

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION,
Petitioners

v.

BOSTON SCIENTIFIC SCIMED, INC.,
Patent Owner

Case No. IPR2017-01301
Patent 6,915,560

**DECLARATION OF NEIL SHEEHAN IN SUPPORT OF PETITION FOR
INTER PARTES REVIEW OF U.S. PATENT NO. 6,915,560**

EDWARDS LIFESCIENCES EX. 1205

Edwards Lifesciences v. Boston Scientific Scimed
U.S. Patent No. 6,915,560

TABLE OF CONTENTS

Page No.

| | |
|---|----|
| I. INTRODUCTION | 1 |
| A. Background and Qualifications | 1 |
| B. Topics of Opinions | 4 |
| C. Materials Considered..... | 4 |
| II. LEGAL STANDARDS..... | 5 |
| A. Claim Construction | 5 |
| B. Obviousness..... | 6 |
| III. FACTUAL BACKGROUND AND RELEVANT CONTEXT | 8 |
| A. Stents and Stent Crimpers | 8 |
| B. The '560 Patent | 10 |
| C. Prosecution History | 17 |
| 1. October 9, 2003 Restriction | 17 |
| 2. October 22, 2003 Office Action and Response | 18 |
| 3. April 22, 2004 Office Action and Response..... | 24 |
| 4. October 19, 2004 Office Action and Response | 29 |
| IV. LEVEL OF ORDINARY SKILL IN THE ART | 33 |
| V. CLAIM CONSTRUCTION..... | 33 |
| A. “A stent crimper comprising” | 34 |
| B. “Dies” and “blades” | 35 |
| C. “Stationary end-walls” and “stationary plates” | 36 |
| VI. THE PRIOR ART..... | 37 |

TABLE OF CONTENTS
(cont'd)

| | Page No. |
|---|-------------------------------------|
| A. Analogous Art | 37 |
| 1. Field of Endeavor..... | 37 |
| 2. Pertinent To The Particular Problem | 41 |
| B. Yasumi..... | 42 |
| C. Williams | Error! Bookmark not defined. |
| D. Morales | 55 |
| VII. INVALIDITY ANALYSIS | 58 |
| A. Obviousness Of Claims 1, 2, 6, 8-10, 14, 15, 18, 23, 25, 27, 28, 31, 33, 37 and 40 Over Yasumi In View Of Williams | 58 |
| 1. Claim 1 | 58 |
| 2. Claim 10..... | 75 |
| 3. Claim 18..... | 88 |
| 4. Claim 27 | 92 |
| 5. Claim 37 | 96 |
| 6. Claim 40..... | 100 |
| 7. Claims 2 and 28..... | 102 |
| 8. Claims 6 and 15..... | 103 |
| 9. Claims 8, 25 and 33 | 103 |
| 10. Claims 9, 14, 23 and 31 | 106 |
| 11. Reason, Basis or Motivation to Combine | 108 |

TABLE OF CONTENTS
(cont'd)

| | Page No. |
|---|-----------------|
| B. Obviousness of Claims 11, 17, 19, 26, 34, 35 and 39 Over Yasumi In View Of Williams And Morales | 114 |
| 1. Claim 39 | 114 |
| 2. Claims 11, 19 and 35 | 122 |
| 3. Claims 17, 26 and 34 | 125 |
| 4. Reason, Basis or Motivation to Combine | 128 |
| VIII. CONCLUSION | 129 |

I. INTRODUCTION

A. Background and Qualifications

1. My name is Neil Sheehan. I am currently self-employed as a consulting engineer in the field of medical products. A copy of my *Curriculum Vitae*, which includes, among other things, my academic credentials and my employment history, is attached to the Petition as Exhibit 1206.

2. My field of expertise in this matter is medical products or devices (both reusable and disposable), including mechanisms, tooling, mechanical assemblies and components. This Declaration is based upon my own personal knowledge, skill, experience, training and education in my field of expertise, and upon information I have reviewed in connection with my retention in this matter.

3. I have worked extensively in the areas of catheters, balloons, plastic and metallic materials (including nitinol), inferior vena cava filters, vascular access, syringes, pumps, tubing, bonding methods and the like. Over the course of my many years in the medical device industry, I have learned much about stents and their typical balloon deployment systems. In fact, I have two stents in my right coronary artery owing to a congenital, tortuous path configuration.

4. I received my Bachelor of Science in Mechanical Engineering, *summa cum laude*, from Villanova University in 1968. I was the recipient of their 1993 Alumni Achievement Award for my work in the medical device field. I took

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.