Royal Courts of Justice, Rolls Building
Fetter Lane, London, EC4A 1NL

Date: 03/03/2017

Before :

HIS HONOUR JUDGE HACON
(SITTING AS A HIGH COURT JUDGE)

- -

Between :

EDWARDS LIFESCIENCES LLC	**Claimant**
- and -	
BOSTON SCIENTIFIC SCIMED, INC.	**Defendant**
- and -	
(1) EDWARDS LIFESCIENCES CORPORATION	**Third Party**
(2) EDWARDS LIFESCIENCES AG	**Fourth Party**
(also known as EDWARDS LIFESCIENCES SA)	
(3) EDWARDS LIFESCIENCES LIMITED	**Seventh Party**

- -

- -

Piers Acland QC and **Miles Copeland** (instructed by **Powell Gilbert LLP**) for the **Claimant** and the **Third, Fourth** and **Seventh Parties**
Richard Meade QC and **Kathryn Pickard** (instructed by **Olswang LLP**) for the **Defendant**

Hearing dates: 18-20, 23-24 and 26-27 January 2017

- -

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.

.....

HIS HONOUR JUDGE HACON

referred to as 'transcatheter heart valves' or THVs.

2. The claimant sought revocation of Boston's EP (UK) 2 749 254 ("254") and EP (UK) 2 926 766 ("766") patents ("the Patents"). They are both divisional patents derived from the same parent application. The relevant priority date for both was 23 December 2003. The description in the specification of each of the Patents is largely the same.

3. Boston counterclaimed for infringement and brought additional claims against five other companies in the same group as the claimant. The Fifth Party was in fact the same as the Fourth Party (being Swiss, it alternatively uses German or French designations) and the claim against the Sixth Party was later dropped. That left the claimant and three remaining companies as defendants in the additional claim, all of them part of the same group. I need not distinguish them and will refer to them individually and collectively as 'Edwards'.

4. Despite this being formally a claim for revocation with a counterclaim for infringement, the trial went forward in the usual way, as if Boston were the claimant in an infringement action against Edwards. The product alleged to infringe is Edwards' Sapien 3 THV.

5. Edwards argued that both the 254 and 766 Patents lacked novelty and inventive step, relying on four items of prior art. A squeeze was run against both Patents, alleging in each case that if the invention claimed was not obvious, necessarily it was not sufficiently disclosed in the specification. Finally, there was an allegation of added matter in relation to both.

6. In argument attention was paid only to claim 1 of each Patent, save for a brief reference to other claims in the context of infringement of 254. Subject to that, I need therefore consider only the first claims of the Patents.

7. Richard Meade QC and Kathryn Pickard appeared for Boston, Piers Acland QC and Miles Copeland for Edwards.

The technical background to the inventions

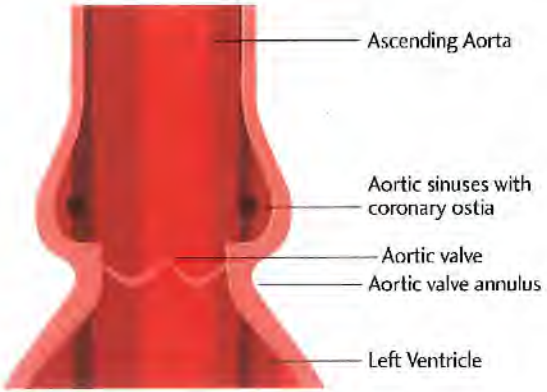
8. The parties provided me with a helpful primer, largely plagiarised from the judgments of Kitchin J in *Edwards Lifesciences AG v Cook Biotech Incorporated* [2009] EWHC 1304 (Pat) and of Mr Peter Prescott QC in *Corevalve Inc v Edwards Lifesciences AG* [2009] EWHC 6 (Pat). It was

10. The end of the pulmonary circulation is marked by oxygenated blood returning from the lungs to the heart via the pulmonary vein, entering the left atrium. From there it passes to the left ventricle, ready to be pumped around the rest of the body – the systemic circulation. Between the left atrium and the left ventricle there is a valve: the mitral valve. When the left ventricle contracts, the mitral valve closes preventing the blood from flowing back into the left atrium. Instead the blood flows under high pressure into the main artery of the systemic circulation, the aorta.

11. The phase in which the ventricle contracts is known as 'systole', as opposed to the phase in which the wall muscle relaxes and the ventricle expands, which is known as 'diastole'.

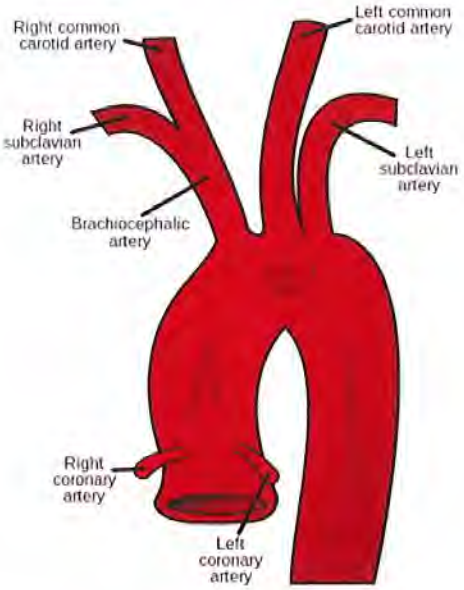
12. Between the left ventricle and the aorta is the aortic valve. As diastole begins pressure inside the ventricle rapidly drops, falling below that of the blood in the aorta. The difference in pressure causes the aortic valve to close so that the blood does not return to the left ventricle during its expansion in preparation for a further contraction.

13. The following is a diagrammatic representation of the location of the aortic valve between the left ventricle and the aorta.



14. In this diagram the aortic valve is represented by two leaflets. In about 1-2% of the population, mostly males, there are indeed two leaflets, but in the rest of the population there are three. These leaflets are flaps of tissue which operate as the valve. When the left ventricle contracts, the pressure of blood pushes the leaflets apart, allowing the blood through. When the contraction ends at the start of diastole, the difference in blood pressure across the aortic valve is

an arch to the descending aorta. These are shown in the diagram below along with the coronary arteries and other arteries which branch off the aorta and form part of the systemic circulation. A THV intended to replace the aortic valve is usually passed up the descending aorta, via the arch, down into the ascending aorta and thence to the native valve.



Heart Valve Disease

17. Heart valve disease may be congenital or it may be acquired. If acquired, it is often the aortic or mitral valve that will be affected. The most common afflictions are stenosis and regurgitation. In the former condition the leaflets of the valve fail to open fully, blocking the passage of the blood into the aorta or left ventricle as the case may be. If the patient suffers from regurgitation, the leaflets do not fall together to form a tight seal. Consequently some blood leaks backwards.

18. These are not mutually exclusive conditions. Both are commonly caused by degenerative calcification, which is the accumulation of calcium carbonate in the leaflets and the parts of the heart surrounding the valve. The calcium carbonate collects to form very hard nodules, stiffening the tissue in which they form.

are mechanical. These have a long life span but tend to cause thrombus formation (blood clots) which require the patient to undergo life-long anti-coagulation therapy. Others are biologically derived. The leaflets are either homograft (human whole valves), xenograft (animal whole valves) or fabricated (tailored from animal pericardium, the tissue that covers the outside of the heart). In each case they are mounted within a textile cuff, or in a metallic or plastic frame.

Interventional Cardiology

21. In the 1960s a new branch of medicine emerged known as 'interventional cardiology', that is to say the practice of treating patients with heart problems percutaneously rather than by surgery. It was and remains the province of physicians rather than surgeons. Physicians specialising in this field have become known as 'interventional cardiologists'.

22. In 1977 the first human balloon angioplasty procedure was performed. A catheter carrying a balloon was inserted into an occluded human coronary artery and then expanded to force the artery open. In the 1980s other procedures were developed, including valvuloplasty: inflating a balloon catheter to open up a stenotic heart valve.

Stents

23. During the 1980s and 90s there was a related development, namely the design of expandable stents to treat occluded vessels, in particular coronary arteries. These stents have an initial structure of narrow diameter to permit percutaneous introduction in a catheter. Then, once in place, they are expanded in diameter to form a scaffold inside the artery to hold it open. By the year 2000 stents were preferred over balloon angioplasty because they were less likely to result in restenosis (re-occlusion).

24. Stents essentially fall into two categories. The first are those which are balloon expandable. Once the stent has reached its destination, a balloon inside is expanded to force the stent open by plastic deformation. The balloon is then deflated and the catheter withdrawn. The second category is self-expanding stents. These are made of a spring or 'memory metal', typically nitinol. They require a sheath to maintain the stent in its compressed form of narrow diameter. Once the stent is in place the sheath is withdrawn and the stent expands.

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.