

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND
EDWARDS LIFESCIENCES LLC

Petitioners

v.

COLIBRI HEART VALVE LLC

Patent Owner

Case IPR2020-01649

Patent No. 9,125,739

DECLARATION OF STEVEN L. GOLDBERG, M.D.
SUBMITTED ON BEHALF OF PETITIONERS EDWARDS LIFESCIENCES
CORPORATION AND EDWARDS LIFESCIENCES LLC

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. BACKGROUND AND QUALIFICATIONS	1
III. PRIORITY DATE AND ONE OF SKILL IN THE ART	6
IV. BACKGROUND AND STATE OF THE ART	7
V. SUMMARY OF THE '739 PATENT	29
A. Overview of the '739 Patent.....	29
B. Claims of the '739 Patent	36
C. Overview of the Prosecution History of the '739 Patent	38
D. Claim Construction of the '739 Patent's Claims	48
VI. THE CHALLENGED CLAIMS ARE INVALID	54
A. Legal Standards	54
1. Anticipation.....	54
2. Obviousness	54
3. Written Description.....	57
B. Ground 1: Paniagua Anticipates Claims 1-5 of the '739 Patent	58
1. Claim 1 Preamble: An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising.....	61
2. Element 1[a]: a prosthetic heart valve including: a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery	61
3. Element 1[b]: wherein the stent member include a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration; and.....	62
4. Element 1[c]: a valve means including two to four individual leaflets made of fixed pericardial tissue	62
5. Element 1[d]: wherein the valve means resides entirely within the inner channel of the stent member, and.....	63

6.	Element 1[e]: wherein no reinforcing members reside within the inner channel of the stent member.....	64
7.	Element 1[f]: a delivery system including a pusher member and a moveable sheath	64
8.	Element 1[g]: the pusher member including a guidewire lumen.....	64
9.	Element 1[h]: wherein the pusher member is disposed within a lumen of the moveable sheath	64
10.	Element 1[i]: wherein the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath	65
11.	Element 1[j]: wherein a distal end of the prosthetic heart valve is located at a distal end of the moveable sheath, and.....	65
12.	Element 1[k]: wherein the valve means resides entirely within the inner channel of the stent member in said collapsed configuration and is configured to continue to reside entirely within the inner channel of the stent member upon deployment in the patient.....	65
13.	Claim 2: The assembly of claim 1, wherein the stent member is self-expanding.....	66
14.	Claim 3: The assembly of claim 2, wherein the stent member comprises nitinol.....	66
15.	Claim 4: The assembly of claim 1, wherein the stent member includes two circles of barbs on an outer surface of the stent member.....	66
16.	Claim 5: The assembly of claim 1, wherein the pusher member includes a controlled release mechanism that can be activated.	66
C.	Grounds 2 & 3: Bessler (Ex. 1006) in View of Teitelbaum (Ex. 1007) (Ground 2); or, in the Alternative, Bessler (Ex. 1006) in View of Leonhardt (Ex. 1012) (Ground 3), Renders Obvious Claims 1-5 of the '739 Patent.....	66

1.	Claim 1 Preamble: An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising.....	67
2.	Element 1[a]: a prosthetic heart valve including: a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery	68
3.	Element 1[b]: wherein the stent member includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration; and.....	69
4.	Element 1[c]: a valve means including two to four individual leaflets made of fixed pericardial tissue	74
5.	Element 1[d]: wherein the valve means resides entirely within the inner channel of the stent member, and.....	75
6.	Element 1[e]: wherein no reinforcing members reside within the inner channel of the stent member	77
7.	Element 1[f]: a delivery system including a pusher member and a moveable sheath	78
8.	Element 1[g]: the pusher member including a guidewire lumen.....	80
9.	Element 1[h]: wherein the pusher member is disposed within a lumen of the moveable sheath	80
10.	Element 1[i]: wherein the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath	81
11.	Element 1[j]: wherein a distal end of the prosthetic heart valve is located at a distal end of the moveable sheath, and.....	86
12.	Element 1[k]: wherein the valve means resides entirely within the inner channel of the stent member in said collapsed configuration and is configured to continue to reside entirely within the inner channel of the stent member upon deployment in the patient.....	87

13.	Claim 2: The assembly of claim 1, wherein the stent member is self-expanding.	88
14.	Claim 3: The assembly of claim 2, wherein the stent member comprises nitinol.	88
15.	Claim 4: The assembly of claim 1, wherein the stent member includes two circles of barbs on an outer surface of the stent member.	89
16.	Claim 5: The assembly of claim 1, wherein the pusher member includes a controlled release mechanism that can be activated.	90
D.	Grounds 4 & 5: Bessler (Ex. 1006) in View of Teitelbaum (Ex. 1007) + Klint (Ex. 1019) (Ground 4); or, in the Alternative, Bessler (Ex. 1006) in View of Leonhardt (Ex. 1012) + Klint (Ex. 1019) (Ground 5), Renders Obvious Claims 1-5 of the '739 Patent.	91
VII.	OBJECTIVE INDICIA OF NON-OBVIOUSNESS	94
VIII.	CONCLUSION.....	95

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.