Neutral Citation Number: [2009] EWHC 1304 (Pat)

Case No: HC08 C 00934

**IN THE HIGH COURT OF JUSTICE**
**CHANCERY DIVISION**
**PATENTS COURT**

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 12 June 2009

**Before** :

**THE HONOURABLE MR JUSTICE KITCHIN**

- - - - - - - - - - - - - - - - - - - - -

**Between :**

| | |
|---|---|
| **EDWARDS LIFESCIENCES AG (a company incorporated under the laws of Switzerland)** | **Claimant** |
| **- and –** | |
| **COOK BIOTECH INCORPORATED (a company incorporated under the laws of the state of Indiana, USA)** | **Defendant** |

**Roger Wyand QC**, **Piers Acland** and **Miles Copeland** (instructed by **Bird & Bird**) for the Claimant
**Simon Thorley QC** and **Adrian Speck (**instructed by **Marks & Clerk Solicitors**) for the Defendant

Hearing dates: 6-8, 11, 12, 14 and 15 May 2009

- - - - - - - - - - - - - - - - - - - - -

# Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

.....

MR JUSTICE KITCHIN

**Mr Justice Kitchin :**

1. This is a patent action in which the Claimant ("Edwards") seeks revocation of European Patent (UK) 1 255 510 ("the Patent"). The Defendant ("Cook") is the proprietor of the Patent and has counterclaimed for infringement.

2. Edwards manufactures the SAPIEN artificial heart valve which was launched in Europe in 2007. It is designed to be compressed onto a balloon catheter for percutaneous delivery via the femoral artery. It can also be delivered transapically through the side of the chest and into the apex (the bottom of the left ventricle) of the heart in patients with severe aortic stenosis. It is primarily used to replace the aortic valve but is also suitable for replacement of the pulmonary valve.

3. Cook alleges the SAPIEN infringes the following claims of the Patent which are said to be independently valid: 1, 12, 15, 22, 23, 28 and 31. Edwards denies infringement and challenges the validity of these claims and claims 3 and 8 (which are also said to be independently valid but not infringed) on the following grounds:

    i) Lack of novelty under section 2(3) of the Patents Act 1977 ("the Act") in the light of WO 01/19285 published on 22 March 2001 ("Thorpe");

    ii) Obviousness in the light of:

        a) U.S. Patent 5,411,552 published on 2 May 1995 ("Andersen");

        b) EP 0 856 300 A1 published on 5 August 1988 ("Moll");

        c) "*Aortic and venous valve for percutaneous insertion*" by D. Pavcnik et al., published in 2000 ("Pavcnik");

        d) common general knowledge.

    iii) Insufficiency. Edwards contends the specification of the Patent does not disclose the alleged invention clearly enough or completely enough for it to be performed arising from the use in claim 1 of the word "substantially". Essentially this is a question of the proper interpretation of the claim.

    iv) Added matter. Edwards contends the matter disclosed in the specification of the Patent as granted has been extended over the original disclosure in the application for the Patent as filed. There are two aspects to the objection. One arises from the use in claim 1 of the word "substantially" and the other turns on the proper interpretation of claim 3.

**Witnesses**

4. Each of the parties called two expert witnesses, an interventional cardiologist and a bioengineer. On behalf of Edwards, I heard evidence from Dr Nigel Buller and Dr Rodolfo Quijano.

5. Dr Buller is a consultant cardiologist in private practice. Until January 2008, he was Head of Interventional Cardiology at the Queen Elizabeth Hospital, Birmingham. The Queen Elizabeth has one of the leading cardiology departments in the UK and one of

only five centres that provide fully comprehensive adult cardiological services. Dr Buller has extensive experience of catheterization procedures, including balloon angioplasty and stent implantation and throughout his career has had a close working relationship with many of the major medical device manufacturers.

6. Cook does not suggest I should reach a general conclusion adverse to Dr Buller but invites me to say that he may have lost total objectivity in a limited number of instances. I decline that invitation. Dr Buller was measured, careful and precise in expressing his opinions and I have found his evidence of great assistance.

7. Dr Quijano has been involved in the design and development of biological and mechanical replacement heart and venous valves for more than 35 years. Cook makes no criticism of Dr Quijano, and rightly so. He clearly has a passion for and a deep understanding of the technical issues involved in the design of replacement cardiac and venous valves.

8. On behalf of Cook, I heard evidence from Professor Martin Rothman and Professor David Williams.

9. Professor Rothman is a consultant cardiologist and the Director of Cardiac Research & Development at Barts and the London NHS Trust and Honorary Professor of Interventional Cardiology at Queen Mary, University of London. Interventional cardiology has been the focus of Professor Rothman's entire career and he is recognised as one of its pioneers. He has worked with cardiovascular stents since the early 1980s and over the years has advised many different companies operating in the pharmaceutical and medical device sectors in relation to a wide range of devices used in conjunction with interventional cardiology.

10. Edwards accepts that Professor Rothman is a skilled and expert cardiologist but contends his evidence was partisan, as illustrated by a marked shift in his opinions from those he held in an earlier case between Edwards and a company called CoreValve. I think it fair to say the opinions expressed by Professor Rothman in his reports in the two cases are indeed different in material respects and this formed the basis of a good deal of his cross examination. However, as Cook submits, opinions may change in the course of a case, particularly after cross examination, and I accept that in formulating his reports in this case Professor Rothman may have given further consideration to the abilities of the ordinary skilled person. Importantly, I believe Professor Rothman answered the questions put to him fairly and frankly and I found his opinions cogent and reasonable.

11. Professor Williams is currently Professor and Director of International Affairs at the Wake Forest Institute of Regenerative Medicine in North Carolina. He is also Visiting Professor in the Christiaan Barnard Department of Cardiothoracic Surgery at the University of Cape Town. His career over the last forty years has been devoted to the fields of bioengineering, biomaterials science and regenerative medicine. Among his many activities he has been directly concerned with the development of new materials for use in surgically implantable heart valves.

12. Edwards says Professor Williams did not seem to appreciate the role of the skilled person in his approach to the prior art and appeared reluctant to attempt to correct

deficiencies so as to make it work. I reject this criticism. I found Professor Williams to be careful and fair in addressing the questions put to him.

13. Edwards also adduced evidence of fact from Mr Stanton Rowe, an employee of Edwards, who was involved in the development of the SAPIEN. Mr Rowe's evidence was directed to the suggestion made by Professor Rothman in his first report that it took ten years of research to develop the ideas described in Andersen into the SAPIEN. He was not cross examined and his evidence ultimately played no real part in the matters I have to decide.

**The skilled person**

14. There was little between the parties as to the identity of those persons to whom the Patent is addressed. Professor Rothman and Professor Williams considered the Patent is directed towards a skilled team comprising an interventional cardiologist (in so far as it concerns heart valves) or a general vascular surgeon (in so far as it concerns vein valves) and, in either case, a bioengineer. Professor Rothman considered the team might also consult a cardiac surgeon in order to find out about contemporary work with surgically implantable replacement heart valves. Professor Williams elaborated, and I accept, that in practice a number of engineers might be involved in the team, depending on their specific areas of expertise. For example, one might have particular experience of stent design, another experience of the design of cardiac valve replacements and a third experience of biomaterials. He too considered that a cardiac surgeon would be involved in order to provide experience of some of the practical problems encountered in using surgically implantable valves.

15. Dr Buller believed that the team would have included an interventional cardiologist and a medical device designer familiar with the design of stents and implantable valves and the materials used to make them.

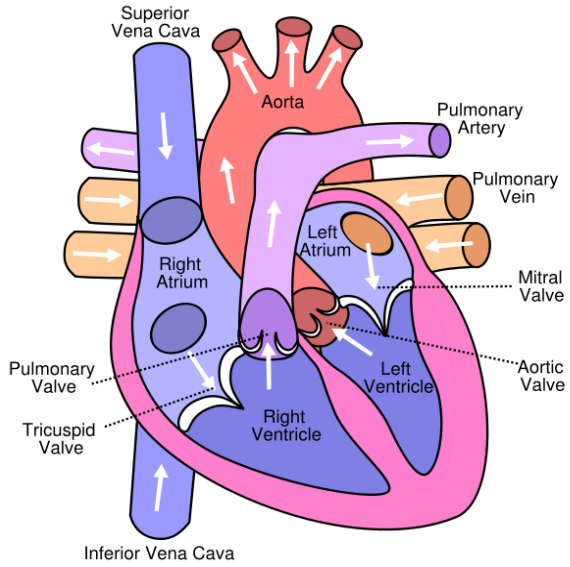
16. In the light of all this evidence I am content to adopt the formulation of the skilled team propounded by Professor Rothman and Professor Williams, subject to the following qualification. I am entirely satisfied that the team would have contained or at least consulted with a person familiar with the design of implantable surgical heart valves.

**Common general knowledge**

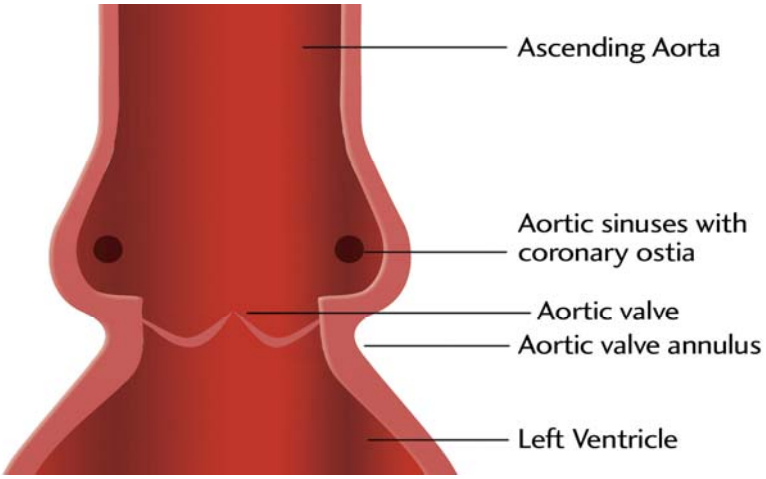
17. There was no real dispute as to much of the common general knowledge and the following description is drawn largely from the reports of the experts.

*The cardiovascular system*

18. The cardiovascular system is divided into the pulmonary circulation which supplies blood to the lungs and the systemic circulation which supplies blood to the rest of the body. The heart lies at the centre of the system. It pumps blood through the blood vessels by repeated rhythmic contractions and it consists of four chambers, two atria and two ventricles, as shown in the diagram below:




19. An enlarged section of the aortic valve may be represented like this:




20. De-oxygenated blood from the body is collected in the right atrium, passes through the tricuspid valve into the right ventricle and is then pumped through the pulmonary artery into the lungs where carbon dioxide is removed and oxygen absorbed. As the right ventricle contracts, the tricuspid valve closes, ensuring that blood is not injected back into the right atrium. At the same time the pulmonary valve opens allowing the blood to flow from the right ventricle into the pulmonary artery.

21. Blood returns to the heart from the lungs through the pulmonary vein and it collects in the left atrium. From the left atrium the blood flows to the left ventricle through the mitral valve. When the left ventricle contracts, the mitral valve closes, the aortic valve opens and the blood is duly pumped through the aorta to the body. The pulmonary valve and aortic valve prevent blood returning to the ventricles from the pulmonary artery and aorta respectively.

22. The enlarged section of the diagram of the heart set out above depicts the arrangement of the aortic valve, a matter of particular importance in this case. The aortic valve sits in the aortic valve annulus, a fibrous ring at the junction between the left ventricle and

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.