categories of patients currently being served by the CoreValve device. The SAPIEN device cannot treat the 10-15% of patients with annulus sizes larger than 25 mm. A10658. Nor can the SAPIEN be used to treat patients with a septal bulge or a bicuspid aortic valve. A18948-49, A18951-52. In addition, the SAPIEN is dangerous for patients with coronary ostia less than 1.5 mm from the native aortic valve. A19195, A18955-56.

Furthermore, femoral access in some patients is available only by using the CoreValve device in a "subclavian" technique, a minimally invasive procedure that requires no surgical support or general anesthesia. A18872, A18883, A18947. If SAPIEN alone were available, these patients' only option would be the "far more invasive" transapical technique, which entails "considerably more pain and discomfort," requires a "longer and more painful recovery," and poses "a risk for far more severe complications." A18947-48, A18885-86, A18896. Many patients are not suited for this high impact procedure at all, and without the CoreValve option would be entirely deprived of treatment. A18951. Furthermore, some medical centers cannot support the resource demands of transapical procedures. A18958-59, A19195, A11202-03.

Without the CoreValve device, these thousands of patients, and all those in entire regions, would be deprived of treatment and "would likely die." A18956 (there are few Edwards-trained physicians in Australia); see A18958 (without CoreValve, a region in the U.K. of 5.8 million people would have no transcatheter heart valve options). Indeed, the two companies collectively have been unable to train enough doctors to treat all patients eligible for a transcatheter heart valve (A10681-83), and [[CONFIDENTIAL MATERIAL OMITTED]] (see A18477). Even if Edwards could initiate an enhanced training program, the inherent delays "would surely result in patient deaths." A18958. See *Scripps Clinic & Research Found. v. Genentech, Inc.*, 666 F. Supp. 1379, 1401 (N.D. Cal. 1987) (rejecting injunction where patients might be harmed by delay in bringing medical product to market), *aff'd in part, rev'd in part on other grounds*, 927 F.2d 1565 (Fed. Cir. 1991).

Finally, the many problems with the SAPIEN device have led physicians to prefer the CoreValve device [[CONFIDENTIAL MATERIAL OMITTED]] A18149, A18951; see *Datascope Corp. v. Kontron Inc.*, 786 F.2d 398, 401 (Fed. Cir. 1986) ("the public will be harmed by an injunction" against a medical product "that some physicians prefer"). For example, physicians prefer the CoreValve device because, unlike the SAPIEN, it can be repositioned after placement, or even retracted back into the delivery catheter. A18948, A18951; see also A18902. Edwards issued at least two Field Safety Notices in 2010 about potential problems with the SAPIEN (A18937-

43), and proctors for Edwards found that patients receiving balloon expandable devices (the SAPIEN) suffered a much higher rate of acute renal failure than those receiving self-expanding devices (the CoreValve). A18881 (45% versus 17%).

In sum, Edwards' requested injunction would be either (i) ineffective because CoreValve would continue to manufacture its devices in Mexico, or (ii) dangerous to public health. Thus, the district court properly ruled that Edwards failed to meet its burden on the public interest factor of the injunction test.

B. This Court Should Not Disturb The District Court's Prosecution Bar Ruling.

Edwards also challenges the district court's order barring Edwards' trial counsel and technical expert from participating in the PTO's '552 reexamination proceeding. Edwards' cross-appeal from that ruling is moot.

As Edwards notes, "the PTO issued its final action in the '552 Patent reexamination" on May 20, 2011, rejecting CoreValve's invalidity arguments (which were unrelated to the issues raised on this appeal). Red Br. 22. Thus, there is no live controversy over the participation of Edwards' trial counsel and technical expert in the '552 reexamination proceeding, rendering this cross-appeal issue moot. See *Nasatka v. Delta Sci. Corp.*, 58 F.3d 1578, 1580 (Fed. Cir. 1995) ("If an event occurs while a case is pending on appeal that makes it impossible for the court to grant 'any effectual relief whatever' to a prevailing party, the appeal must be dismissed as moot"). Although Edwards contends that this same issue may

arise in litigation regarding *other* patents (Red Br. 22), if so the issue should be addressed in the concrete circumstances of any litigation and reexamination involving *those* patents. See *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 109 (1998) (requiring that "allegations of future injury be particular and concrete" to avoid mootness).

Even if the issue is not moot, the district court did not abuse its discretion in barring Edwards' trial counsel and technical expert from participating in the '552 reexamination proceeding. The court properly found that such participation "would create a high risk that confidential CoreValve/Medtronic information would be used or disclosed." A00054. Moreover, because the defendants "limited themselves to the use of the public record in making their reexamination arguments," the court properly found no "prejudice or undue burden that could result from Edwards being similarly restricted in making its reexamination arguments." A00055, n.1.

Edwards denies that the '552 reexamination proceeding posed any risk of improper disclosure of confidential information, citing several district court rulings. However, other district courts have ruled otherwise and barred persons who received confidential information in litigation from participating in reexamination. *E.g., Visto Corp. v. Seven Networks, Inc.*, 2006 WL 3741891 (E.D. Tex. Dec. 19, 2006); *Methode Elecs., Inc. v. Delphi Auto. Sys. LLC*, 2009 WL

3875980 (E.D. Mich. Nov. 17, 2009); *Silicon Graphics, Inc. v. ATI Techs., Inc.*, 2007 WL 5433478 (W.D. Wis. Aug. 8, 2007). Each case rests on its facts, and thus district courts have "broad discretion to decide what degree of protection is required." *In re Deutsche Bank Trust Co. Americas*, 605 F.3d 1373, 1380 (Fed. Cir. 2010).

Moreover, in this Court's only decision involving application of a prosecution bar to reexamination proceedings, it held that the district court did not abuse its discretion in barring a patent infringement plaintiff from participating in a PTO reexamination proceeding. *Grayzel v. St. Jude Med., Inc.*, 162 F. App'x 954, 966 (Fed. Cir. 2005). While that unreported decision is not precedential, it exemplifies the deference accorded district courts with respect to such decisions.

Edwards too blithely dismisses the risk of disclosure of confidential information. A recent article describes a case where trial counsel apparently placed confidential information in the public record after being permitted to participate in a reexamination. Scott A. McKeown, *Should a Protective Order Bar Participation in Patent Reexamintion?*[3] Edwards' further contention that CoreValve's information is "irrelevant to the reexamination" (Red Br. 83, 29) is refuted by Edwards' filing of confidential CoreValve documents in an Information

[3] Available at http://www.patentspostgrant.com/lang/en/2011/02/should-a-protective-order-bar-participation-in-patent-reexamination (visited August 3, 2011).

Disclosure Statement filed with the PTO in the '552 reexamination proceeding (and related proceedings). *Information Disclosure Statement*, USPTO Control No. 90/009779, April 25, 2011, http://portal.uspto.gov/external/portal/pair. These parties are fierce competitors, and thus the district court was right to be concerned about Edwards' access to confidential information in a reexamination proceeding where the defendants were relying solely on publicly available information.

The district court evaluated each side's arguments as to the risks of disclosure and potential prejudice and exercised its "broad discretion" in reasonable fashion. *Deutsche Bank*, 605 F.3d at 1373. Edwards has not shown any abuse of discretion and thus, even if this issue is not moot, Edwards' cross-appeal on this point should be rejected.

CONCLUSION

On CoreValve's appeal, the judgment below should be reversed and judgment entered in favor of CoreValve. On Edwards' cross-appeal, the rulings below should be affirmed.

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

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Dated: August 8, 2011

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2011-1215, -1257

United States Court of Appeals

For the Federal Circuit

EDWARDS LIFESCIENCES AG and

EDWARDS LIFESCIENCES LLC,

Plaintiffs-Cross Appellants,

v.

COREVALVE, INC. and

MEDTRONIC COREVALVE, LLC,

Defendants-Appellants,

APPEALS FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE
IN CASE NO. 08-CV-0091, CHIEF JUDGE GREGORY M. SLEET

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TABLE OF CONTENTS

Page

INTRODUCTION 1

ARGUMENT 2

I. THE DISTRICT COURT'S DENIAL OF A PERMANENT INJUNCTION SHOULD BE REVERSED 2

A. The Denial of a Permanent Injunction [[CONFIDENTIAL MATERIAL OMITTED]] 2

B. The District Court Erroneously Overlooked Edwards' Prospective Harm that Cannot Be Compensated by Monetary Damages 9

II. THE PROTECTIVE ORDER RULING SHOULD BE REVERSED 15

A. CoreValve Improperly Tries to Confine the Protective Order Ruling to the '552 Reexamination, Declaring It Is Now "Moot" 15

B. Medtronic's New Reexamination Proceedings Demonstrate the Protective Order Ruling Is Far from Moot 16

C. The Court Should Clarify that Reexamination Does Not Fall Under a Patent Prosecution Bar 18

D. CoreValve's Authorities Have No Application Here 19

E. CoreValve Failed to Carry Its Burden of Showing a Risk of Inadvertent Disclosure 21

CONCLUSION 27

CONFIDENTIAL MATERIAL OMITTED

The material omitted on pages i, 1-4, 7, and 11-14 contains information regarding CoreValve's ongoing manufacturing activities from Defendants' Answering Brief in Opposition to Plaintiffs' Motion for Permanent Injunction (Dkt. No. 392, A18032-57), and the Parties' Statements Regarding Accounting of Monetary Damages and Interest for the Period March 16, 2010 – February 7, 2011 (Dkt. No. 439, A20305-64), both of which were filed under seal.

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Page(s)

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Acumed LLC v. *Stryker Corp.*,
551 F.3d 1323 (Fed. Cir. 2008) 4, 14

Data Gen. Corp. v. *Johnson*,
78 F.3d 1556, 1565 (Fed. Cir. 1996) 3

Datascope Corp. v. *Kontron Inc.*,
786 F.2d 398 (Fed. Cir. 1986) 7

Grayzel v. *St. Jude Med., Inc.*,
162 Fed. App'x 954 (Fed. Cir. 2005) 19

I-Flow Corp. v. *Apex Med. Techs., Inc.*,
No. 07cv1200 DMS (NLS), 2010 WL 141402
(S.D. Cal. Jan. 8, 2010) 8

i4i Ltd. P'ship v. *Microsoft Corp.*,
598 F.3d 851 (Fed. Cir. 2010) 4, 9, 14

In re Deutsche Bank Trust Co. Ams.,
605 F.3d 1373 (Fed. Cir. 2010) 21, 22, 23

Martek Biosciences Corp. v. *Nutrinova Inc.*,
520 F. Supp. 2d 537 (D. Del. 2007) 12

Methode Elecs., Inc. v. *Delphi Auto. Sys. LLC*,
Civil Action No. 09-13078, 2009 WL 3875980
(E.D. Mich. Nov. 17, 2009) 20

Ortho-McNeil Pharm., Inc. v. *Lupin Pharm., Inc.*,
603 F.3d 1377 (Fed. Cir. 2010) 12

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Case No. 06-C-611-C, 2007 WL 5433478
(W.D. Wisc. Aug. 8, 2007) 20

Stone Strong, LLC v. *Del Zotto Prods. of Fla., Inc.*,
No. 5:08-cv-503-Oc-10DAB, 2010 WL 4259371
(M.D. Fla. Oct. 25, 2010) 8

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Civil Docket 3:08-cv-00025-NKM-JGW 23

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(E.D. Tex. Dec. 19, 2006) 20

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958 F.2d 355 (Fed. Cir. 1992) 3

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Civ. No. 10-136-LPS, 2010 WL 3502546
(D. Del. Sept. 8, 2010) 18

STATUTES

35 U.S.C. § 271(a) 1, 10, 12

35 U.S.C. § 314 17

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(8th ed. rev. 8 July 2010) 18

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(8th ed. rev. 8 July 2010) 17

Manual of Patent Examining Procedure § 2666
(8th ed. rev. 8 July 2010) 17

INTRODUCTION

The portion of CoreValve's Yellow Brief devoted to Edwards' cross-appeal cannot obscure two essential points:

First, the District Court [[**CONFIDENTIAL MATERIAL OMITTED**]] The Court took CoreValve at its word, and denied an injunction based on what it was told. [[**CONFIDENTIAL MATERIAL OMITTED**]] Undeterred by the jury verdict and judgment below, CoreValve simply chose to continue willfully infringing, in violation of 35 U.S.C. § 271(a) ("[W]hoever without authority makes . . . any patented invention, within the United States . . ., infringes the patent."). CoreValve's ploy worked. It temporarily escaped an injunction, trampling Edwards' patent rights in the process. To correct this manifest injustice, the denial of a permanent injunction should be reversed.

Second, CoreValve advances no reason in law or fact why Edwards' trial counsel and expert should be precluded from participating in the wider patent war CoreValve's parent Medtronic has launched against Edwards. With nothing else to say, CoreValve falsely accuses Edwards of violating the Protective Order in this case. This accusation is unworthy of being presented to this or any other court. CoreValve itself stipulated that the documents Edwards filed in the PTO were part

of the public trial record below. To bring this case in conformity with numerous other decisions, including other decisions in the District of Delaware, this Court should reverse the District Court's Protective Order ruling and hold that reexaminations are not included in a patent prosecution bar.

ARGUMENT

I. THE DISTRICT COURT'S DENIAL OF A PERMANENT INJUNCTION SHOULD BE REVERSED

A. The Denial of a Permanent Injunction [[CONFIDENTIAL MATERIAL OMITTED]]

The denial of a permanent injunction requires reversal because [[

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]] the District Court concluded that three of the four *eBay* factors were tied to CoreValve's move and thus did not favor an injunction. A00027-29 (discussing irreparable harm, balance of hardships, public interest); Red Br. 66. [[

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]] The District Court was misled. As was Edwards. The denial of the permanent injunction should be reversed for that reason alone.

Unable to conceal its continuing willful infringement in the U.S., CoreValve changes its tune on appeal. [[

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]] *See, e.g., Data Gen. Corp.* v. *Johnson*, 78 F.3d 1556, 1565 (Fed. Cir. 1996); *Wang Labs., Inc.* v. *Applied Computer Sciences, Inc.*, 958 F.2d 355, 358-59 (Fed. Cir. 1992).

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CoreValve continues to willfully infringe and harm Edwards by manufacturing in the U.S.

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]] As this Court has made plain, the cost of an injunction borne by an infringer is not a relevant consideration for granting an injunction. *See, e.g., i4i Ltd. P'ship* v. *Microsoft Corp.*, 598 F.3d 851, 863 (Fed. Cir. 2010) ("Similarly irrelevant [to an injunction analysis] are the consequences to Microsoft of its infringement, such as the cost of redesigning the infringing products."), *aff'd*, 131 S. Ct. 2238 (2011); *Acumed LLC* v. *Stryker Corp.*, 551 F.3d 1323, 1330 (Fed. Cir. 2008) ("One who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected.") (internal citations omitted). Importantly, CoreValve has said that it is ready to move. A15139 (April 1, 2010 Medtronic press release on the day of the jury verdict: "In the event of a U.S. injunction, Medtronic has manufacturing capabilities for CoreValve products outside the United States to ensure continued supply worldwide."); A15142 ("[Medtronic] is in the process of moving manufacturing for CoreValve's European business to Mexico."); A15183 ("[A]

2nd facility is expected in Tijuana, Mexico."). As a result, any cost incurred to move at this point should be minimal at best.

Equally unavailing is CoreValve's lengthy argument that, "*if an injunction were effective*, it would create serious public health risks." Yellow Br. 51 (emphasis added), 52-54. CoreValve sacrifices its credibility and resorts to scare tactics in attempting to fend off an injunction, claiming patients will die if an injunction is issued. Yellow Br. 44. But CoreValve has told the public – *and hence its shareholders* – that it was ready and able to move its manufacturing operations to Mexico. A15139; A15142; A15183. CoreValve's new story that perhaps it "could not" move is nothing more than a desperate attempt to avoid an injunction once again. Yellow Br. 51.[1] There is simply no risk of harm to the public in issuing an injunction in this case.

CoreValve devotes over three pages of its Yellow Brief to alleged differences between the CoreValve infringing device and Edwards' product. Yellow Br. 51-54. This is a sideshow. If CoreValve moves its manufacturing to Mexico, as it said it would and could, and continues to supply its customers, there will be no disruption in the current supply of the CoreValve device. This conclusion was reached by the District Court. A00029 ("The public interest would

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[1] Given Medtronic's size and worldwide resources, it is not credible for CoreValve to suggest it cannot move outside the U.S. *See* Red Br. 77.

not be substantially advanced or harmed by the issuance of an injunction, since CoreValve would be able to continue manufacturing accused product abroad without seriously affecting the supply of the product available to the public.").

For completeness, it is worth noting that CoreValve's alleged "superiority" claims are meritless. In the District Court below, Edwards proved that CoreValve's purported fears were fabricated and amounted to no more than limited physician preference. A19227-28; A19354-61 (Declaration of Dr. Eric Horlock in reply to CoreValve); A19362-69 (Declaration of Dr. Helmut Baumgartner in reply to CoreValve); A19370-405 (Declaration of Dr. Martin Rhys Thomas in reply to CoreValve). Importantly, the Court need not reach CoreValve's claims, because, as noted, it represented that there will be no disruption in the supply of the CoreValve device were an injunction to issue. A15139 (April 1, 2010 Medtronic press release: "In the event of a U.S. injunction, Medtronic has manufacturing capabilities for CoreValve products outside the United States to ensure continued supply worldwide.").

Notably, CoreValve makes no mention that Edwards can indeed "treat the entire CoreValve patient population." Red Br. 80-81. As CoreValve knows, on February 24, 2011, Edwards announced regulatory approval in Europe for its 29mm valve, which can treat the larger size annulus patients not previously

treatable by Edwards.[2] [[

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Moreover, on the law, none of CoreValve's authorities is applicable here. Both *Scripps Clinic & Research Found.* v. *Genentech, Inc.*, 666 F. Supp. 1379 (N.D. Cal. 1987) and *Datascope Corp.* v. *Kontron Inc.*, 786 F.2d 398 (Fed. Cir. 1986) involved preliminary injunctions where, because little to no discovery was available, the public interest calculus was far more speculative. Here, the District Court did not make any findings that the public health would be at risk. What the Court did find is that "CoreValve would be able to continue manufacturing accused product abroad without seriously affecting the supply of the product available to the public." A00029.

More fundamentally, however, the question of whether CoreValve could move its infringing operations to Mexico is not the point. Even if CoreValve

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[2] *See* http://www.edwards.com/newsroom/Pages/NR20110224.aspx (last visited Aug. 22, 2011). It is for the health of those patients that Edwards' initial injunction request, dated May 29, 2010, allowed for CoreValve to treat this limited patient population until Edwards received approval for its 29mm device. A14985.

was moving to Mexico, Edwards would still be entitled to a permanent injunction. CoreValve's ability to meet market demand by manufacturing abroad is not a reason to deny an injunction. As noted in Edwards' Red Brief, this Court has expressly ruled that cessation of infringement – here, by moving abroad – is no reason to deny an injunction against future infringement. *See W.L. Gore & Assocs., Inc.* v. *Garlock, Inc.*, 842 F.2d 1275, 1281-82 (Fed. Cir. 1988) ("The fact that the defendant has stopped infringing is generally not a reason for denying an injunction against future infringement . . . ."). Post-*eBay*, district courts follow this practice. *See, e.g., I-Flow Corp.* v. *Apex Med. Techs., Inc.*, No. 07cv1200 DMS (NLS), 2010 WL 141402, at *1 (S.D. Cal. Jan. 8, 2010) (granting motion for permanent injunction even after defendants had ceased manufacturing the infringing product); *Stone Strong, LLC* v. *Del Zotto Prods. of Fla., Inc.*, No. 5:08-cv-503-Oc-10DAB, 2010 WL 4259371, at *3 (M.D. Fla. Oct. 25, 2010) (same). Making matters worse, without an injunction CoreValve is free to manufacture both in the U.S. and abroad. This compounds the harm to Edwards.

CoreValve elected to stay put in the U.S. and willfully infringe. As noted below and in Edwards' Red Brief, pp. 70-76, CoreValve's U.S. manufacturing activities continue to harm Edwards. These activities should be enjoined.

B. The District Court Erroneously Overlooked Edwards' Prospective Harm that Cannot Be Compensated by Monetary Damages

Edwards continues to suffer prospective harm absent an injunction. This evidence was entirely overlooked by the District Court in assessing the second *eBay* factor (inadequacy of monetary damages). A00028; Red Br. 70-76 (collecting evidence of prospective harm).

CoreValve, the copier and not the innovator, was able to obtain its first-mover advantage in the transcatheter heart valve market because it violated Edwards' patent rights. The dilution of Edwards' market share and reputation is thus both permanent and ongoing. *See i4i*, 598 F.3d at 1330 ("It is proper for a district court to consider evidence of past harm to a patentee's market share, revenues, and brand recognition in determining whether the patentee has suffered irreparable harm."). CoreValve does not and cannot dispute this.

Instead, CoreValve's only response is that the loss of customers and reputation that Edwards suffered is "simply irrelevant given the futility of an injunction." Yellow Br. 47. Once again, CoreValve retreats to claiming it could move its operations to Mexico. *Id.* Because no such move has occurred, the loss of customers and reputation that Edwards continues to suffer is not, as CoreValve suggests, "simply irrelevant."

The District Court was correct that history cannot be changed. No remedy can "change the fact that CoreValve was the first to bring its technology to market." A00027. No remedy can "reverse the reputational damage done to Edwards as a result of CoreValve getting its product to market before Edwards." *Id.* However, the District Court was addressing the past. Going forward, which the District Court never considered, continued erosion of Edwards' market share and reputation is the very definition of irreparable harm that monetary damages cannot address.[3]

The fact that CoreValve's current infringement is limited to manufacturing (and not selling) an infringing device in the U.S. is of no consequence. *See* Yellow Brief 45, 47, 49 (stating there was "no finding of infringing *sales*") (emphasis original). The law is clear that a patent holder is entitled to exclude the making of the invention. Indeed, the patent statute lists "making" as the first prohibited act of infringement. 35 U.S.C. § 271(a). CoreValve came to Irvine for a reason. In Irvine, it found a skilled labor pool (often trained by Edwards) and facilities that enabled it to manufacture its infringing device. Red Br. 17, 64, 65-66, 69; A16094. When CoreValve failed in France, it moved to Irvine so it could implement its business plan. *Id.* An

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[3] Tellingly, CoreValve fails to respond to Edwards' showing that the District Court misinterpreted the 3F license relating to the '552 patent. Yellow Br. 48-49; Red Br. 78-79.

injunction should have stopped that plan. When it was denied, CoreValve's plan was allowed to flourish and accelerate. [[

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]] These figures confirm Medtronic's prediction that after it acquired CoreValve, Medtronic's "scale and expertise" would "accelerate the use" of CoreValve's infringing product. A15137; Red Br. 77. *See also* A15184 (December 2009 analyst report stating that "[Medtronic] [m]anagement indicated that the integration of CoreValve was ahead of its plans and manufacturing output has tripled since the acquisition . . . .").

Absent an injunction, the harm to Edwards will continue for years to come, both as a result of CoreValve's U.S. manufacturing activities and its threat to enter the U.S. sales market. CoreValve expects FDA approval in 2014 allowing it to commercially sell its infringing device in the U.S. Yellow Br. 48; A19229 n.14. The '552 Patent will not expire in 2012, as CoreValve claims. Yellow Br. 44, 48-49. The patent is eligible for patent term extension, which is estimated to extend the life of the patent until at least 2016. A15142. Additionally, Federal Circuit law is clear that injunctions may extend through the patent term extension.

Ortho-McNeil Pharm., Inc. v. *Lupin Pharm., Inc.*, 603 F.3d 1377, 1381-82 (Fed. Cir. 2010) (affirming permanent injunction "during the extended term"). Without an injunction, CoreValve can willfully infringe, both by manufacturing and selling its infringing devices in the U.S., for the next five years. Future customers will be lost, and Edwards will be forced to compete head-to-head with its only competitor in the new U.S. market. Given the "sticky" nature of customers in this market, these new U.S. customers will be lost beyond the life of the patent. Red Br. 73-74. Monetary damages cannot compensate this harm. This decidedly tips an injunction analysis in Edwards' favor. *See Martek Biosciences Corp.* v. *Nutrinova Inc.*, 520 F. Supp. 2d 537, 558-59 (D. Del. 2007) (holding that plaintiff will continue to suffer irreparable harm that cannot be compensated monetarily, including the loss in market share, if defendant, plaintiff's *only* competitor, is not enjoined), *aff'd-in-part, rev'd-in-part*, 579 F.3d 1363 (Fed. Cir. 2009) (permanent injunction not at issue on appeal).

* * *

Based on the facts and the equities, Edwards respectfully requests that the denial of the permanent injunction be reversed. [[

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]] It continues its willful infringement daily, in violation of 35 U.S.C. § 271(a). Each of the *eBay* factors favors the grant of an injunction:

(1) Irreparable Harm

Edwards proved both past and prospective irreparable harm, including ongoing loss of the first-mover advantage and reputational damage. Red Br. 70-76. The District Court discounted this harm, [[

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]] A00027-28. Lost in the shuffle was Edwards' uncontested proof of prospective irreparable harm. *See* A00026-27, where the District Court only addressed past harm and incorrectly stated "Edwards makes no allegations of prospective lost customers or harms . . . ." (emphasis in original). Taken together, CoreValve's continued U.S. manufacture and the past and prospective harm to Edwards, constitute irreparable harm under the first *eBay* factor.

(2) Inadequate Remedy at Law

As canvassed in Section I.B, *supra*, and in Edwards' Red Br. 76-79, Edwards has no adequate remedy at law. Money damages are insufficient to compensate Edwards for the ongoing harm CoreValve is causing. A compulsory license to Edwards' far larger and only competitor (the upshot if an injunction is denied) will cause loss of market share, brand recognition, customer goodwill and reputation that cannot be quantified. Red Br. 76-77. The District Court simply misread the prior 3F license (A00028), a point that CoreValve does not contest on

the merits here on appeal. Red. Br. 78-79; Yellow Br. 48-49. Given these facts, the second *eBay* factor is also met.

(3) Balance of Hardships

If CoreValve moves [[**CONFIDENTIAL MATERIAL OMITTED**]] it will suffer no hardship other than the cost of moving its manufacturing facilities outside the U.S. This Court made clear in its *i4i* and *Acumed* decisions, *supra*, that the cost of avoiding infringement (in this case by moving abroad) is irrelevant to the *eBay* analysis.

Edwards, on the other hand, will suffer severe ongoing hardship if CoreValve remains in the U.S. and continues to willfully infringe. *See eBay* factors (1) and (2), *supra*; Red Br. 79. The third *eBay* factor favors Edwards.

(4) Public Interest Would Not be Disserved by an Injunction

CoreValve's move abroad is also conclusive here. The supply of its product will not be interrupted. And, in any event, Edwards can treat the entire CoreValve patient population. The public will simply not be impacted if CoreValve is enjoined. *See* Section I.A, *supra*; Red. Br. 80-81.

The District Court's proposed solution was to withhold an injunction and invite Edwards to sue CoreValve again if it remains in the U.S. A00028; Yellow Br. 47. This would disserve the public interest in many ways. *See* Red Br. 80-81. Among others, it undercuts the integrity of the patent system and the strong

public policy in favor of the finality of judgments, and imposes an unwarranted burden on patent holders to conduct serial litigations. Here, the public interest favors an injunction.

For all of these reasons, an injunction should be entered.

II. THE PROTECTIVE ORDER RULING SHOULD BE REVERSED

A. CoreValve Improperly Tries to Confine the Protective Order Ruling to the '552 Reexamination, Declaring It Is Now "Moot"

CoreValve makes a threshold error when discussing the Protective Order ruling. It claims the District Court's Order (A00054-55) only barred Edwards' trial counsel and expert from participating in the '552 Patent reexamination. Yellow Br. 54-55. CoreValve is simply wrong. The Order reaches beyond the '552 reexamination for several reasons:

First, nothing in the Order limits its terms to the '552 reexamination. In fact, the Order refers on its face to two patent reexaminations. A00054-55.

Second, the parties' letter briefs below on the Protective Order issue also referred to two reexaminations, and specifically cited the reexamination of Andersen U.S. Patent No. 6,582,462 in addition to the '552 reexamination, both of which were provoked by Medtronic. *See* A19929-79 (January 18, 2011 letter); A19982-20009 (January 24, 2011 letter); A20032-33 (January 26, 2011 letter).

Third, the Stipulated Protective Order at issue never mentions the '552 Patent or its reexamination. A00312-30. The bar covers only "patent

prosecution" and never mentions any reexamination, least of all the '552 reexamination. A00317; A00320; Red Br. 81.

This record makes plain that the District Court's Order precludes Edwards' trial counsel and expert from participating in not just the reexamination of the '552 Patent, but in other reexamination proceedings as well.

B. Medtronic's New Reexamination Proceedings Demonstrate the Protective Order Ruling Is Far from Moot

Medtronic's recent activities prove that the Protective Order ruling is anything but moot and continues to harm Edwards.

Just last month, the PTO granted Medtronic's requests for *inter partes* reexamination of two other Andersen patents in the same family as the '552 Patent: Andersen U.S. Patent No. 7,618,446 (Grant of *Inter Partes* Reexamination, USPTO Control No. 95/001,616, July 25, 2011, http://portal.uspto.gov/external/portal/pair) and Andersen U.S. Patent No. 7,789,909 (Grant of *Inter Partes* Reexamination, USPTO Control No. 95/001,615, July 29, 2011, http://portal.uspto.gov/external/portal/pair). Medtronic requested reexamination of these two Andersen patents based on prior art that had been at issue in the litigation below, including U.S. Patent Nos. 4,922,505 (Strecker) and 3,656,744 (Ersek). CoreValve – having been found to willfully infringe Edwards' valid '552 Patent at trial – sought to use a post-trial reexamination of the '552 Patent to avoid the verdict against it. When that failed (Red Br. 14 n. 4),

Medtronic simply escalated its attacks on the Andersen patent portfolio with new *inter partes* Andersen reexamination requests.

These latest *inter partes* reexamination proceedings are fundamentally different from the earlier '552 *ex parte* reexamination. Both Edwards and Medtronic will be involved. Medtronic, as the requestor of the *inter partes* reexaminations, can comment on Edwards' responses to the Examiner. *See* 35 U.S.C. § 314. Experts can also participate. *See Manual of Patent Examining Procedure* § 2616 (8th ed. rev. 8 July 2010); *id.* at § 2666. In short, Medtronic's new Andersen *inter partes* reexaminations are litigations disguised as reexaminations. They will mirror the prior art battle between Edwards and CoreValve below before CoreValve tactically folded on the eve of trial and moved its validity challenges to the Patent Office.

The upshot: If the Protective Order ruling is not reversed, Edwards will be forced to hire a new expert and engage new counsel for the new reexaminations. All to plow the same ground covered during the District Court litigation. This makes no sense and is fundamentally unfair. Edwards made a tremendous investment in its trial counsel, who devoted years working on the Andersen patents and the prior art involved in the reexaminations. A00065-112 (docket sheet in Court below). Dr. Buller, Edwards' expert, issued three expert reports on the validity and infringement of the Andersen patents. To replicate that

work is a burden Edwards cannot and should not shoulder. *See Xerox Corp.* v. *Google, Inc.*, Civ. No. 10-136-LPS, 2010 WL 3502546, at *3 (D. Del. Sept. 8, 2010) ("[P]reventing trial counsel exposed to defendants' confidential information from fully participating in reexamination proceedings would force plaintiff to split its resources between two fronts of the same war.").

C. The Court Should Clarify that Reexamination Does Not Fall Under a Patent Prosecution Bar

The District Court's ruling should also be reversed because it is wrong as a matter of law. As noted in Edwards' Red Brief, numerous decisions, including those by other judges of the Court below, have held that a patent prosecution bar does not include reexamination. Red Br. 83. These decisions have recognized that the risk of inadvertent disclosure in a reexamination of an issued patent is much lower than the risk in the prosecution of a new or continuing application. Significantly, reexaminations cannot be used to broaden claims. *Id.* at 82-83. A patent claim cannot emerge from reexamination to cover a product that it did not already cover before the reexamination.

It should be noted that Medtronic's latest *inter partes* reexaminations are on expired Andersen patents. Specifically, both Andersen U.S. Patent Nos. 7,618,446 and 7,789,909 expired on May 16, 2011 (20 years from May 16, 1991 PCT filing date). Thus, the claims of these patents cannot be amended, let alone broadened, in the reexaminations. *See Manual of Patent Examining Procedure*

§ 2250(j) (8th ed. rev. 8 July 2010) ("No amendment may be proposed for entry in an expired patent.").

The District Court's ruling that reexamination is covered by the prosecution bar in the Protective Order is a split from other rulings, both within that same court and in other courts. There are no precedential decisions from this Court on the subject. Respectfully, for the benefit of the bench and the bar, this Court should address the issue.

D. CoreValve's Authorities Have No Application Here

Edwards seeks to have its expert and trial counsel respond to reexaminations that CoreValve's parent Medtronic filed against Edwards' patents. These reexaminations were filed as part of a larger patent dispute between the parties. It is illogical to restrict Edwards' expert and trial counsel to one phase (this case) and preclude them from participating in the overall controversy.

The prosecution bar cases cited by CoreValve are far different. None is applicable here. They all involved an active use of information learned during litigation for offensive purposes or for competitive decision-making, or included egregious conduct.

Thus, the non-precedential decision of this Court that CoreValve cites, *Grayzel* v. *St. Jude Med., Inc.*, 162 Fed. App'x 954 (Fed. Cir. 2005), largely dealt with whether, under the protective order, the patentee could use prior art identified

during litigation to initiate a reexamination of his own patent. The patentee's offensive use of information learned during litigation to file reexamination is a far cry from the situation here, where Medtronic is attacking Edwards' patents. Similarly, in *Visto Corp.* v. *Seven Networks, Inc.*, Case No. 2:03-CV-333-TJW, 2006 WL 3741891 (E.D. Tex. Dec. 19, 2006), the District Court interpreted the prosecution bar broadly to cover reexaminations, but only after egregious behavior by trial counsel was revealed. In that case, prior to the Court's ruling, trial counsel participated in prosecution of a continuation application despite the protective order prosecution bar. Once caught, trial counsel agreed to cease prosecution activities, but continued to participate in reexamination proceedings for the patent-in-suit and concealed his involvement in the reexamination to avoid detection. Only upon further discovery did the level of counsel's participation in various prosecution activities become apparent. In *Silicon Graphics, Inc.* v. *ATI Techs., Inc.*, Case No. 06-C-611-C, 2007 WL 5433478 (W.D. Wisc. Aug. 8, 2007), the issue did not even involve whether trial counsel could participate in a reexamination. The movant was seeking to modify the protective order so that it could disclose confidential information to its client for the purpose of deciding whether reexamination should be initiated. In *Methode Elecs., Inc.* v. *Delphi Auto. Sys. LLC*, Civil Action No. 09-13078, 2009 WL 3875980 (E.D. Mich. Nov. 17, 2009), the court adopted a strict prosecution bar in the disputed protective order to

prevent Methode's joint litigation and patent prosecution counsel, who was involved in Methode's patent applications and patent-related competitive decision-making for years prior to the subject litigation, from simultaneously participating in prosecution, reexamination and litigation.

In contrast, Edwards' expert and trial counsel used in the trial below are litigation focused. CoreValve simply changed the venue of the prior art fight, choosing to drop all of its prior art defenses the night before trial in favor of post-trial reexamination requests. Such gamesmanship should not be rewarded. Edwards' expert and trial counsel do not prosecute the Edwards patent portfolio, are not the competitive decision-makers (with respect to either business decisions or patent prosecution decisions), and do not decide whether to file reexaminations of the patents at issue or new patent applications.

E. CoreValve Failed to Carry Its Burden of Showing a Risk of Inadvertent Disclosure

As this Court has made clear, the question of whether a prosecution bar is appropriate requires balancing the risk of inadvertent disclosure of confidential information by trial counsel against the potential harm of restricting a party's right to have the benefit of counsel of its choice. *See In re Deutsche Bank Trust Co. Ams.*, 605 F.3d 1373, 1380 (Fed. Cir. 2010). Just as it failed to do so below, CoreValve has not presented any arguments specific to Edwards' trial counsel or expert demonstrating they are at risk of inadvertently disclosing

CoreValve's confidential materials.[4] Instead, CoreValve cites a "recent article [that] describes a case where trial counsel apparently placed confidential information in the public record after being permitted to participate in a reexamination." Yellow Br. 56. CoreValve follows up with the accusation that Edwards filed "confidential CoreValve documents in an Information Disclosure Statement filed with the PTO in the '552 reexamination proceeding (and related proceedings)." *Id.* at 56-57. The "article" is a speculative blog post. The accusation is simply false.

First, the blog post merely presents the blog author's guess that G.E. confidential information was disclosed in a reexamination filing by trial counsel. The author specifically cautions that he has no idea whether this in fact occurred: "it may be that the specific relaxation timing of G.E.'s devices is public knowledge." Scott A. McKeown, ***Should a Protective Order Bar Participation in Patent Reexamination?***, available at http://www.patentspostgrant.com/lang/en/2011/02/should-a-protective-order-bar-participation-in-patent-reexamination (last visited Aug. 22, 2011).

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[4] Nor did the District Court provide any explanation for its finding that there would be a risk of inadvertent disclosure of CoreValve's confidential information were Edwards' trial counsel and expert to participate in the reexamination proceedings, as required by *Deutsche Bank*. A00054.

CoreValve cites nothing to demonstrate that G.E. confidential information had, in fact, been disclosed.[5] Yet, it argues that Edwards' trial counsel and expert should not be allowed to participate in reexamination proceedings based on the blog's speculation. In asking this Court to consider what may or may not have happened in an unrelated case, CoreValve essentially requests the Court to hold that the mere possibility of disclosure is enough to constitute a risk of disclosure. Such a *per se* rule makes no sense and is contrary to this Court's directive in *Deutsche Bank* that participation should be evaluated on a counsel-by-counsel basis. *See* 605 F.3d at 1380.

Second, CoreValve falsely accuses Edwards. It cites an Information Disclosure Statement ("IDS") submitted by Edwards in the '552 Patent reexamination proceeding purportedly containing CoreValve confidential information. Yellow Br. 57.[6] A34510-23. CoreValve's accusation is simply not true, because no CoreValve confidential information was submitted in that IDS.

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[5] One would expect that, if G.E.'s confidential information had indeed been improperly disclosed, G.E. would have moved for contempt of the protective order or taken some related action. However, no such motion was filed. *See* docket in *Univ. of Va. Patent Found.* v. *Gen. Elec. Co.*, Civil Docket 3:08-cv-00025-NKM-JGW.

[6] CoreValve also mentions that Edwards filed an IDS in "related proceedings." The reference is apparently to the reexamination of Andersen U.S. Patent No. 6,582,462. The IDS filed in the '462 reexamination is identical to the IDS filed in the '552 reexamination. *Compare* A34510-23 *with* Information Disclosure Statement, USPTO Control No. 90/009,791, April 25, 2011 http://portal.uspto.gov/external/portal/pair.

Edwards submitted only non-confidential, publicly available exhibits that were admitted into evidence at the trial. CoreValve knows this since it stipulated that those very exhibits were non-confidential. *See* A08905-51 (Parties' Joint List of Exhibits Admitted Into Evidence During Trial (Excluding Those Exhibits Admitted Under Seal)).[7]

To prove the point, set forth below is a comparison of what was filed in the IDS (A34510-23) with the stipulated list of non-confidential trial exhibits (A08905-51). Of the 270 exhibits listed in the IDS, only 32 contain CoreValve information. All 32 were admitted into evidence and are part of the public record of the trial below:

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[7] Moreover, the District Court's Order explicitly provided that Edwards may "use the public record relating to this case in its reexamination responses." A00054.

Exhibit Listed on April 25, 2011 IDS in '552 Patent Reexamination Containing CoreValve Information (A34510-23)	Publicly Available Exhibit Admitted in Evidence in Trial Below (A08905-51)
AY	PTX 23
AZ	PTX 49
AAA	PTX 56
AAC	PTX 109
AAD	PTX 151
AAH	PTX 168
AAJ	PTX 380
AAK	PTX 401
AAN	PTX 879
AAS	PTX 1092
AAD	PTX 1635
AAF	PTX 1712
AAG	PTX 1713
AAH	PTX 1747
AAI	PTX 1748
AAK	PTX 1900A
AAM	PTX 2030
AAN	PTX 2031
AAO	PTX 2032
AAP	PTX 2033
AAQ	PTX 2034
AAT	PTX 2090
AAA	PTX 2135
AAB	PTX 2136
AAC	PTX 2137
AAD	PTX 2141
AAE	PTX 2142
AAG	DTX 239
AAJ	DTX 1313
AAK	DTX 1314
AAU	DTX 1478
AAV	DTX 1479

Significantly, CoreValve's Yellow Brief was the first time Edwards was advised there was an alleged improper disclosure of CoreValve confidential information. Had a violation of the Protective Order actually occurred in the IDS, one would expect that CoreValve would have contacted Edwards' trial counsel or the District Judge below. Conceivably, CoreValve might have moved for contempt of the Protective Order. None of this ever occurred. Instead, CoreValve chose to make this baseless charge in its Yellow Brief in a desperate attempt to restrict Edwards' trial counsel and expert from participating in Medtronic's war in the PTO against the Edwards THV patent portfolio.

CoreValve has not set forth any reason for this Court to believe that Edwards' trial counsel and expert would do anything other than strictly follow the Protective Order in this case and refrain from disclosing confidential information. While Edwards disagrees with the Protective Order ruling, it is committed to following its terms pending review of this Court. The very IDS that CoreValve cites demonstrates the care Edwards has taken with respect to CoreValve's confidential information. There is simply no support for a finding that CoreValve faces a risk of having its confidential information inadvertently disclosed by Edwards' trial counsel or expert. There is no justification for denying Edwards its choice of counsel and expert.

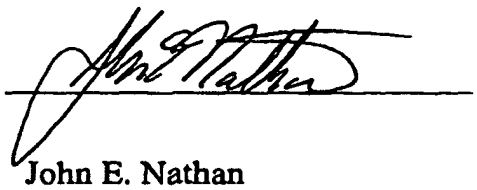
On the law, the facts and the equities, the District Court's ruling that Edwards' trial counsel and expert are barred from participating in reexaminations should be reversed.

CONCLUSION

The District Court's denial of a permanent injunction and its ruling on the Protective Order should be reversed.

Edwards Lifesciences AG and Edwards Lifesciences LLC

By its attorneys,



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Certificate of Service

The undersigned, an attorney, hereby certifies that on August 22, 2011, he caused two copies of the foregoing Plaintiffs-Cross Appellants' Non-Confidential Cross-Appeal Reply Brief to be served upon the following individuals by Federal Express overnight express and email:

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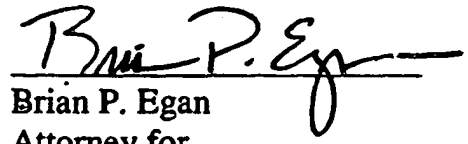

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