Neutral Citation Number: [2009] EWHC 6 (Pat)

Case No: HC 07 C01243

IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 9 January 2009

Before :

MR PETER PRESCOTT QC
(sitting as a Deputy Judge of the High Court)

- -

Between :

COREVALVE INC	**Claimants**
- and -	
(1) EDWARDS LIFESCIENCES AG	**Defendants**
(2) EDWARDS LIFESCIENCES PVT, INC	

- -
- -

Mr Antony Watson QC and **Mr Thomas Mitcheson** (instructed by **Simmons and Simmons**) for the Claimants
Mr Roger Wyand QC and **Mr Piers Acland** (instructed by **Bird & Bird**) for the Defendants

Hearing dates : 25th -27th and 30th June and 2nd July 2008

JUDGMENT

Mr Peter Prescott QC:

1. Irvine, California is home both to Edwards Lifesciences – the largest artificial heart valve company in the world – and its competitor, CoreValve Inc. I shall call them "Edwards" and "CoreValve".

2. Edwards owns European Patent No 0592410. CoreValve says this patent is invalid for anticipation, obviousness and insufficiency, and applies for its revocation. Edwards says that, on the contrary, the patent is valid and CoreValve has been infringing it by supplying its ReValving system; Edwards counterclaims accordingly. CoreValve denies that its product is covered by the claims of this patent, even if it is valid. As an extra line of defence, CoreValve says that it has been supplying the product for experimental purposes relating to the subject-matter of the invention (section 60(5)(b) of the Patents Act 1977).

3. As I assimilated the evidence and arguments in this case I gradually and increasingly formed the impression that the patent is valid, but that CoreValve's product does not infringe it. And that is what I hold in this judgment. I must confess, however, that after the conclusion of the argument I had second thoughts: I was side-tracked by a consideration which caused me much trouble, which took up a lot of time in the preparation of this judgment, but which I now believe to be without substance. I shall return to that later. I greatly regret the resulting delay.

4. The priority date claimed for the patent, and not disputed in this case, is 18 May 1990. Therefore I shall need to consider the state of the art at that date, including what was common general knowledge.

5. The patent is about artificial valves for implantation in the human body. Such a valve might be used to replace a natural valve. For certain medical conditions it might even be implanted where no natural valve exists e.g. in the oesophagus. But the main focus of the patent is about valves for replacing defective heart valves.

6. A little introductory terminology may be helpful. Before the date of the patent it was known to assist the *patency*, or openness, of a blood vessel e.g. a coronary artery by implanting a supporting scaffold called a *stent*, which may be

thought of as a slender wire cage. The stent could be delivered remotely from a blood vessel in the patient's leg by a technique called *catheterisation*. In essence, a tube was passed up into the coronary artery and the stent was delivered over an internal guide wire. A small balloon was inflated inside the stent to cause it to expand and the catheter apparatus was withdrawn, leaving the stent in place.

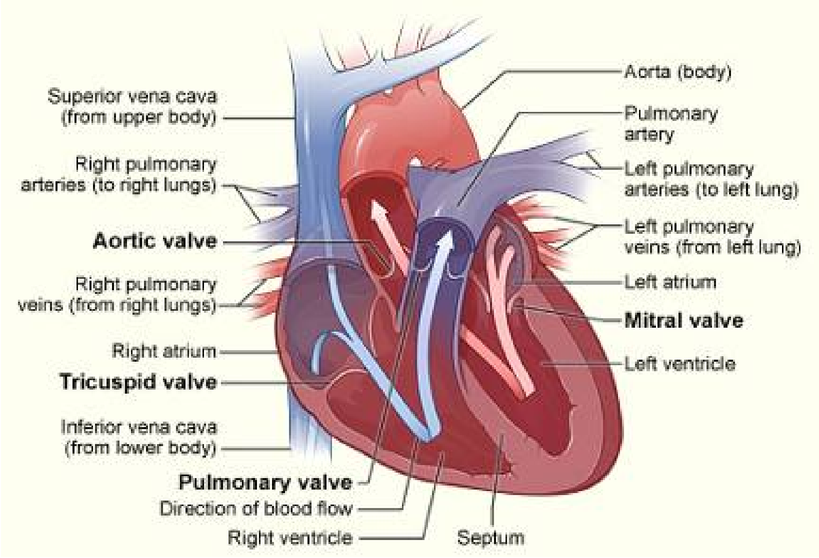
7. The general idea of the patent is to implant a replacement valve remotely by catheterisation e.g. through a vein, without major interventional surgery, and to leave it in place, so that the patient may lead a normal life. This is to be achieved by mounting the valve on a stent; both the valve and the stent are elastic and can collapse i.e. they can squash inwards in order to be narrow enough to navigate through small passages e.g. arteries. On arriving at the correct site the valve and stent can be re-expanded and left in place.

The Heart, Its Valves and Its Main Blood Vessels

8. The heart is a remarkable organ. It took centuries for the world's best anatomists and physiologists to figure out its mode of operation and I understand that they have not finished even now.

9. The heart is a pumping device. All vertebrate hearts work on the principle that a muscular chamber, called a *ventricle*, contracts to drive out blood (during *systole*) and expands to admit it (during *diastole*). A pump engineer would say: why not have an antechamber, where returning blood can be collected so that it can be discharged into the ventricle at the right time during the pumping cycle? But nearly all vertebrate animals have evolved one of those, and it is called an *atrium.*

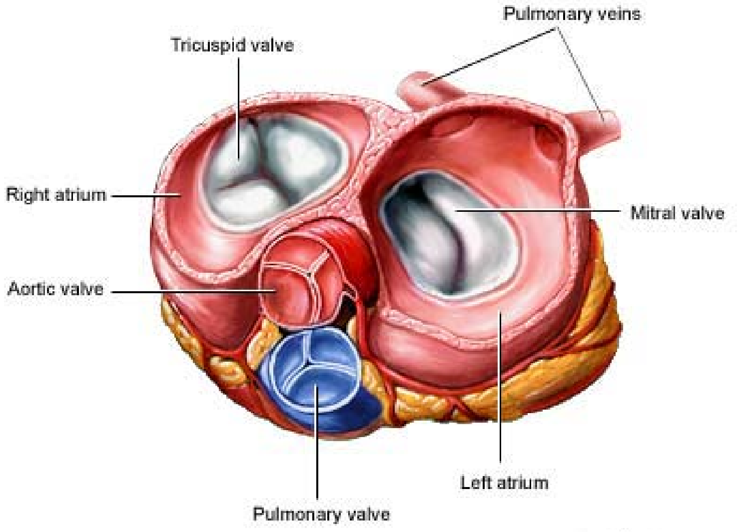
10. We mammals (and also birds) have also evolved an ingenious arrangement to overcome the problem that a substantial pressure drop occurs as the blood passes through the lungs. The solution is to have parallel circulation systems or, in other words, a left heart and a right heart. The left heart drives the main or *systemic circulation* of the body. The right heart drives the *pulmonary circulation*. This arrangement was evolved in rudimentary form by our amphibian ancestors but in our heart the *septum* provides a complete division between left and right ventricle.



11. Consider blood returning to the heart from the main tissues of the body through the veins. It enters the right atrium through the *vena cava*. From there it passes to the right ventricle through the *tricuspid valve*. Our pump engineer would rightly say that since the heart is a positive displacement pump it should have valves to prevent the blood flowing the wrong way during the compression stroke. That is indeed what the healthy valves of the heart do; and we can start with the function of the tricuspid valve. During systole the rising blood pressure in the right ventricle causes this valve to slam shut, and so it prevents the blood running back into the right atrium. Instead the rising blood pressure causes another valve to open – the *pulmonary valve* – so that the blood is driven through the *pulmonary artery* and thence to the lungs. The function of the pulmonary valve is to stop back pressure causing blood to flow backwards into the right ventricle during diastole.

12. Having dropped waste gases in the lungs and picked up oxygen, the blood now proceeds – to the left heart, this time – through the *pulmonary veins* and thence to the left atrium. Blood proceeding in this direction opens the *mitral valve* and hence passes to the left ventricle. This chamber of the heart does more work than the others and so the heart muscle (*myocardium*) that surrounds it is correspondingly thicker. During left ventricular systole the rising blood pressure causes the mitral valve to slam shut and so the only way out is through the *aortic valve*, thence to the *aorta*, which is an enormous artery that feeds the other arteries of the systemic circulation.

13. Each of the four valves of the heart is formed from three leaflets, except for the mitral valve, which has two (and so it also known as the bicuspid valve).



14. Heart valve disease may be congenital or it may be acquired. If acquired, it is often the mitral or aortic valve that will be affected. For present purposes the most common afflictions are *stenosis* (where the valve fails to open fully, a common cause being degenerative calcification) and *regurgitation* (where the valve does not close tightly, thus allowing some of the blood to leak backwards). Regurgitation is also called *insufficiency*.

15. Blood is supplied to heart muscle itself by the *coronary arteries*. They are connected to the aorta, the biggest artery in the body – maybe 25 mm diameter at its root. Here is a simplified diagram. It can be seen that the *ascending aorta* leads to its *arch*, in the region of which there are various branches that deliver arterial blood to the upper body. The *descending aorta* delivers arterial blood to the lower body through various branches, not shown. Two of these are the *iliac arteries* (10 mm diameter) which supply the pelvis and lower limbs (where they become the *femoral arteries*, diameter 6-8 mm).

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