

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. IPR2017-00444
Patent 6,915,560

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

EDWARDS LIFESCIENCES EX. 1127 Edwards Lifesciences v. Boston Scientific Scimed IPR2017-00444

I. INTRODUCTION

A. Qualifications

1. Patent Owner states that my opinions are entitled to little or no weight because I do not have experience designing stents or stent crimpers. Paper 15 at 2, 13-15. Dr. Solar also questions whether my experience is sufficient to render opinions on whether Yasumi could be used to crimp a stent. Ex. 2016 at ¶ 61.

2. I am more than qualified to render an opinion in this case. My qualifications are summarized in my original declaration, Exhibit 1105 at ¶ 1-8, and included in my *Curriculum Vitae*, Exhibit 1106. I provide a brief summary of relevant portions herein.

3. I have a degree in mechanical engineering from Villanova University. I also engaged in graduate studies at Harvard University in the Department of Engineering and Applied Physics.

4. I have nearly 50 years of engineering experience, over 40 of which are in the medical device field. Over the course of my medical device career, I have worked at seven different medical device companies. I have held numerous positions, ranging from Product Development Engineer to Vice President of Engineering and Manufacturing.

5. For the past 25 years I have been working as a consulting engineer and expert witness. In this capacity, I provide consulting engineering services both

in a litigation context as well as in a product design and development context. I specialize in medical device product design and development, and estimate that over 95% of my consulting work over the years has been related to medical devices. All my expert witness work over the years has been related to medical devices.

6. I have forty two issued patents, forty of which are related to medical devices. More than half of my patents result from work I performed while a consultant, as opposed to work I performed while an employee or officer of a company.

7. Although Patent Owner suggests that I have no experience with stents or stent crimping, Paper 15 at 13, during my deposition I noted that two of my previous expert witness engagements involved balloon catheters and stents. Ex. 2017 at 84:3-24, 85:11-23; *see also id.* at 81:17-23.

8. In particular, I was previously retained by the plaintiff in the patent infringement matter *Medtronic Vascular Inc. et al. v. Boston Scientific Corp. et al.* (E.D. Tex. 2006). The technology at issue included balloon catheter devices for use with delivering stents. In the course of rendering my opinions in that case, I was called upon to remove hundreds of stents from the balloon catheter products in order to test the balloons.

9. I also served as an expert for the defendant in the patent infringement matter *Angioscore v. TriReme Medical* (N.D.Cal. 2012). The technology at issue involved an angioplasty balloon catheter including a non-deployable stent adapted to be secured to the balloon. In the course of rendering my opinions in that case, I spent considerable time investigating how the accused TriReme Chocolate® brand percutaneous transluminal angioplasty catheter was made. In fact, I tested many of them. Through this investigation and testing I gained experience regarding how the stent portion was put on the balloon portion and reduced in size (*i.e.*, crimped).

10. Finally, I have been retained by Petitioner to serve as an expert in the district court litigation related to the present IPR proceeding. In that capacity, I have reviewed design and engineering documents related to Petitioner's accused heart valve crimpers. I have also inspected or reviewed photographs of several crimpers involved in the district court litigation.

11. I consider my work as an expert witness to be part of my engineering consulting activities. Both product design and development consulting and expert witness consulting require me to engage my engineering skills to address the technology at issue. Therefore, I am more than familiar with the design and operation of stents and stent crimpers through my consulting work, including my expert witness consulting.

12. It is true that I have not crimped a stent using a mechanical device like the one described in the '560 patent. I also note that Dr. Solar does not indicate that he has ever used a mechanical device like the one described in the '560 patent to crimp a stent. Nevertheless, I am able to understand the operation of the invention and to determine what a POSITA would have understood at the time of the invention in view of the available prior art. The '560 patent is a relatively straightforward mechanical system for reducing the size of a tubular object, and I have been working with mechanical devices my entire career.

13. Patent Owner also alleges that I rely on unsupported, conclusory assertions to support my opinions. Paper 15 at 16. To the contrary, my original declaration, Exhibit 1105, includes an extensive discussion of the '560 patent, the prior art to the '560 patent, and what a POSITA would have understood based on the disclosures of each document. This provides credible evidence that supports my opinions.

14. Patent Owner alleges that I advertise my expert witness services through three online services. Paper 15 at 15. I do advertise my expert witness services using JurisPro. *See* Ex. 2018. I do not have a relationship with the other two online services. *See* Exs. 2019-20. I am not familiar with these services and have never contacted or been contacted by them regarding posting my expert qualifications. To the extent they have information about my expert witness

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