Filed: June 2, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC COREVALVE LLC,

PETITIONER,

V.

COLIBRI HEART VALVE LLC,

PATENT OWNER.

Case No. IPR2020-01454
U.S. Patent No. 9,125,739

DECLARATION OF DR. LAKSHMI PRASAD DASI

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

TABLE OF CONTENTS

I. INTRODUCTION 3

II. BACKGROUND AND QUALIFICATIONS 4

III. PERSON OF ORDINARY SKILL IN THE ART 9

IV. HEART VALVE BACKGROUND 10

A. Anatomy and Function of a Native Heart Valve 10

B. TAVR 14

C. Differences Between the Aortic Valve and Mitral Valve 15

V. OVERVIEW OF THE '739 PATENT 20

VI. THE CLAIMS OF THE '739 PATENT SUBJECT TO REVIEW 23

VII. PROSECUTION HISTORY 25

VIII. CLAIM CONSTRUCTION 36

A. "trumpet-like" (claim 1) 37

B. "valve means" (claim 1) 38

C. "controlled release mechanism" (claim 5) 38

IX. RELEVANT LEGAL STANDARDS 39

A. Invalidity 39

B. Obviousness 39

C. Priority 42

D. Enablement 43

X. THE '739 PATENT WOULD NOT HAVE BEEN OBVIOUS TO A PERSON OF ORDINARY SKILL IN THE ART 44

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

A. A Person of Skill Would Not Have Started with Garrison 45

B. Garrison alone 62

1. Garrison was Considered During the '739 Patent's Prosecution 62

2. Claim 1 62

3. Claims 2-5 75

C. Garrison in View of Leonhardt 79

1. Garrison and Leonhardt were considered during the '739 patent's prosecution 80

2. A Person of Skill Would Not Have Combined Garrison with Leonhardt ..80

3. Claim 1 86

4. Claims 2-5 93

D. Garrison in View of Nguyen / Garrison in View of Leonhardt and Nguyen 93

1. Claim 1 94

E. Andersen in View of Limon, Garrison, Nguyen, and Gabbay or Phelps...100

2. Claim 1 115

3. Claims 2-5 142

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

I, Dr. Lakshmi Prasad Dasi, hereby declare as follows:

I. INTRODUCTION

1. I am over the age of eighteen (18) years and otherwise competent to make this declaration.

2. I have been retained as an expert witness on behalf of Colibri Heart Valve LLC for the above-captioned *inter partes* review ("IPR"). I understand that the petition for *inter partes* review involves U.S. Patent No. 9,125,739 ("the '739 Patent"), Exhibit 1001, which was filed on April 15, 2014. (Ex. 1001 at Cover.) The '739 Patent issued on September 8, 2015, and names David Paniagua and David Fish as co-inventors. (*Id.*)

3. I make this declaration based on my personal knowledge, consideration of the materials I discuss herein, and my expert opinion.

4. In preparing this Declaration, I have reviewed the '739 Patent, the '739 Patent prosecution history, and considered each of the documents cited herein, in light of general knowledge in the art as of January 4, 2002. In formulating my opinions, I have relied upon my experience, education, and knowledge in the relevant art. In formulating my opinions, I have considered the viewpoint of a person of ordinary skill in the art prior to January 4, 2002, as well as the relevant legal standards, including the standard for obviousness.

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

5. I have been asked to provide my opinions regarding whether Petitioner in this IPR has met its burden of proving that the claims of the '739 Patent at issue are, as Petitioner alleges, obvious in light of Petitioner's Grounds 1-10 (Petition at 11.) It is my opinion that Petitioner has failed to meet its burden of demonstrating that any of the Challenged Claims would have been obvious to a person of ordinary skill in the art, after reviewing the Petition and its supporting documents.

6. This Declaration is being submitted together with the Patent Owner Response to IPR2020-01454, upon which review of claims 1-5 was instituted.

II. BACKGROUND AND QUALIFICATIONS

7. I am currently a tenured professor position at Georgia Institute of Technology in Atlanta, Georgia with the Department of Biomedical Engineering, where I have been since January 1, 2020. I have also been Associate Chair for Undergraduate Studies since August 1, 2020. In this position, I direct a research program in heart valve engineering, particularly related to emerging transcatheter technologies for both pediatric and adult structural heart diseases.

8. In early 2021, I was elected to be a Fellow of the American College of Cardiology and Fellow of the American Institute of Medical and Biological Engineering. Fellows of the AIMBE represent the top 2% of the medical and biological engineering community. Similarly, Fellows of the ACC are selected

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

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.