

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

EDWARDS LIFESCIENCES CORPORATION,

Petitioner,

v.

ENDOHEART AG

Patent Owner.

---

Case IPR2016-00299  
U.S. Patent No. 8,182,530

---

**DECLARATION OF DR. JOHN R. GARRETT, M.D.**

I, Dr. John R. Garrett, M.D. declare as follows:

## **I. INTRODUCTION**

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

### **A. Engagement**

2. I have been retained on behalf of Edwards Lifesciences Corporation (“Edwards”) to provide my opinion on the scope and content of “prior art,” that is technology related, but predating the application for U.S. Patent No. 8,182,530 (“the ‘530 patent”), and regarding the subject matter recited in the claims of the ‘530 patent, in particular claims 1 and 6 of the ‘530 patent. I understand that this Declaration relates to a petition for the above-captioned inter partes review (IPR) of the ‘530 patent.

### **B. Background and Qualifications**

3. A detailed description of my professional qualifications, including a listing of my specialties/expertise and professional activities, is contained in my curriculum vitae, a copy of which is attached as Appendix A.

4. I am currently the Chief of the Department of Cardiac, Thoracic and Vascular Surgery, the Director of Physician Operations, and the Chairman of the Board of Directors at the Virginia Hospital Center.

5. I earned both my M.D. and M.S. in physiology and biophysics from the University of Alabama in 1979 and 1975, respectively. I received my B.S. in biology from Emory University in 1972.
6. My postgraduate training included a residency in cardiothoracic and vascular surgery at the Texas Heart Institute, where I studied under Dr. Denton Cooley, one of the leading heart surgeons in the world. I became an attending surgeon in 1986 and by 1990 had performed approximately 500 open-chest heart valve replacement surgeries. A complete listing of my postgraduate training, university service and hospital appointments can be found in my curriculum vitae (*see Appendix A*).
7. My Professional Activities include the following:
  - American College of Surgeons Fellow
  - Cooley Hands Society
  - Denton A. Cooley Cardiovascular Surgical Society
  - Society of Thoracic Surgeons
  - Arlington County Medical Society
8. I have contributed to several articles in various journals, including, but not limited to:
  - Schwartz, R. L., **Garrett, J. R.**, Karp, R. B., Kouchoukos, N. T.  
“Simultaneous Myocardial Revascularization and Carotid  
Endarterectomy.” *Circulation*, 66:197-101 (1982).

- Cooley, D.A., **Garrett, J.R.** “Septoplasty for Left Ventricular Outflow Obstruction Without Aortic Replacement: A New Technique.” *Ann Thorac Surg*, 42:445-448 (1986).
- Rhee, J.W., **Garrett, J.R.** “Use of a Cast Spreader During Reoperative Sternotomy.” *Ann Thorac Surg*, 64(3):863 (1997).

9. I have also been involved as a principal investigator in several research projects, namely one related to coronary artery bypass graft (“CABG”) surgery with cardiopulmonary bypass and one related to the risk of myocardial necrosis during and after CABG surgery, both completed in 2002. I was also awarded a research grant funded by Davis and Geck, Medical Device Division, American Cyanamid to develop and evaluate small diameter vascular prostheses from 1987-1989. A more complete description of the projects described above can be found in my curriculum vitae (*see* Appendix A).

10. I have reviewed the ‘530 patent and its file history. I have reviewed the prior art and other documents and materials cited herein. My opinions are also based in part upon my education, training, research, knowledge, and experience. For ease of reference, the full list of information that I have considered is included in Appendix B.

### C. Legal Standards for Patentability

11. A patent claim is unpatentable if the differences between the patented subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art.

I am informed that this standard is set forth in 35 U.S.C. § 103(a).

12. When considering the issues of obviousness, I am to do the following: (i) determine the scope and content of the prior art; (ii) ascertain the differences between the prior art and the claims at issue; (iii) resolve the level of ordinary skill in the pertinent art; and (iv) consider objective evidence of non-obviousness. I appreciate that secondary considerations must be assessed as part of the overall obviousness analysis (*i.e.*, as opposed to analyzing the prior art, reaching a tentative conclusion, and then assessing whether objective indicia alter that conclusion).

13. Put another way, my understanding is that not all innovations are patentable. Even if a claimed product or method is not explicitly described in its entirety in a single prior art reference, the patent claim will still be denied if the claim would have been obvious to a person of ordinary skill in the art at the time of the patent application filing.

14. In determining whether the subject matter as a whole would have been considered obvious at the time that the patent application was filed, by a person of

# 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.