

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 IPR2017-00444

Patent 6,915,560 B2

Before the Honorable NEIL T. POWELL, JAMES A. TARTAL, and STACY B. MARGOLIES, *Administrative Patent Judges.*

DECLARATION OF RONALD J. SOLAR, Ph.D.

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<p>Edwards Lifesciences v. Boston Scientific U.S. Patent No. 6,915,560 IPR2017-00444 EX. 2016</p>
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I, Ronald J. Solar, state and declare as follows:

I. INTRODUCTION

1. I am currently the President of Renaissance Biomedical, Inc., which performs research and consultation in technical, marketing, commercialization, patent, clinical, and regulatory issues related to the medical device industry. I am also currently the President and CEO of ThermopeutiX, Inc., a company which designs, develops, manufactures, and sells vascular catheter technology and devices, including coronary, peripheral and neuro-vascular catheters and related medical devices.

2. I obtained a Bachelor of Science degree in Metallurgy and Materials Science from the Pennsylvania State University in 1972. My undergraduate thesis was entitled “Failure Analysis of Orthopaedic Implants.” I also received a Ph.D. in Materials Science and Biomaterials from the University of Pennsylvania in 1977. My doctoral dissertation was entitled “Corrosion Behavior of Surgical Implant Alloys.”

3. I first began working in the balloon catheter field in 1980 when the field was in its infancy and with relatively few procedures using balloon catheters being performed worldwide. Over the next 30 plus years, I worked extensively in researching and developing coronary and peripheral vascular medical devices

including balloon catheters and stents. In particular, my expertise includes stent crimping, which is the subject matter of this proceeding.

4. I subscribe to a number of medical journals and medical device industry journals. I attend medical conferences, courses, symposia and workshops, as well as trade shows sponsored for the medical device industry. I attend roughly eight to twelve of such events per year to continue and maintain my expertise and education in the medical device industry, including Transcatheter Cardiovascular Therapeutics (TCT), Leipzig Interventional Course (LINC), EuroPCR, New Cardiovascular Horizons (NCVH), Cardiovascular Revascularization Therapies (CRT), International Conference for Innovations in Cardiovascular Systems (ICI), and courses and annual meetings of the American College of Cardiology (ACC), the European Society of Cardiology (ESC) and the American Heart Association (AHA). I am currently a professional member of the Horizons International Peripheral Group (HIPG), the ESC, and the AHA.

5. To date, I have obtained, as inventor or co-inventor, 58 United States patents and numerous foreign patents, all in the medical device area. Many of these patents relate to stents or stent applications:

- U.S. Patent No. 5,403,341 filed in 1994 and entitled “Parallel Flow Endovascular Stent and Deployment Apparatus Therefore”
- U.S. Patent No. 5,407,432 filed in 1992 and entitled “Method of Positioning a Stent”

- U.S. Patent No. 5,549,635 filed in 1994 and entitled “Non-Deformable Self-Expanding Parallel Flow Endovascular Stent and Deployment Apparatus Therefore”
- U.S. Patent No. 5,669,880 filed in 1993 and entitled “Stent Delivery System”
- U.S. Patent No. 6,004,328 filed in 1997 and entitled “Radially Expandable Intraluminal Stent and Delivery Catheter Therefore and Method of Using the Same”
- U.S. Patent No. 6,254,608 filed in 1997 and entitled “Sheathless Delivery Catheter for Radially Expandable Intraluminal Stents and Stented Grafts”
- U.S. Patent No. 6,447,501 filed in 1998 and entitled “Enhanced Stent Delivery System”
- U.S. Patent No. 9,254,208 filed in 2013 and entitled “Oblique Stent”

Specifically, two of the U.S. Patents I hold relate to methods and apparatuses for crimping a stent, which will be discussed in more detail below.

6. I am also the author or co-author of about 30 peer-reviewed articles in medical or scientific journals, 7 book chapters, and 54 presentations at scientific sessions of major medical meetings. Many of my articles and presentations relate to stents or stent applications:

- T. Ischinger and R. Solar, “Optimal Stent Expansion by Predilatation with a New Focused Force Balloon Device”, *CARDIOVASCULAR RADIATION MEDICINE*, 4 (Abst.), 2003.
- T. Ischinger, R. Solar and E. Hitzke, “Improved Outcome with Novel Device for Low-Pressure PTCA in De Novo and In-Stent Lesions”, *CARDIOVASCULAR RADIATION MEDICINE*, 4 (1):2-7, 2003.

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