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**

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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

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Judgment

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.

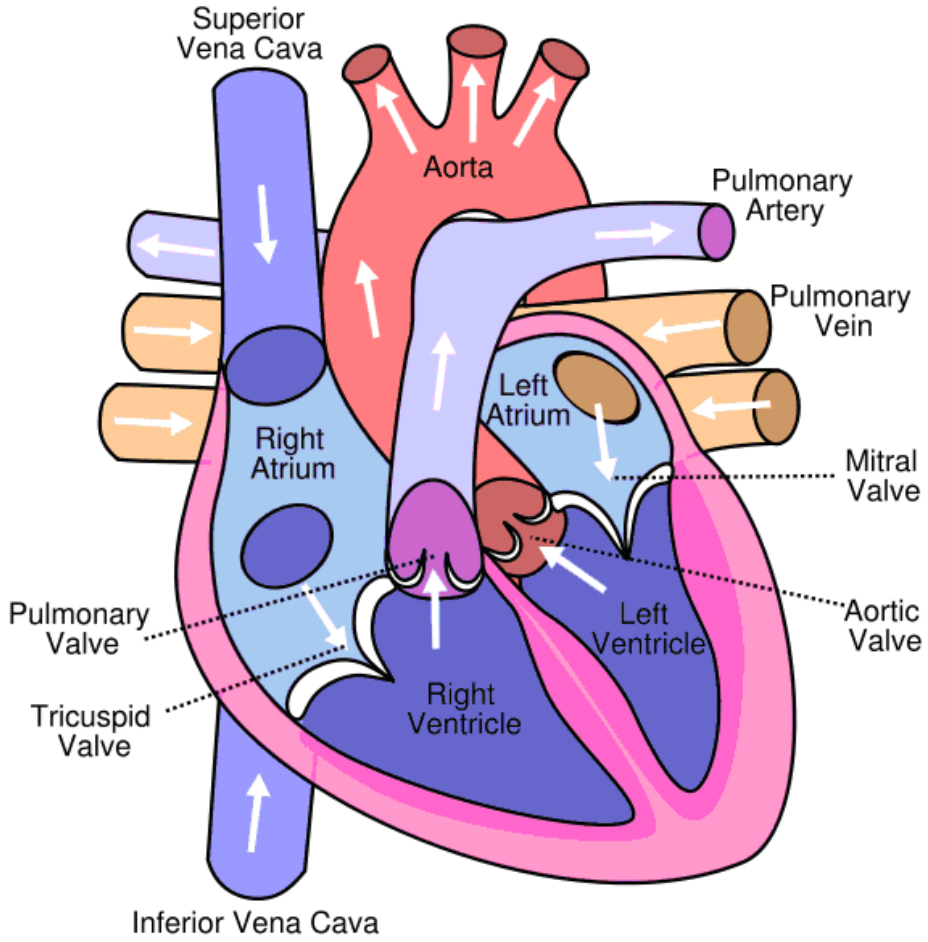
16. In the light of all this evidence I am content to adopt the formulation of the skilled team propounded by Professor Rothman and Professor Williams, subject to the following qualification. I am entirely satisfied that the team would have contained or at least consulted with a person familiar with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

Common general knowledge

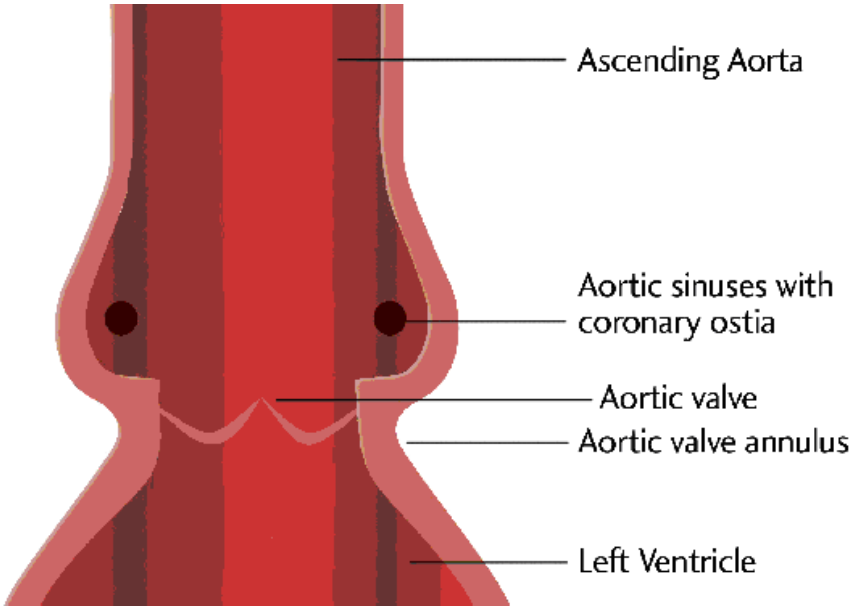
17. There was no real dispute as to much of the common general knowledge and the following description is drawn largely from the reports of the experts.

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 the aorta immediately below the sinuses. The aortic valve itself has three leaflets (or cusps) which are half moon shaped. As mentioned, when the left ventricle contracts, the pressure inside the ventricle increases until it is greater than in the aorta, at which point the aortic valve opens. When the ventricular contraction ends, pressure in the left ventricle rapidly drops. When it falls below the pressure in the aorta, the leaflets of the aortic valve collapse and come together along their edges (commissures) and flow of blood from the aorta back to the heart is prevented. Sitting within the aortic sinuses and within a few millimetres of the leaflets are the coronary ostia, which are openings that lead to the coronary arteries. It is crucial that these are not blocked when a valve is replaced because the coronary arteries provide the heart muscle with blood.

23. Veins in the limbs also have valves, called venous valves, which prevent blood flowing backwards and pooling in the extremities due to the effects of gravity. Venous valves have two leaflets. Replacement of faulty veins and venous valves has been the subject of much experimentation, but is not yet done routinely in clinical practice with treatment primarily centering on removal of abnormal veins or systemic treatment with anticoagulants. As Professor Rothman explained, there has been little commercial or clinical incentive to develop replacement vein valves and such development that there has been has lagged behind the development of percutaneously delivered heart valves.

Cardiac surgery and prosthetic valves

24. Surgeons have been replacing diseased or malfunctioning heart valves for over 40 years. They have used for this purpose a range of prosthetic valves, both mechanical and biological.

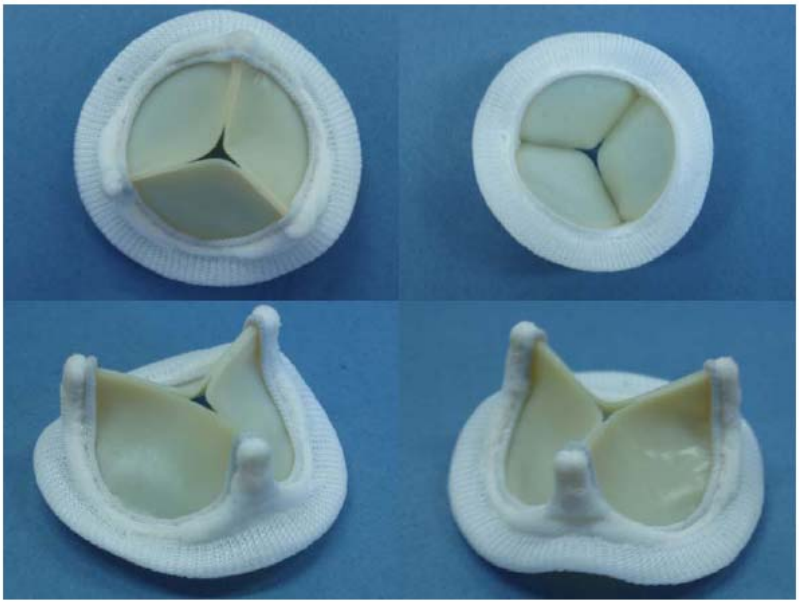
25. Mechanical replacement heart valves are generally made from a combination of metal, carbon and plastic and typically provide a valve function through a tilting disc or a ball moving within a cage. They have a long life span but patients suffer an increased risk of thrombus formation which requires them to undergo life-long anticoagulation therapy.

26. Biologically derived (bioprosthetic) valves attempt to replicate more closely the structure and dynamics of a physiological heart valve. They are made of tissue, generally mounted on a textile cuff or metallic or plastic frame and fall into three

categories: homograft (human whole valves), xenograft (animal whole valves) and fabricated (valves tailored from animal pericardium, the tissue that covers the outside of the heart). The latter two categories are those of most importance in the context of the present case.

27. Xenograft valves are normally of porcine origin, but can also be of equine or bovine origin. The valve is physically removed from the animal and treated chemically in order to make the biological tissue immunologically inert and sterile and to improve its mechanical properties. It is then attached to a textile cuff allowing it to be sutured to the heart tissue or mounted on a frame which provides some mechanical support. Such a frame is usually referred to as a stent. In 2000, a well established bioprosthetic valve using a porcine valve was called the "Hancock". In this device the valve is fixed to a non-collapsible stent covered with fabric, allowing it to be sutured into the patient around its circumference. The valve has three leaflets which, when the valve is closed, meet at their free margins, that is to say the edges which are free to move from the centre of the valve towards the circumference of the valve when opening and free to return to the centre when closing. The line at which any two of these free edges meet is referred to as the commissure or line of coaption.

28. In the case of fabricated valves, leaflets, normally three in number, are fashioned from a sheet of pericardium and again attached to a frame and sewing cuff. In 2000, one of the most successful fabricated bioprosthetic heart valves was the "Carpentier-Edwards pericardial aortic prosthesis", also known as the "Perimount". It was implanted as early as 1980 in France and approved for use in the US in 1991. It looks like this:



29. Like the Hancock, the Perimount comprises a non-collapsible stent, covered with fabric, which provides a means to suture it into the patient. The stent has three projecting portions known as commissural posts to which the leaflets are connected at the periphery of their commissures. The leaflets are also sutured to the fabric covered stent along the entirety of the inflow side of the valve (the margin of attachment) to preserve the valvular mechanism geometry and ensure the valve does not leak peripherally.

30. Pericardium is the only natural tissue that has ever been used commercially to fabricate a bioprosthetic valve. Its advantages are numerous. It is available in relatively large quantities, permits the production of leaflets that have uniform thickness, strength and flexibility, can be cut to any desired size and, after suitable chemical treatment, possesses physical properties that closely resemble those of the leaflets of human valves. Moreover, pericardium is biocompatible and exhibits low thrombogenicity. For all these reasons, for many years before 2000, pericardium was the only tissue used for the production of commercialised fabricated bioprosthetic valves. However, such valves do suffer from the drawback that they have a tendency to denature or calcify, which affects their long term performance.

31. As Professor Williams explained, by 2000, attempts had been made to develop a surgically implantable polymer leaflet heart valve which was seen as having the potential to avoid the difficulties of thrombosis caused by the mechanical valves and calcification which tends to occur with bioprosthetic valves. However, no commercial polymer leaflet surgical valves existed at that time.

Interventional cardiology

32. Surgical heart valve replacement involves a major operation and is not suitable for all patients. However, from the 1960s a new branch of medicine emerged known as interventional cardiology. This is the practice of percutaneously treating problems within the heart and associated vessels and is the province of physicians rather than surgeons. Interventional procedures are carried out using a catheter to access the site in the heart or vasculature where the intervention is to be performed.

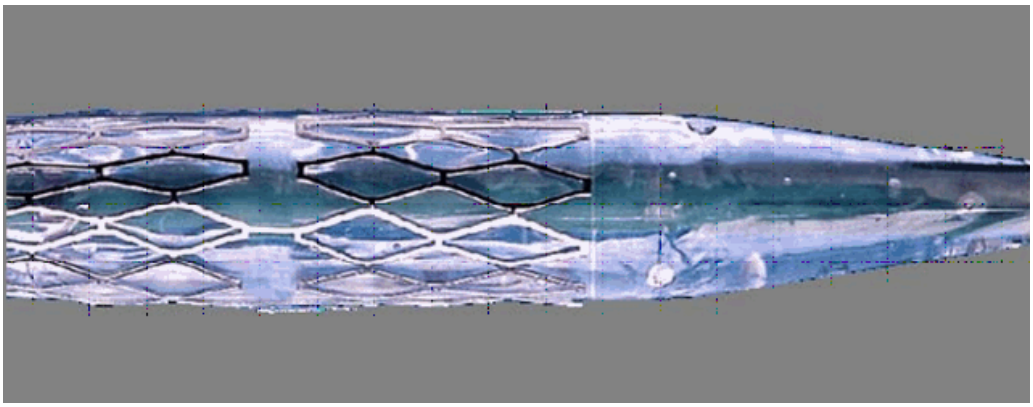
33. As Professor Rothman elaborated, in 1977, Andreas Gruentzig performed the first human balloon angioplasty procedure in which a catheter carrying a balloon was inserted into an occluded human coronary artery and then expanded to force the artery open. By 1990, balloon angioplasty and two related techniques called valvuloplasty (using inflation of a balloon catheter to try to open up a stenotic (narrowed) heart valve and improve blood flow) and atherectomy (using a high speed rotating device or a directional slicing device to remove plaque from the inside of an artery) were regularly being undertaken.

34. Most interventional cardiology is performed percutaneously using a needle inserted into the femoral or radial artery. But it is also possible to cut through the skin over the vessel using a procedure known as "cut-down". Once access to the artery is secured, the catheter is passed to the heart against the blood flow in what is known as a "retrograde" approach. Access to the heart can also be achieved by means of an "antegrade" approach, that is to say passing the catheter in the same direction as the blood flow. In this case the catheter is introduced into a peripheral vein and then advanced along the vena cava to the right side of the heart. If access to the left side of the heart is required then the catheter must be fed through the wall (called the septum) which lies between the two atria of the heart. This technique is used to perform mitral valvuloplasty.

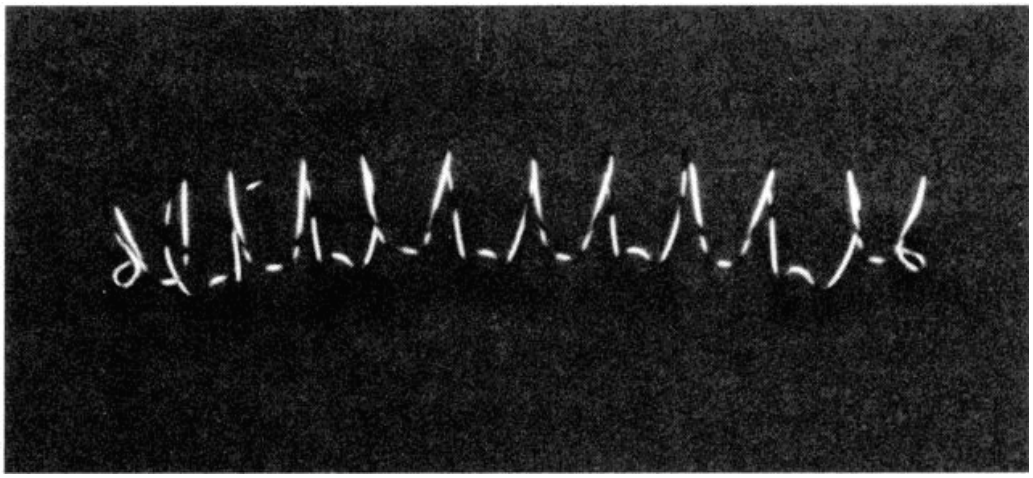
35. In the course of the 1980s and 1990s a great deal of work was also being carried out into the design of expandable stents for translumenal implantation. These were developed to scaffold the internal surface of an artery, initially to prevent an acute closure at the time of a balloon angioplasty procedure, particularly of the coronary

artery. However, in the 1990s two major randomised trials known as Benestent and Stress showed that the use of stents also resulted in reduced occurrence of re-narrowing (restenosis) compared with patients receiving balloon angioplasty. As a result, by 2000, stents were being used electively with balloon angioplasty in the majority of cases. They also allowed interventional cardiologists to attempt angioplasty in higher risk and more diseased vessels because they knew that stents had the capacity to prevent short-term and long-term complications.

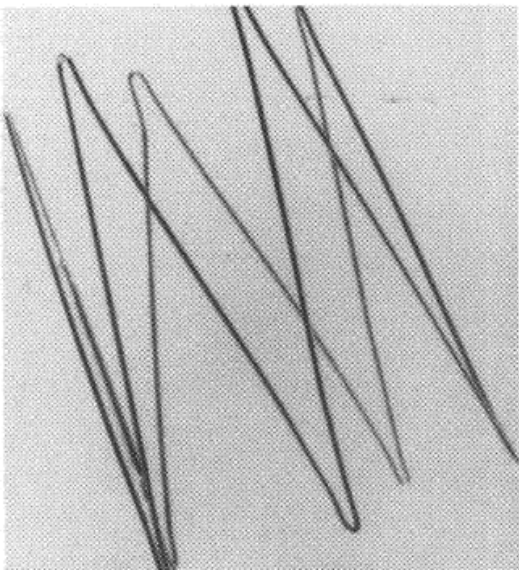
36. Stents essentially fall into two categories, those which are balloon expandable and those which are self-expanding. Balloon expandable stents are compressed around a balloon and inserted into a peripheral vessel by catheter. Once the balloon expandable stent reaches its destination the balloon is expanded to force open the stent by plastic deformation. The balloon is then deflated and the catheter withdrawn. Some, like the Palmaz-Schatz had a slotted tube design:

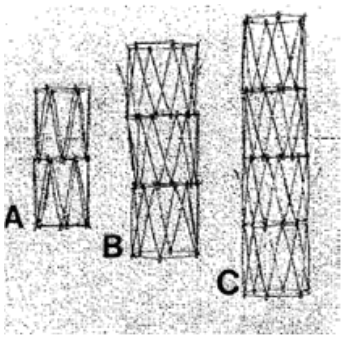


37. Others, such as the Gianturco-Roubin had an expandable wire coil design:



38. Self-expanding stents are made of a spring or of a “memory metal” such as nitinol. These require a sheath to maintain the stent in its compressed form during delivery. Once the stent reaches its desired location the sheath is withdrawn and the stent expands. One of the first self-expanding stents was the Gianturco Z-stent, which was first used in the mid-1980s. It has a “zigzag” design and, in a later modification, multiple zigzags were joined together by metal struts or monofilament line to provide a greater degree of stability:





39. By January 2000, many devices consisted of a number of rings joined together and those in the art tended to describe the whole of any such device as a single stent, irrespective of how many rings it might contain.

40. Clearly, stents of different lengths and diameters may be required for different applications. By 2000, it was the general practice to "size" the stent to a diameter approximately 10 to 20% greater than the normal diameter of the treated vessel so as to ensure it would remain in place once deployed and leave the lumen of the vessel unobstructed.

41. Finally, I should mention that for many years prior to 2000 sheaths had been used to cover or contain stents prior to deployment. It was also well known to cover the outside of stents with bio-compatible material such as Dacron, for example to create stent grafts used to support or isolate a weak portion in a vessel, such as an arterial aneurysm.

The Patent

42. The Patent opens with a description of the "Technical field of the invention". It states that the invention includes a medical device and, more specifically, a valve found generally within a frame which, in preferred devices, comprises a radially expandable stent which can be delivered through a delivery device such as a catheter.

43. Paragraph [0002] explains that the closest prior art is EP-A-0808614 (the "614 application") which, it is said, discloses the preamble to claim 1. The 614 application relates to a self-expandable stent with a tri-leaflet or bi-leaflet valve member, preferably "made of parts from living organisms such as a valve from a pig or a pericardium from a cow".

44. The "Background of the invention" is set out from paragraphs [0003] to [0007]. Two types of known replacement valves are described: mechanical devices with moving ball valves which are susceptible to clot formation and problems associated with long-term wear and tear; and biological valves which suffer from a variety of problems including the supply of valves, immune response and problems associated with positioning. The Patent explains there is therefore a need for alternative and

improved devices and methods of providing valvular function within vessels of the body.

45. Paragraph [0008] contains a “Summary of the Invention”. It discloses a medical device comprising a frame with a valve located within it. The frame comprises a radially-expandable stent (including especially a self-expanding stent) which can be delivered using a catheter and then deployed and expanded at a target site in a body lumen such as an artery or vein. A preferred use is for the treatment of incompetent veins in the legs or feet.

46. There then follows a “Detailed description of the invention”. Paragraph [0010] explains that a valve assembly may have two or more leaflets or cusps. The structure of a typical stent of the invention is depicted in figures 1-3 and described in paragraphs [0011] to [0013]. One embodiment is said to be a self-expanding stent such as the Gianturco and the figures depict a simple arrangement of a cylinder formed by a wire bent or otherwise formed into a zigzag configuration. The specification explains that the bends at the proximal and distal ends of the stent may be connected by sutures which can be used to adjust the size of the stent lumen upon expansion.

47. Paragraphs [0014] to [0017] explain how the valve may be fashioned from a sheet of valve material draped over the stent lumen and then pushed down into its interior. According to the invention, the valve material is said to be a collagen containing bio-material comprising pericardium which is then fixed to the stent frame by a variety of well known means including sutures, adhesives and folds. Connection of the valve to the frame is shown in figures 6A and 6B and the Patent explains that it may be sutured at its distal and proximal ends.

48. Paragraph [0018] relates that once the sutures are generally in place, the valve sheet will form a valve pocket, as shown in figure 6B:

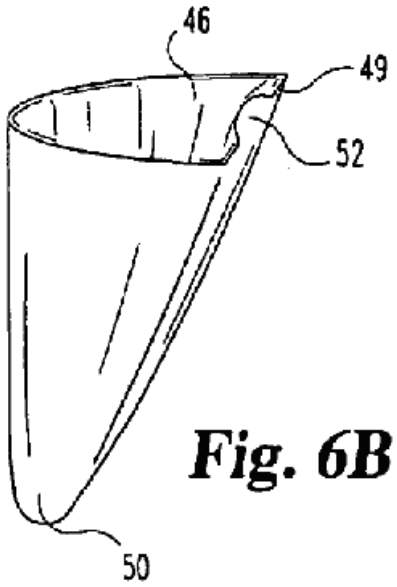


Fig. 6B

49. The pocket has a valve apex (50) which extends inside the stent lumen and may be sutured to the distal end of the stent frame. There is a part of the valve that will form a central valve portion (49) that is not directly sutured to the stent, but otherwise the

valve is sutured around its proximal perimeter to the proximal end of the stent. The valve portion (49) forms the valve opening (52) through which fluid can pass as it flows from the distal to the proximal end of the device. However, if the flow is reversed then the valve pocket (46) fills and the fluid pressure causes the valve portion (49) to extend outwards and, when it does so, to contact the other leaflets or cusps and so form a seal to stop or impede fluid flow.

50. Figure 8, reproduced below, illustrates the valve set in the stent with its distal apex (50) sewn to a distal bend of the stent with a suture (40). It also shows the proximal perimeter of the valve connected to the proximal portion of the stent with two sutures (44):

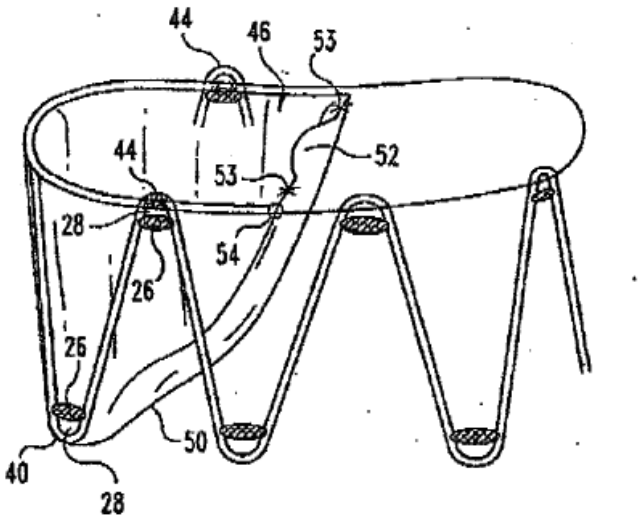


Fig. 8

51. Paragraph [0021] continues that the valve opening is actually created in the final step of preparation of the preferred device. First, a second valve pocket is made by pushing the same sheet of valve material down into the interior on the other side of the stent. The two valve pockets are now sitting side by side. The opening can then be created by cutting a slit in the sheet which can be sized according to the intended flow rate of the passing fluid. The Patent also recognises that opening and closing the valve may cause increased wear and tear at the corners of the opening and, for this reason, reinforcements may be provided in the form of sutures, as illustrated at (53), or by the use of adhesives or any other material or mechanism that permits increased structural integrity. The Patent also explains in paragraph [0033] that the slit may terminate several millimetres (say 1 to 5 mm) before reaching the edge.

52. There then follows a description of how the devices of the invention may be made to different sizes. Paragraph [0022] explains this may be achieved either by elongating the length of the struts of a single stent or by joining a number of stents together (by, for example, sutures). It is preferred that the overall length of the device provides an aspect ratio (length to expanded diameter) sufficiently high to permit proper alignment of the device and that aspect ratios of length to expanded diameter of 1:1 or greater are preferred. It is to be noted, however, that in devices comprising multiple

stents there is no requirement that the individual stents should themselves be of any particular length. The teaching of the Patent is simply that the length of the whole device should be appropriate for its intended application and its aspect ratio should be such as to allow proper alignment.

53. A variety of multiple stent structures are then described and depicted but some are said not to be part of the invention, a reflection of the citation by the examiner of the 614 application. Thus figure 12, described in paragraph [0028], is said to be a multi-stent device of the invention:

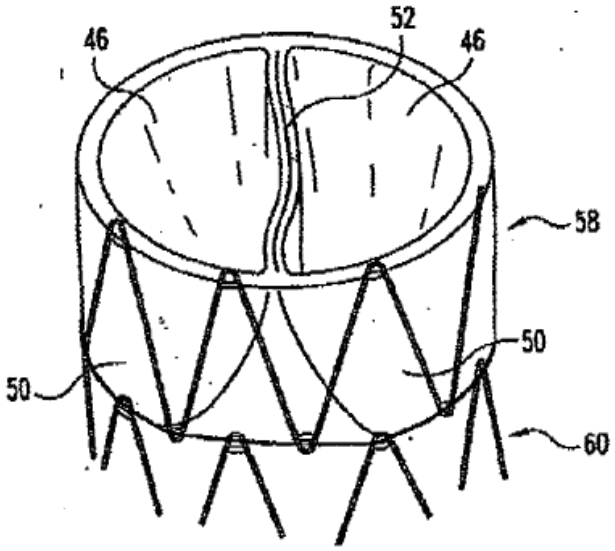


Fig. 12

54. As is figure 17:

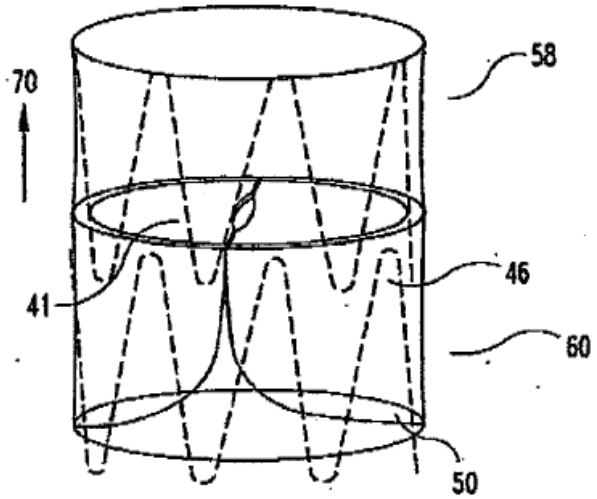


Fig. 17

55. Conversely, figure 15, which comprises two stents, with the valve extending half way down the upper stent, is expressly said by paragraph [0023] to be *not* part of the invention:

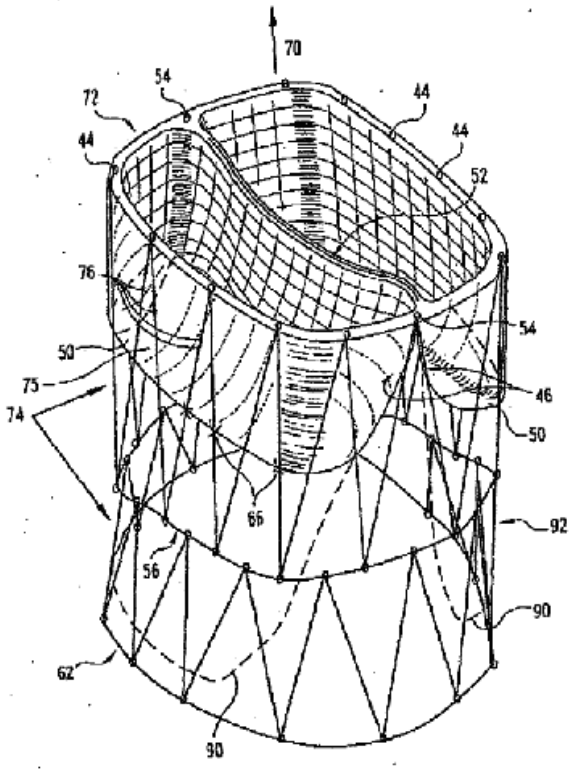


Fig. 15

56. Likewise figure 19, described in paragraph [0037], is *not* part of the invention. In this case the valve (41) begins in the second stent (6) and extends into the third stent (61):

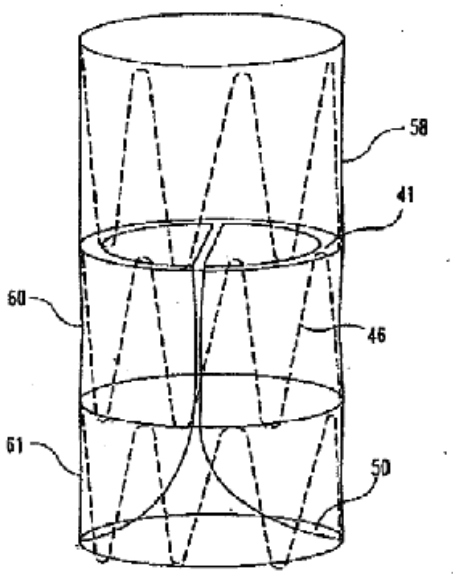


Fig. 19

57. There is one other element of the description to which I should refer. The Patent explains in paragraphs [0029] to [0031] that the outside of the stent may be wholly or partly covered by a sheath. So, for example, excess valve material may be folded over to increase the structural integrity of the device and to present a smoother surface to the body upon implantation. Alternatively the sheath may be made of a synthetic material such as Dacron.

58. Before turning to the claims, I think it is of some note that the Patent contains no experimental results and no detailed discussion of how the invention may be implemented. It assumes, for example, the skilled person can work out the necessary structural characteristics of the stent, such as its length and diameter (both crimped and expanded) and the dimensions and configuration of its struts and the thickness, strength and resilience of the wire from which it is to be made.

The claims - interpretation

59. The parties sensibly agreed a breakdown of the integers of claim 1:

[A] A stent valve, suitable for placement in a vessel, the vessel further having a diameter (84) and an inner lumenal surface, comprising:

[B] a) a radially expandable stent (20) having a proximal stent end (31) and a distal stent end (33),

[C] the stent having an expanded diameter (86) sized to permit contact with an inner lumenal surface of the vessel;

[D] b) a valve (41) having a proximal valve end (48) and a distal valve end (50),

[E] the valve being at least partially located within an inner portion of the stent,

[F] wherein the valve is formed with a collagen containing bio material (38),

characterised in that

[G] said collagen containing bio material comprises pericardium

[H] and extends within said stent (20) substantially from said proximal stent end (31) to said distal stent end (33)

[I] and forms at least two valve leaflets (46)

[J] that extend substantially from said proximal stent end (31) to said distal stent end (33),

[K] with the proximal valve end (48) connected to the proximal stent end (31)

60. It is also helpful to have to have in mind the dependent claims in issue:

> 3. The stent valve of claim 1, wherein a sheath (42) partially covers the stent.
>
> 8. The stent valve of claim 6, wherein a sheath (42) partially covers the exterior surface of the stent (20).
>
> 12. The stent valve of claim 1, wherein the valve comprises three leaflets (46).
>
> 15. The stent valve of claim 14, wherein the valve opening (52) extends across the diameter of the stent (20) so as to terminate at least 1 mm from a stent perimeter (34).
>
> 22. The stent valve of claim 21, wherein the valve opening (52) terminates at least 1 mm from a stent perimeter (34).
>
> 23. The stent valve of claim 21, wherein a reinforcement (53, 54) is generally located at a valve opening (52) and a stent perimeter.
>
> 28. The stent valve of claim 1, wherein the stent (20) is a non-self expanding stent.
>
> 31. A stent valve of any of claims 1 to 29, which is a heart valve.

61. The claims gave rise to a myriad of disputes as to their proper interpretation. I will address them in turn. In doing so I have had well in mind the principles explained by the House of Lords in *Kirin Amgen v Hoechst Marion Roussel* [2004] UKHL 46; [2005] RPC 169. In summary, the question is what the skilled person would have understood the patentee to be using the language of the claim to mean. And for this purpose, the language of the claim is usually of critical importance.

Integer [B] – stent

62. This is primarily relevant to validity over Andersen but it also has a bearing on infringement. Edwards recognises that "stent" was a term of art. To the interventional cardiologist a stent was a device which could be expanded in the lumen of a vessel to provide a scaffolding structure to hold the vessel open. To the cardiac surgeon it was the frame or structure which supported a mechanical or bioprosthetic replacement valve. In both cases the term stent was generally used to refer to the whole structure.

63. Edwards contends, however, that the Patent uses the term stent in a different sense, that devices made from zigzag units were at the forefront of the patentee's mind and that where the device comprises multiple zigzag units joined together, the Patent

treats each one as a separate stent and that is so even if they form part of one integral structure. Edwards continues that such is apparent from, for example, figures 12, 15, 17 and 19 reproduced above, each of which is said by the Patent to comprise a number of stents.

64. I agree that the Patent describes each of the zigzag units in these figures as separate stents but it is, I think, significant that the various units are recognisably distinct structures which are sutured together and, moreover, each of them has the appearance of and may be said to be performing at least some of the functions of a stent, that is to say holding the lumen open, keeping the device in position and supporting the valve. I consider the Patent is doing no more than saying that the devices of the invention may comprise what the skilled person would understand to be a series of individual stents joined together. It is true that the Patent says these units are still to be regarded as stents for the purposes of the invention, and to this extent I accept Edwards' submission. But there is no text or figure which suggests that the patentee intended integral parts of a composite structure should be considered as stents and that would be entirely contrary to the understanding of the skilled person based upon his common general knowledge.

Integer [B] - radially expandable

65. This is relevant to validity over Andersen, Moll and Pavcnik and I consider it further in that context. But briefly the point is this. Cook contends the claim is limited to stents which expand symmetrically along radii and in which the direction of expansion is at all times in the radial direction. In other words, expansion is uniform, like a balloon, and each point of the stent stays in the same plane as it moves outwards, as if it were moving along the spokes of a bicycle wheel.

66. I reject this contention. There is nothing in the Patent to suggest the invention is limited to stents which expand uniformly in the way Cook describes. Indeed paragraph [0011] makes clear it covers all stents whether self-expanding or non self-expanding. These stents had a wide variety of structures and configurations including coils, clam-shells, meshes and slotted tubes, and their various elements certainly did not all expand symmetrically and only in the radial direction. However, the stents were all radially expandable in the sense that they each formed a tubular structure which had a radius less than that of the lumen so as to allow them to be delivered into position and then, upon deployment, a radius at least that of the lumen so as to fix them in position and hold the lumen open. In my judgment that is what the claim requires.

Integer [B] - proximal and distal end

67. This is also important to validity over Andersen and infringement and it ties in to some extent with the immediately foregoing feature, "radially expandable". As will be seen, Andersen has three loops which extend from the proximal end of the stent. Edwards contends these form part of the stent, a matter which Cook disputes. I consider the skilled person would understand the ends of the stent to be the ends of the device that carries out any of the functions of the stent, namely holding the lumen open, keeping the device in position and supporting the valve. I say any of these because it would be apparent to the skilled person from the description and his common general knowledge that a stent of the invention placed in the aortic annulus

might extend into the aortic sinuses and, if so, it would not at that point be holding the lumen open or keeping the stent in position. However it would still be supporting the valve, a vital function and one which was performed by the commissural posts of the stents of surgical prosthetic valves.

Integer [D] - valve

68. This integer and the next are of considerable importance to infringement, as will be seen. Cook contends and Edwards disputes that the valve of the invention and the valve leaflets are one and the same, that the valve is limited to those elements which actually move to allow or restrict the flow of blood and that the valve does not include other elements, for example the rest of a pocket which may provide a region for blood to collect so as to exert pressure on the elements which do move and cause them to close, or otherwise to provide additional functionality, such as acting as an aid to deployment or reducing leakage potential.

69. I think it is clear that the Patent does not consider the valve to comprise only the elements which move. So, for example, paragraph [0014] and figures 4 and 5 respectively describe and depict the construction of *the valve* from a sheet of *valve material* which is pushed down into the stent lumen to form a pocket. Excess material can either be trimmed off or become a potential "fold over". The Patent then explains that the *valve material* is connected to the stent by any of the well known ways including a distal valve-stent suture (40).

70. Even more clearly, figure 6B (reproduced at paragraph [48] above) depicts what is described in paragraphs [0017] and [0018] of the Patent as being *the valve*. This is made from the valve sheet and is said to have formed a pocket (46) extending inside the stent lumen which will be filled by fluid when the flow is reversed. The moving part of the valve is identified as the "central valve portion" (49) which forms the valve opening (52). The Patent also explains that, as shown in figure 8 (reproduced at paragraph [50] above), the proximal portion of the valve is sutured to the stent frame by sutures (44). These are plainly around the outer perimeter of the proximal end of the valve pocket.

71. A little confusingly, claim 1 of the Patent identifies the leaflet as component (46), whereas throughout the description component (46) is referred to as the valve pocket. This would be consistent with claim 27 which is not asserted to be independently valid and is directed to a valve in which the *leaflets comprise a pocket*. Be that as it may, I am entirely satisfied the skilled person would understand the valve is not limited to the elements of the device which move to permit or restrict the flow of blood through its lumen, for the reasons I have given. I would add that this is the result the skilled person would expect. For example, the prosthetic devices with which he was familiar were referred to as "valves" and they included moving and non moving parts.

Integer [F] - formed with a collagen containing biomaterial

72. The claim specifies that "the valve is formed with a collagen containing biomaterial". Cook says it is enough if the valve *contains* a collagen containing biomaterial. I disagree. The words of the claim are clear and unambiguous. They are also consistent with the description which states at column 4, lines 14 to 16:

> "According to the invention the valve material 38 is a collagen containing biomaterial comprising pericardium."

73. The patentee has limited the claim to devices in which the valve is made of collagen containing biomaterial.

Integers [H] and [J] - extends substantially from said proximal stent end to said distal stent end

74. These integers are relevant to validity over Andersen, insufficiency, added matter and infringement. They were introduced by amendment and form part of the characterising portion of the claim. I have to say I have not found Cook's case on them to be entirely consistent. In his first report, Professor Williams thought it enough that the valve and leaflets extend over the majority of the length of the stent, by which I understood him to mean more than 50%. In cross examination he said he could not be precise but that two thirds was about the right figure. Edwards, on the other hand, says the valve and the leaflets must extend the whole or virtually the whole length of the stent.

75. A search for the purpose of these limitations in the body of the specification proves fruitless. There is no explanation of the benefits they purport to bring. Professor Rothman thought they would assist in bringing about an effective seal when the valve closes. Professor Williams considered that the steeper the angle of the leaflets the easier it would be for the blood to force the leaflets open and to close them under conditions of reverse flow.

76. The difficulty I have with both of these explanations is that they depend upon the absolute length of the leaflets whereas the claim is concerned with their length relative to the length of a stent. As has been seen, the Patent contemplates that a device of a particular overall length may comprise one or more stents – how many and what their individual length must be is not specified. Hence a valve and leaflets may extend substantially the whole length of a stent of a two or three stent device. If, however, the device is now made of only one stent, the same valve and leaflets will extend only half the length of the stent. Yet their efficacy will be unchanged.

77. The skilled person would, however, note that the figures of the Patent all appear to show the valve and leaflets extending the whole length of a stent. In the light of all these matters I think the skilled person would conclude that the Patentee intended the claim to be limited to devices in which the valve and leaflets extend essentially the whole length of a stent, which is to say virtually from one end of a stent to the other.

Claim 15 - extends across the diameter

78. Edwards submits that the valve opening can only extend across the diameter of the stent in the case of a bi-leaflet valve (or any other valve with an even number of leaflets) and, more specifically, that the reference to diameter necessarily excludes tri-leaflet valves. The valve opening of such products takes the form of a Mercedes logo rather than a diameter.

79. I am unable to accept this submission. Such an interpretation would exclude the well known tri-leaflet valve arrangement and, although it is true the figures all depict bi-

leaflet valves, the Patent expressly teaches in paragraph [0010] that the invention can comprise two, three or four leaflets.

Claim 15 - terminate at least 1mm from the stent perimeter

80. The dispute here is whether the measurement is taken from the inside or outside of the stent wire. The Patent explains in paragraph [0021] that the slit which forms the valve opening can be sized according to the intended flow rate of the passing liquid. Dr Buller explained in cross examination that he could not imagine wanting to limit the flow across a one-way valve, but if one did then any structure that helped to limit the stent perimeter would achieve that object, including the thickness of the stent itself.

81. I understand Dr Buller's viewpoint but I do not believe that is how the limitation would be understood by the skilled person. The natural interpretation of the limitation and the one which is consistent with the figures of the Patent is that the claim calls for a narrowing of the opening beyond that caused by the stent wire. I note this was also Dr Buller's initial opinion. In his first report he explained that he understood the claim to require a feature whereby there is a length of the leaflets between the end of the valve opening and the inner perimeter of the stent that cannot open. In my judgment he was right.

Priority

82. The international application (the "PCT application") which led to the grant of the Patent has an international filing date of 31 January 2001 and it claims priority from US patent application No. 60/179,195 (the "US application") filed on 31 January 2000. The claim to priority is disputed by Edwards, a matter of some importance because, if priority is lost, Pavcnik, published later in 2000, is relevant prior art.

83. The priority dispute is an unusual one and depends upon the proper interpretation of Article 4 of the Paris Convention. But first I must explain the relevant factual background.

84. The US application was filed in the names of Joe Obermiller, Francisco Osse and Patricia Thorpe, all as joint inventors. Mr Obermiller was an employee of Cook at the time the invention was made. Mr Osse and Ms Thorpe were not.

85. The PCT application was filed in the name of Cook but at that time the only interest it had in the invention was via Mr Obermiller's contract of employment. It is accepted that Mr Obermiller's interest, such as it was, belonged to Cook.

86. The interests of Mr Osse and Ms Thorpe were not assigned to Cook until September 2002, that is to say 21 months after Cook filed the PCT application but before the grant of the Patent.

87. In these circumstances Cook says the claim to priority is a good one because it had acquired all rights in the invention before the date of grant of the Patent and in any event always owned Mr Obermiller's interest. Edwards says the claim is misconceived because the right of priority may only be enjoyed by the person who filed the priority application or his successor in title as at the date the right to priority

is claimed, and on 31 January 2001 that was Mr Osse, Ms Thorpe and Cook, not Cook alone.

88. Entitlement to priority is addressed in section 5 of the Patents Act 1977 ("the Act") which (as it existed at the relevant time) says:

> "5(1) For the purpose of this Act the priority date of an invention to which an application for a patent relates and also of any matter (whether or not the same as the invention) contained in any such application is, except as provided by the following provisions of this Act, the date of filing the application.
>
> (2) If in or in connection with an application for a patent (the application in suit) a declaration is made, whether by the applicant or in any predecessor in title of his, complying with the relevant requirements of rules and specifying one or more earlier relevant applications for the purposes of this section made by the applicant or a predecessor in title of his and each having a date of filing during the period of twelve months immediately preceding the date of fling the application in suit, then-
>
> (a) if an invention to which the application in suit relates is supported by matter disclosed in the earlier relevant application or applications, the priority date of that invention shall instead of being the date of filing of the application in suit be the date of filing the relevant application in which that matter was disclosed or, if it was disclosed in more than one relevant application, the earliest of them;
>
> (b) the priority date of any matter contained in the application in suit which was also disclosed in the earlier relevant application or applications shall be the date of filing the relevant application in which that matter was disclosed or, if it was disclosed in more than one relevant application, the earliest of them."

89. It is also convenient to refer to section 7 of the Act which deals with the right to apply for and obtain a patent:

> "7(1) Any person may make an application for a patent either alone or jointly with another.
>
> (2) A patent for an invention may be granted-
>
> (a) primarily to the inventor or joint inventors:
>
> (b) in preference to the foregoing, to any person or persons who, by virtue or any enactment or rule of

law, or any foreign law or treaty or international convention, or by virtue of an enforceable term of any agreement entered into with the inventor before the making of the invention, was or were at the time of the making of the invention entitled to the whole of the property in it (other than equitable interests) in the United Kingdom;

(c) in any event, to the successor or successors in title of any person or persons mentioned in paragraph (a) or (b) above or any person so mentioned and the successor or successors in title of another person so mentioned;

and to no other person.

(3) In this Act "inventor" in relation to an invention means the actual deviser of the invention and "joint inventor" shall be construed accordingly.

(4) Except so far as the contrary is established, a person who makes an application for a patent shall be taken to be the person who is entitled under subsection (2) above to be granted a patent and two or more persons who make such an application jointly shall be taken to be the persons so entitled."

90. Section 5, but not section 7, is one of those sections said by section 130(7) of the Act to have been framed as to have, as nearly as practicable, the same effect as the corresponding provisions of the EPC (Article 87) and the PCT (Article 8).

91. Of these I need only refer to the relevant parts of Article 8 of the PCT:

"(1) The international application may contain a declaration, as prescribed in the Regulations, claiming the priority of one or more earlier applications filed in or for any country party to the Paris Convention for the Protection of Industrial Property.

(2) -

(a) Subject to the provisions of sub-paragraph (b), the conditions for, and the effect of, any priority claim declared under paragraph (1) shall be as provided in Article 4 of the Stockholm Act of the Paris Convention for the Protection of Industrial Property.

92. This takes one back to the Paris Convention (Stockholm revision), Article 4, which reads, so far as relevant:

"A (1) Any person who has duly filed an application for a patent, or for the registration of a utility model, or of an industrial design, or of a trademark, in one of the countries of

> the Union, or his successor in title, shall enjoy, for the purpose of filing in other countries, a right of priority during the periods hereinafter fixed.
>
> (2) Any filing that is equivalent to a regular national filing under the domestic legislation of any country of the Union or under bilateral or multilateral treaties concluded between countries of the Union shall be recognized as giving rise to the right of priority.
>
> (3) By a regular national filing is meant any filing that is adequate to establish the date on which the application was filed in the country concerned, whatever may be the subsequent fate of the application.
>
> ….
>
> D (1) Any person desiring to take advantage of the priority of a previous filing shall be required to make a declaration indicating the date of such filing and country in which it was made. Each country shall determine the latest date on which such declaration must be made.
>
> (2) These particulars shall be mentioned in the publications issued by the competent authority, and in particular in the patents and the specifications relating thereto."

93. So Article 4 specifies a person is to enjoy a right of priority if he has filed a relevant application for a patent or if he is the successor in title to such a person. Successor in title here must mean successor in title to the invention, as the parties before me agreed. Further, any person wishing to take advantage of the priority of such a filing must be required to make an appropriate declaration.

94. Both elements of Article 4 are reflected in section 5 of the Act which requires a declaration made by the applicant which complies with the relevant rules and specifies one or more earlier relevant applications made by the applicant or a predecessor in title.

95. In my judgment the effect of Article 4 of the Paris Convention and section 5 of the Act is clear. A person who files a patent application for an invention is afforded the privilege of claiming priority only if he himself filed the earlier application from which priority is claimed or if he is the successor in title to the person who filed that earlier application. If he is neither the person who filed the earlier application nor his successor in title then he is denied the privilege. Moreover, his position is not improved if he subsequently acquires title to the invention. It remains the case that he was not entitled to the privilege when he filed the later application and made his claim. Any other interpretation would introduce uncertainty and the risk of unfairness to third parties. In reaching this conclusion I derive a measure of comfort from the fact that the Board of Appeal of the EPO has adopted the same approach to the interpretation of Article 87 EPC in two cases: J 0019/87 and T 0062/05.

96. Nevertheless, Cook contends this interpretation is inconsistent with section 7 of the Act which distinguishes between an application for a patent and its grant. Section 7(1) permits any person to make an application for a patent. Section 7(2), on the other hand, restricts the persons to whom a patent may be granted to the inventor or inventors, to any person or persons entitled to the property in the invention when it was made or to the successor or successors in title to any such person or persons. It follows, says Cook, that, as "any person", it was entitled to make the application for the Patent in January 2001 and, as the successor in title to all the inventors as a result of the assignment of September 2002, it was entitled to the grant of the Patent in April 2007. If this is the position in relation to grant then, Cook continues, it must be the same in relation to priority.

97. I am unable to accept this submission. The two sections are dealing with separate issues, the right to claim priority in the case of section 5, and the right to the grant of a patent in the case of section 7. Further, section 7 is not one of those sections said by section 130(7) of the Act to have a corresponding provision in the EPC, the CPC or the PCT. By contrast, section 5 has been framed so as to have the same effect as Article 8 of the PCT and so also Article 4 of the Paris Convention. I do not consider it permissible to interpret the Paris Convention in the light of section 7 of the Act. Finally, section 7 provides a complete code as to those persons entitled to the grant of a patent. In the case of a successor in title, he must have derived title by the date of grant. There is no equivalent provision in Article 4 of the Paris Convention.

98. I therefore conclude that the acquisition by Cook of all rights in the invention in September 2002 does not permit it to claim priority from the US application.

99. That leaves the alternative argument advanced by Cook, namely that it always owned Mr Obermiller's interest in the invention and that is sufficient. I can deal with this argument quite shortly. The US application was filed in the names of Mr Obermiller, Mr Osse and Ms Thorpe, all as joint inventors. It was not filed by Mr Obermiller alone and therefore he was not "a person" who had "duly filed an application for a patent" within the meaning of Article 4A(1) of the Paris Convention. Once again, this approach is consistent with that adopted by the Board of Appeal of the EPO in case T 0788/05.

100. In summary, the Patent is not entitled to a priority date earlier than 31 January 2001 and so Pavcnik is relevant prior art.

Novelty – general

101. The law in relation to novelty was explained by the House of Lords in *Synthon v Smithkline Beecham* [2005] UKHL 59; [2006] RPC 323. There are two requirements. First, the matter relied upon must disclose matter which, if performed, would necessarily result in an infringement of the patent. Secondly, the disclosure must have been enabling, that is to say the ordinary skilled person would have been able to perform the invention without undue difficulty if he had attempted to do so.

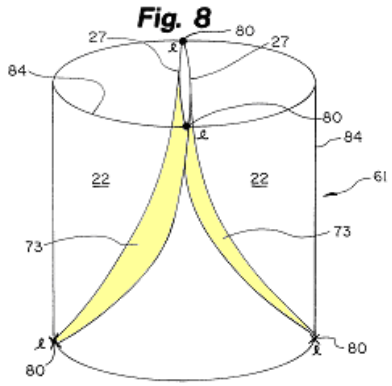
Novelty - Thorpe

102. Thorpe is a PCT application which was filed on 22 December 1999 and published on 22 March 2001. Hence it is available only to support an allegation of lack of novelty

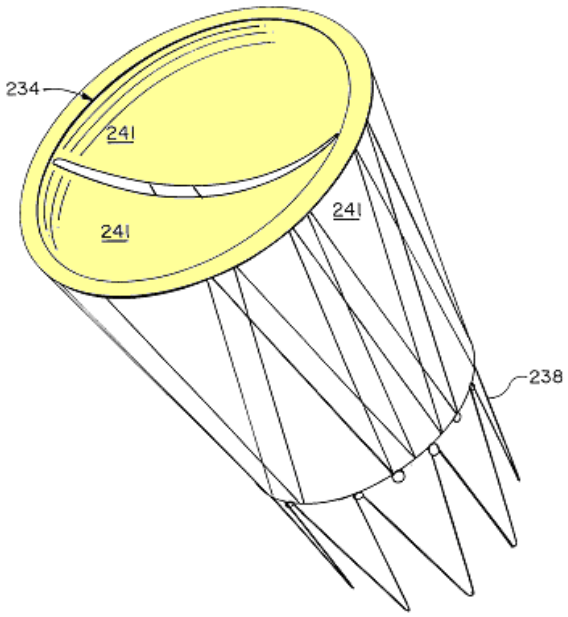
under section 2(3) of the Act. It bears many similarities to the Patent which is, perhaps, not surprising in the light of the fact that Patricia Thorpe is one of the inventors of the Patent.

103. Thorpe is entitled "Endovascular treatment for chronic venous insufficiency" and describes a replacement valve assembly configured for implantation within a vascular lumen. The valve assembly comprises a plurality of flexible members with, in the words of Thorpe, each flexible member "arranged to cooperate with at least one other flexible member to unidirectionally admit vascular fluid through the valve assembly".

104. Figure 8 of Thorpe shows a representative device simplified to demonstrate the connection of the valve material (73) at connection sites (80) on a stent frame (84). Here it is with the valve material shaded:



105. Figure 24 is described as an alternate embodiment stent and valve device with valve material arranged both inside the lumen and outside the structure of the generally tubular shaped device. It has shallow leaflets and is said to be one of several embodiments which have dual application to both venous and other vascular uses, including as an arterial-venous fistula treatment device. It looks like this:



106. As for the material from which the valve is to be made, Thorpe says at page 4, lines 24-28:

> "The use of the material chosen for endovascular valve replacement in this assembly represents a unique application of a biocompatible substance. Whether the material is formed of elastomer, sclera, small intestine sub-mucosa (SIS), other mammalian tissue, or other suitable material, the venous stent device of this invention will serve as a substitute for deteriorated venous valves which have been altered by thrombosis or congenital hypoplasia."

107. In light of the foregoing Edwards contends that Thorpe discloses all the integers of claim 1 of the Patent. I did not understand this to be seriously contested by Cook save for integer [G]. Cook says it does not disclose the use of pericardium as the valve material. Cook's position was supported by the evidence of Professor Williams, which I accept, that the emphasis in Thorpe is on sclera, with small intestine sub-mucosa ("SIS") as a preferred alternative, and then with the further possibility of using other mammalian tissues or synthetic material. As for these other mammalian tissues, the skilled person would consider pericardium and other tissues such as dura, cartilage, fat, fascia and skin. He would not regard the teaching of Thorpe as a direction to use pericardium specifically.

108. I am satisfied on the evidence that the skilled person would understand the reference to "other mammalian tissue" to be teaching him that he could use a range of other mammalian tissues and that pericardium would be one of the obvious tissues, and indeed, the most obvious tissue, which would occur to him. The question is whether that is sufficient for the purposes of anticipation.

109. In my judgment it is not. Anticipation requires prior disclosure of subject matter which, when performed, must necessarily infringe the patent. The distinction between this and obviousness may seem artificial and, on occasion, difficult to draw. But it is a distinction the law demands and is the reason a generic disclosure will not normally take away the novelty of any specific example falling within that disclosure. As Lord Hoffmann said in *Synthon* at [23]:

> "But the infringement must not merely be a possible or even a likely consequence of performing the invention disclosed by the prior disclosure. It must be necessarily entailed. If there is more than one possible consequence, one cannot say that performing the disclosed invention will infringe. "

110. The allegation of anticipation based upon Thorpe therefore fails. I should, however, deal at least briefly with the other claims for which independent validity is contended over Thorpe. In my judgment there is no disclosure of a device falling within the scope of claims 3 and 8 because Thorpe does not describe a sheath save in connection with a device of the kind depicted in figure 24 which does not fall within the scope of claim 1. There is no disclosure of a valve opening that terminates at least 1mm from a stent perimeter as called for by claims 15 and 22 or of any reinforcement as called for by claim 23. Thorpe does describe pockets in connection with a device of figure 24 but, as I have said, this does not fall within the scope of claim 1. Accordingly the

features of claim 27 are not disclosed. Finally, Thorpe does not give clear directions to make a heart valve as called for by claim 31.

Obviousness – general

111. It is helpful to address an allegation of obviousness using the structured approach explained by the Court of Appeal in *Pozzoli v BDMO* [2007] EWCA Civ 588; [2007] FSR 37. This involves the following steps:

(1) (a) Identify the notional "person skilled in the art".

(b) Identify the relevant common general knowledge of that person.

(2) Identify the inventive concept of the claim in question or, if that cannot readily be done, construe it.

(3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed.

(4) Ask whether, when viewed without any knowledge of the alleged invention as claimed: do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

112. In a case such as this, involving as it does devices which are not unduly complicated, it is particularly important to assess the question of obviousness without the benefit of hindsight and to keep well in mind that simplicity is no bar to invention. As Laddie J explained in *Haberman v Jackel* [1999] FSR 683 at 697, the simpler a solution, the easier it is to explain and the easier it is to explain, the more obvious it can appear. This may be unfair to an inventor.

Obviousness - Andersen

113. Andersen is a US patent entitled “Valve prosthesis for implantation in the body and a catheter for implanting such valve prosthesis”. It was published on 2 May 1995. As both parties recognise, this publication forms the basis for the strongest obviousness attack on the validity of the Patent.

114. In the section headed “Background of the Invention”, it is explained that the invention relates to a valve prosthesis, preferably a cardiac valve prosthesis, for implantation in the body and comprises a collapsible elastical valve mounted on an elastical stent. The “Summary of the Invention” elaborates that the invention provides a stent made from a radially collapsible and re-expandable cylindrical support and a collapsible valve for implantation in the body by means of a catheter. The valve is mounted on the stent by, for example, sutures. The stent itself may be grate shaped, loop shaped or helical and may be either self-expanding or non self-expanding, in which case it may be compressed onto a balloon catheter. The valve prosthesis can be used to replace a natural valve or to establish a new valve function in one of the channels in the body which do not naturally contain a valve. When the valve prosthesis is used as a cardiac valve prosthesis in the aorta, it is explained that it can be mounted in the descending part of the aorta, in a position between the coronary arteries and the left

ventricle of the heart, or in the aorta in a position immediately after the mouth of the coronary arteries. It can also be used in the pulmonary artery or the right ventricle for replacing the pulmonary valves.

115. Andersen continues in column 4 that the stent may be made with a relatively great height and with a cylinder surface which is closed by a suitable material. This may facilitate the implantation of the device and securing it in position in the aorta. Such an embodiment is also said to be suitable for a prosthesis inserted into veins which have relatively thin and weaker walls. Here the sheath provides a greater surface over which to distribute the outward pressure necessary to secure it in position.

116. The detailed description of a preferred embodiment begins in column 5 and is illustrated in figures 1 and 2:

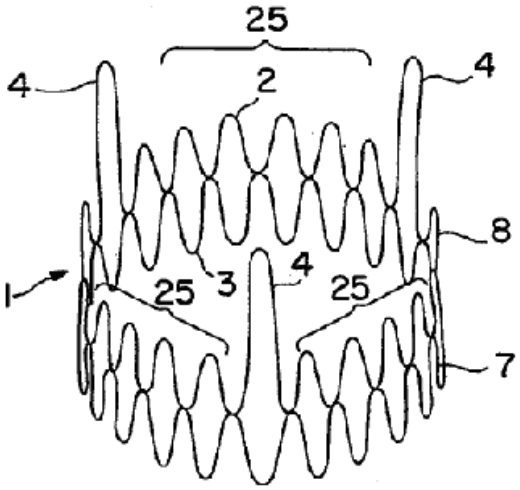


FIG. 1

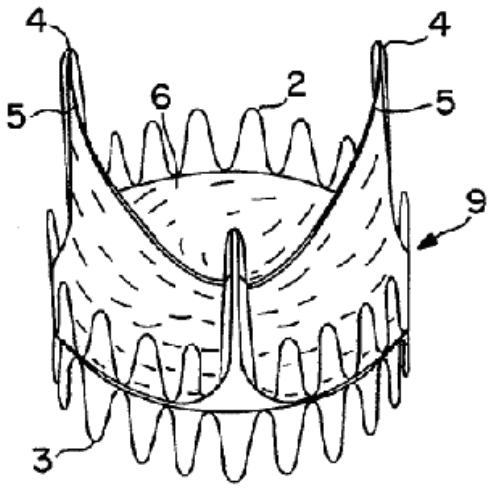


FIG. 2

117. It can be seen that the stent (1) is made from two surgical stainless steel wires ((2) and (3)) folded into loops. Three loops (4) are higher than the others and intended to secure the commissural points (5) of a biological cardiac valve (6) which is mounted in the stent. The remaining loops form circumferentially expandable sections (25) between the commissural points (5). The two folded wires are bent to form rings ((7) and (8)) which are closed by welding their ends. These are placed on top of each other and are secured by a means of a number of sutures.

118. The description continues that in the particular embodiment described the biological valve (6), a xenograft, was removed from a slaughtered pig, cleaned and then mounted in the stent (1). The valve had an outer diameter of 25-27mm and was mounted in the stent by means of sutures.

119. The whole valve prosthesis was then compressed, so reducing its outer diameter to 10mm and mounted on a balloon catheter with an outer diameter of 13.6mm. As Professor Rothman explained, the size of the valve meant that the prosthesis could only be compressed to a certain extent and, as a result, could not have been percutaneously delivered in a human, where the artery in the groin has a maximum diameter of about 8mm.

120. Figures 5 to 7 show a schematic representation of how the device can be deployed in the aorta by using a catheter (11) and an inflatable balloon (13):

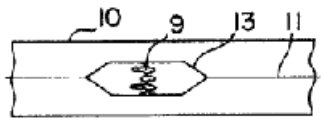


FIG. 5

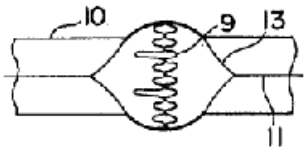


FIG. 6

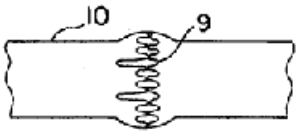


FIG. 7

121. Andersen explains at column 6, lines 30 to 36 that to obtain an effective fastening in the aorta, the outer dimension of the prosthesis is greater than the diameter of the aorta. This means that it fits tightly against the inner wall of the aorta with a pressure which is sufficiently large to prevent detachment due to the flow of blood.

122. Various modifications are proposed from column 6, line 66 to column 7, line 16. Specifically it is explained that the prosthesis may be modified and made solely of one closed ring folded in a number of loops or with three or more mutually secured loop-shaped rings placed on top of each other. Moreover it is possible to make the stent having a thread structure which instead of loops is grate shaped, helical or formed in some other way as to permit the compression and expansion of the stent and the fastening of the collapsible valve inside it. It is further explained that instead of a biological valve it might be possible to use other collapsible valves, such as valves made from synthetic materials such as polyurethane, and valves with more or fewer flaps than three.

123. Finally, Anderson reiterates that the stent may have a closed cylindrical surface, making it especially suitable for use in vessels with weak walls, such as veins.

124. Turning to claim 1, my first task is to identify the differences between what is disclosed in Andersen and what is claimed. The parties were agreed that Andersen does not disclose integers [F] and [G] because it describes the use of a whole animal valve rather than a fabricated valve comprising pericardium. Cook also contends it does not disclose integers [B], [H], [J] and [K], for reasons I must now explain.

125. Cook focuses on the requirements imposed by integer [B] that the stent be radially expandable, integers [H] and [J] that the valve and leaflets extend substantially from the proximal end of the stent, and integer [K] that the proximal end of the valve be connected to the proximal end of the stent. It says that the proximal end of the radially expandable stent is the top of the small loops of the upper ring at the point marked (2) and that the apices of the higher loops (4) extend beyond its end and do not form part of it. Accordingly, it continues, the valve is connected to and extends from three points outside the proximal end of the stent and further, the loops do not themselves expand in a radial direction.

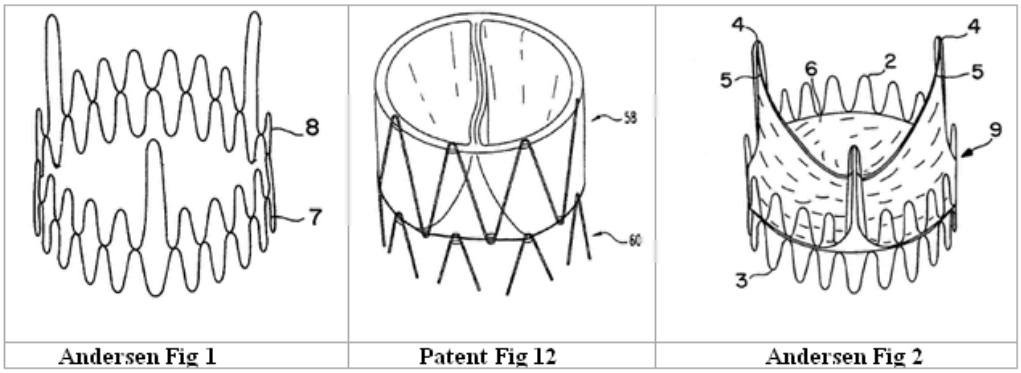
126. Professor Williams was of the view that the loops should be flexible so as to reduce the forces acting on the valve tissue, in the same way as the commissural posts of the surgically implantable valves such as the Perimount and, moreover, that they might or might not touch the lumen and that that he, as a designer, would make sure they did not. For my part I think it is apparent from figures 5 to 7 that they may well contact the lumen, particularly if the valve is placed into the pulmonary artery or into a vein.

However, assuming Professor Williams is right, I have no doubt the skilled person would still regard the loops as part of the stent called for by the Patent for all the following reasons. First, they form an integral part of the upper ring and could not be removed without destroying the integrity of the stent. Second, they support the valve, which is one of the functions of the stent. Third, they would be perceived by the skilled person to be performing a similar role to the commissural posts of the surgically implantable valves, such as the Perimount and, as I have explained, these were part of a frame which was described as a stent. Fourth, and entirely consistently, Andersen itself describes them as forming part of the stent (see, for example, column 5, lines 9 to 28). Fifth, whilst I accept that the loops do not themselves open out as the stent is expanded, they do move radially outwards together with the rest of the stent as the intervening sections (25) open out.

127. For all the foregoing reasons I conclude that Andersen describes a stent valve which comprises a radially expandable stent and a valve which extends within the stent substantially from its proximal end.

128. Cook also focuses on the distal end of the stent and contends that the skilled person would consider the Andersen device to be a single composite stent comprising the two rings (7) and (8). Accordingly it says the valve does not extend to the distal stent end as called for by integers [H] and [J].

129. Now it is true to say that all the experts thought that Andersen's device was a single stent, and that is how Andersen describes it. But that does not determine the matter because it depends not so much on how the skilled person would understand Andersen but rather upon how he would understand the term stent to be used in the Patent. This is an issue which I have considered at paragraphs [62] to [64]. I concluded the Patent contemplates a device which comprises a number of individual stents joined together and that it uses the term stent to describe a recognisably distinct structure which has the appearance of and performs at least some of the functions of a stent. If this approach is applied to Andersen it can be seen that the two rings are joined together by sutures, that each of the two rings does indeed have the appearance of a stent and that each does perform some of the functions of a stent in that it will assist in holding the lumen open and keeping the device in position. In summary, each of the rings is as much of a stent as the individual rings so described in the Patent, and such is apparent from the figures set side by side:



Andersen Fig 1	Patent Fig 12	Andersen Fig 2

130. In the terminology of the Patent I therefore believe that Andersen does comprise two stents and that the valve does extend to the distal end of the upper stent. I would also

observe that if the whole of the Andersen device is considered to be a single stent then the valve extends for about two thirds of its length – the distance which Professor Williams considered to be "substantially" the length of the stent as called for by integers [H] and [J].

131. I turn then to consider the final *Pozzoli* question, namely whether it was obvious to modify Andersen so as to produce a device falling within the scope of claim 1 of the Patent.

132. By the claimed priority date of January 2000, Andersen was around 5 years old. Moreover, Andersen's first paper, which Dr Buller accepted would have been found by the skilled person, had been published as early as 1992. The skilled person reading Andersen in 2000 would therefore have been aware that it had not led to the production of a commercial device in some 8 years. Nevertheless, Professor Rothman explained, and I accept, that the skilled person in 2000 would have considered Andersen to be an interesting idea and that it clearly discloses the idea of a stent that can carry a heart valve.

133. Professor Rothman also considered that the skilled person would have recognised two clear deficiencies in the Andersen device: first, the inherent weakness of a radially expandable stent comprising loops of surgical wire sewn together and second, the size of the compressed device.

134. So far as the weakness of the device is concerned, Professor Rothman thought the skilled person would have considered replacing the radially expandable rings with a device based on one of the known coronary stents, and adding the three apices. He would also have understood that a major contributor to the size of the device was the use of a whole biological valve and that this might be difficult to compress sufficiently for percutaneous delivery. Having regard to the explicit disclosure in Andersen that it might be possible to use other collapsible valves, such as those made from synthetic materials such as polyurethane, an option would have been to use a fabricated valve. As Professor Williams acknowledged, there were difficulties of working with polyurethane in that it had a tendency to degrade. So Professor Rothman thought the skilled person would have considered using pericardial tissue as an alternative. In short, he would have thought pericardial tissue was well worth trying.

135. I must also address Professor Rothman's view that the skilled person would also have replaced Andersen's expandable rings with a single stent, a modification which is suggested by Andersen itself. Cook contends the valve and leaflets would then have extended from the tips of the apices to a point around the middle of the length of the radially expandable stent.

136. Assuming the skilled person did indeed make this modification, I am entirely satisfied it would also have been obvious to extend the valve and leaflets to the distal end of the stent. Professor Williams explained that the benefits of having longer leaflets with a steeper angle would have been apparent to the skilled person in the light of the common general knowledge and these were considerations which a stent designer would have taken into account. So it was obvious to make them as long as possible.

137. In my judgment it was therefore obvious to modify Andersen by replacing the porcine valve with a fabricated valve made of pericardium and this would have resulted in a

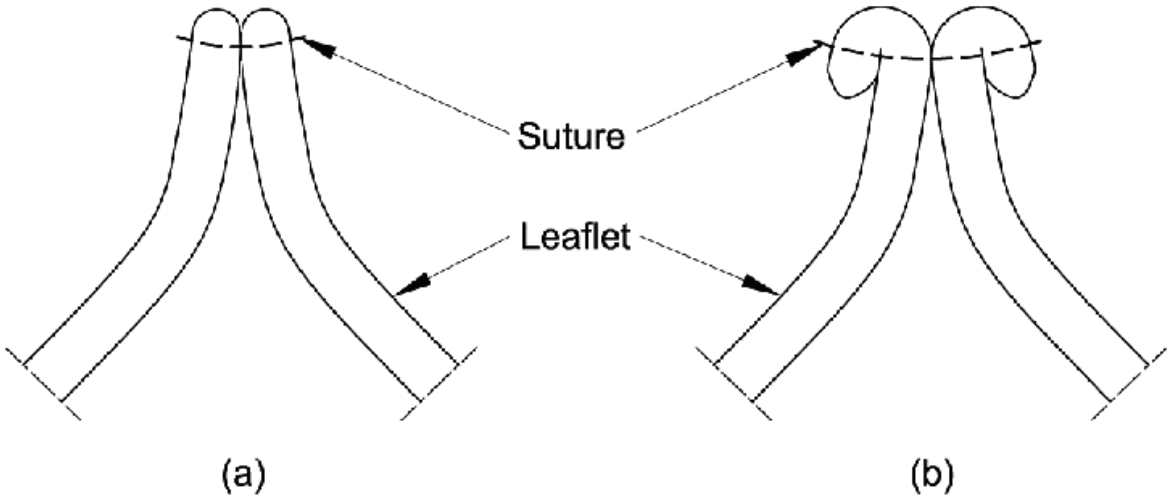
device falling within claim 1. It was also obvious to make the device using one stent and with a valve and leaflets extending substantially from the proximal stent end to the distal stent end.

138. As for the subsidiary claims said to have independent validity over Andersen, by the end of the trial these had been reduced to claims 15 and 22. They introduce the limitation that the valve opening must terminate at least 1mm from a stent perimeter.

139. As I have mentioned, the Patent teaches that narrowing the opening may assist in restricting the flow through the valve but interestingly none of the experts suggested that this is something the stent designer would wish to do, even with the benefit of the teaching of the Patent. The purpose of a heart valve is to let us much blood through as possible in one direction and none in the other. Nor is it suggested to be the reason the opening is narrowed in the SAPIEN device. Instead, it is a consequence of the way the leaflet material is secured to the stent at the proximal stent end.

140. Cook accepts that the skilled person seeking to replace the porcine valve of Andersen with pericardium leaflets might sensibly seek to position them so that they extend radially towards the centre, as they do in the Perimount and SAPIEN devices. But it says it was not obvious to have the leaflets pinched together at least 1mm from the edge of the stent.

141. Professor Rothman agreed in the course of cross examination that if the leaflets are positioned in the way I have described, they will not open all the way to the stent wall and there will always be a section of the valve which is closed. He also explained in his third report that it was obvious to tie the leaflets to the stent with sutures and to buttress their edges. However, he was unable to say how close to the stent the sutures would be. The arrangements he had in mind are reproduced below, with the buttresses shown in figure (b):



142. In his oral evidence Professor Rothman recognised both the need to reinforce the edges of the leaflets and the benefit of keeping the leaflets away from the stent wall.

143. Professor Williams considered the skilled person would have wished to ensure the leaflets were directed towards the centre of the valve and did not come into contact

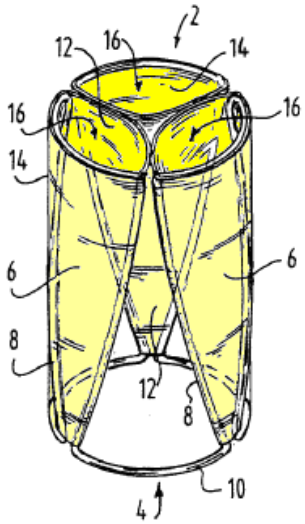
with the stent wall or the lumen wall. For this purpose it was obvious to stitch them together through their faces.

144. In the light of all the evidence I have come to the conclusion that orientating and securing the leaflets in ways which were known to be desirable might easily lead to a restriction of the valve opening of 1mm from the stent perimeter. So also might buttressing or reinforcing their edges. There is nothing significant in the figure of 1mm. These claims add nothing by way of invention over claim 1.

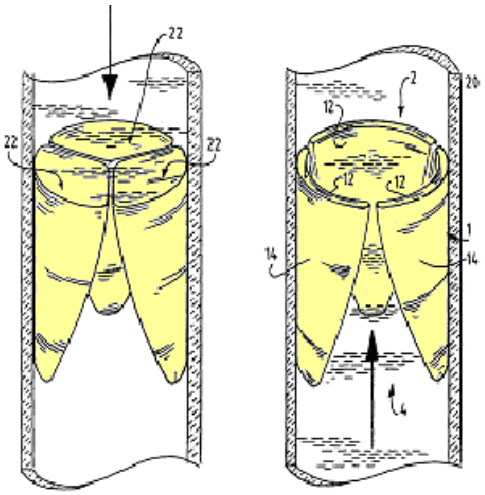
145. I conclude all of the claims of the Patent were obvious over Andersen.

Obviousness -Moll

146. Moll is a patent application entitled "Device for regulating the flow of blood through the system" which was published on 5 August 1998. Moll begins by describing various problems that may occur in the venous blood system of the legs and arms, such as thrombosis and varicose veins. In the mid to late 1990s such problems were generally addressed by using surgical procedures. But those procedures could themselves cause yet further problems, a difficulty that Moll seeks to address. It therefore provides a valve for use in veins which, in the specific embodiment described, looks like this (with the leaflets shaded):



147. In this device leaflets, described as blood flow stoppage elements (6), have the form of flexible hollow cones and are supported on a substantially triangular frame section (8) of a support (10). The leaflets have an inner wall (12) and an outer wall (14) extending from one end of the device to the other. The leaflets may have a flared or flattened configuration depending upon the direction of blood flow, as shown below:



148. The frame (10) is preferably made of a continuous length of memory metal which can be "rolled up" so that the frame sections (8) partially overlap one another, so reducing its overall diameter and permitting its introduction into a blood vessel. Once placed at its desired position, the device self-expands to assume its working form. Moll also teaches that the device must be bio-compatible and that the leaflets are most preferably made of polytetrafluoroethylene ("PTFE").

149. Professor Rothman and Professor Williams questioned whether or not Moll teaches that the ends of the support framework must be connected together to form a continuous structure. For my part, I think it is tolerably clear from the figures of Moll that the two ends are connected. But in any event I am entirely satisfied that this would be an obvious way to implement its teaching.

150. More significantly, Professor Rothman and Professor Williams were concerned that compressing the device or rolling it up would be very difficult to achieve in practice. The description and figures suggest that one corner of each of the three conical flask-shaped parts of the support frame is pushed under the corner of an adjacent conical flask-shaped part. This might work with the frame alone but once covered with material to form the valve pockets, the bottom of each valve pocket would hold together the adjacent corners of two conical flask-shaped parts. It would then be impossible to move one of these corners under and then further away from the other. In short, the device could not be collapsed at all. Professor Williams also anticipated significant difficulties in achieving a uniform expansion of a device that consists of a shape memory metal with a non shape memory material such as PTFE wrapped tightly around it.

151. With this introduction I turn to consider the differences between Moll and the invention of claim 1. As described and depicted, Moll does not disclose integer [B] because it is not radially expandable, or integers [F] and [G] because there is no mention of a collagen containing biomaterial comprising pericardium.

152. Was it obvious to modify Moll to make a device falling within claim 1? Dealing first with integer [B], I am satisfied that if Moll worked in the manner described then it would be radially expandable, as I have interpreted that expression. However, the problem with Moll, as the witnesses recognised, is that if the ends of the support

framework are not joined together then the device will not expand reliably and if they are joined together then it cannot be compressed.

153. Dr Buller believed the skilled person would understand the ends of the framework are joined together and, as I have mentioned, I am satisfied this was obvious. It is the only interpretation consistent with the description of the frame sections partially overlapping one another upon compression. But this leaves the problem of the adjacent corners of two conical flask-shaped parts being constrained by the bottom of the valve pocket – rather like two legs being forced into one trouser leg. Dr Buller thought that this could be solved by hanging the pockets inside the stent rather than having the legs of the stent inside the pockets. Professor Williams disagreed. He thought the skilled person would see the ambiguities and difficulties associated with Moll and turn to another approach.

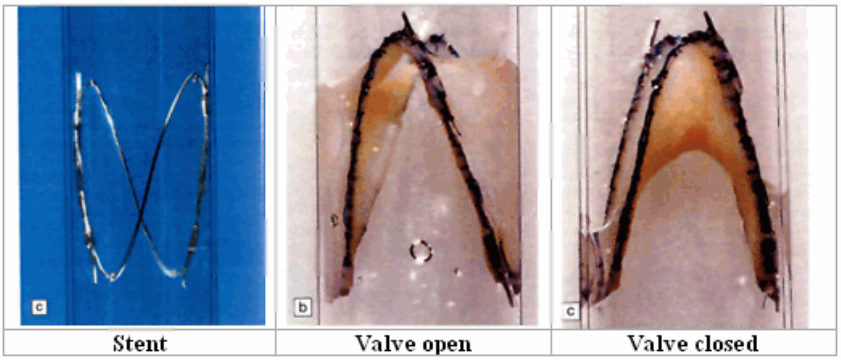
154. In evaluating these rival positions I think it relevant that Moll is directed to valves for use in veins and these were undoubtedly of less interest to the skilled person in 2000 than cardiac valves. Dr Buller was entirely candid in cross examination that he did not think Moll would be suitable for use as a replacement aortic valve and I do not believe he had much enthusiasm for it as a replacement pulmonary valve either. So it would only have been of any real interest to a person seeking a valve for use in a venous application and the evidence did not establish that such a person would have been prepared to engage in the necessary re-design to get Moll to work.

155. Integers [F] and [G] point to the same conclusion. Moll does not teach the use of pericardium and Professor Williams was clear that it was not obvious to adopt pericardium for use in a venous valve.

156. I conclude claim 1 was not obvious over Moll. The case urged by Edwards is coloured by hindsight. It is therefore not necessary to consider subsidiary claims 15, 22 and 31 which are said to be independently valid. I would observe, however, that there is nothing in Moll to suggest the valve opening should terminate at least 1mm from the stent perimeter and it not easy to see how this feature could be the consequence of the way the pockets are positioned. As for claim 31, this is directed to a heart valve and it was not obvious over Moll for the reasons I have given.

Obviousness - Pavcnik

157. Pavcnik is a paper published in 2000 which presents an *in vitro* and *in vivo* experimental evaluation of a new, artificial, bicuspid, aortic and venous valve comprising a self-expandable square stent covered with low porous material, such as SIS. In the particular embodiment described in the paper, two separate triangular pieces of SIS were sutured into the square frame which was then loaded into a guiding catheter. When deployed in a tube the device looks like this:



158. Once deployed, the device remains compressed in a sinusoidal configuration so that it contacts the inside surface of the tube along its entire perimeter.

159. The "valve open" and "valve closed" images depict the complete device together with triangular leaflets of SIS. The "valve open" image shows the configuration of the device when the direction of flow is from the bottom to the top of the page. The two leaflets are then pressed out against the inside surface of the tube. When the direction of flow is reversed, the leaflets are pressed in and against each other, so closing the valve as shown in the "valve closed" image. Pavcnik then describes *in vitro* testing with both continuous and pulsating flow, in which the valve generally appeared to work.

160. Pavcnik also describes pilot animal studies which involved testing of both aortic and venous valves which differ only in the diameter of the wire from which they are made and in overall size. Specifically in the case of the aortic valve study, three devices were placed in the sub-coronary (aortic annulus) position and six in the supra-coronary position. The authors then studied the function and stability of the valves with pressure measurements and aortograms. In the case of the valves placed in the aortic annulus, one resulted in aortic rupture but the other two rendered the natural valve ineffective and operated effectively in its place. The authors concluded their initial studies showed the square stent valve was capable of sustaining aortic and venous back-pressure, while allowing forward-flow with minimal resistance. But they ended with words of caution:

> "The square stent is a new device with the potential to improve minimally-invasive treatment as a venous and aortic valve. The valve design is bicuspid and mimics natural valve anatomy. Initial studies showed that percutaneously-placed SIS square-stent valves are promising one-way valves, capable of sustaining aortic and venous back-pressure while allowing forward-flow with minimal resistance.
>
> Whether square-stent advantages in design, as a carrier for aortic and venous valves, will translate into long-term clinically-useful intravascular devices remains to be determined. More experimental studies are necessary to evaluate their long-term potential for possible future clinical use."

161. As for claim 1, Cook says Pavcnik does not disclose integers [A] because it is not suitable for placement in a vessel, [B] because it is not radially expandable and [F] and [G] because there is no mention of pericardium.

162. So far as integer [A] is concerned, Pavcnik does describe the use of the device in the animal studies to which I have referred. Nevertheless, Professor Rothman and Professor Williams maintained it was not suitable for clinical use, particularly as a cardiac valve. In my judgment this is not the right test. As I have explained, the Patent is drafted at a high level of generality and it contains no details of any experimental work at all. I do not believe it is limited to valves which have secured clinical approval but rather includes valves which would be considered to have promise for a medical application and worth taking forward for that purpose. Pavcnik's square stent falls into this class. It had been shown to be efficacious in animal models, it was considered by the authors to be worthy of further experimental study and it was accepted by the experts to be an interesting device. Indeed Professor Williams acknowledged that the experimental work described in Pavcnik indicated the device could function as a valve, although not necessarily for an extended period of time. I conclude that Pavcnik does disclose a device which is suitable for placement in a vessel within the meaning of claim 1 of the Patent.

163. As for integer [B], this turns on the proper interpretation of this limitation. Cook argues that Pavcnik's stent is not radially expandable because its arms move in an arc. I disagree. I have considered the proper interpretation of this limitation at paragraphs [65] to [66] and in my judgment Pavcnik's stent expands radially in essentially the same way as the Gianturco Z-stent and the stents depicted in the Patent.

164. That leaves integers [F] and [G]. In my judgment it was entirely obvious to use pericardium, at least for any embodiment intended for use as a heart valve and none of the experts suggested the contrary. It follows that claim 1 is obvious over Pavcnik.

165. Cook contends that claims 3, 8, 12, 15, 22, 28 and 31 are, however, independently inventive. I will consider them in turn.

166. Claims 3 and 8 require the valve to be partially covered by a sheath. Professor Rothman thought covering Pavcnik's stent would be a complex exercise. I accept this evidence. There is not an obvious way it could be done. The attack on claims 3 and 8 therefore fails.

167. Claim 12 is directed to a valve with three leaflets. It will be appreciated that Pavcnik's stent has only two leaflets and it would require a significant change in the design of the frame for it to accommodate three. Dr Buller thought it would be obvious to choose a single serpentine ring with three peaks at either end and that the simplest thing to do would be to use a known stent such as the Gianturco Z-stent. I am not persuaded that is right and believe that Dr Buller's approach requires the skilled person to abandon the essence of Pavcnik's disclosure of a new stent which was different from and potentially an improvement upon the stents used as carriers for earlier devices. Professor Rothman gave evidence to much this effect. He thought the Gianturco-Z stent was a very different concept and one which Pavcnik had moved away from. I agree. I do not believe that claim 12 is obvious over Pavcnik.

168. Claims 15 and 22 require a restriction of the valve opening of 1mm from the stent perimeter. These claims add nothing inventive in this context for like reasons to those I have given in relation to Andersen. Moreover, if the opening is made by cutting a slit in a sheet then I am satisfied on the evidence that it was obvious to reinforce the edges of the slit, just as in the case of a button hole.

169. Claim 28 is limited to non self-expanding stents. As I think Edwards was disposed to accept, it was not obvious to modify Pavcnik in this way because the configuration of the stent would not allow the insertion of a balloon without tearing the SIS.

170. Finally, claim 31 is disclosed. In my judgment Pavcnik does describe a heart valve.

171. In summary, I conclude claims 1, 15, 22 and 31 were obvious over Pavcnik.

Obviousness – common general knowledge

172. The case of obviousness over the common general knowledge runs as follows. Edwards contends that interventional cardiologists were aware of and interested by the idea of replacement heart valves which could be delivered translumenally, essentially as a result of the pioneering work of Andersen. It also relies on the 1994 edition of the Textbook of Interventional Cardiology ("Topol") which, in a chapter entitled "Percutaneous Expandable Prosthetic Valve" states, at page 1271:

> "Biologic valves may be sewn onto a ring or stent as with pericardial valves or sewn in without a ring as homografts are placed. Since many valves require sewing ring or stent with which to anchor the valve, placing tissue valves on metallic stent struts offers the opportunity for the marriage for two currently available technologies in a rapid fashion."

173. In the light of the foregoing Edwards contends it was common general knowledge that a stent valve could be made by taking a known radially expandable stent and adding a valve. It was obvious to attach a valve in such a way that it was coterminous with the stent and hence it was obvious to make a valve fall within the scope of claim 1.

174. I did not understand this case to be pressed very strongly, and rightly so. I am not satisfied that the 1994 edition of Topol was common general knowledge in 2000. It was not something which Professor Rothman had read. Moreover, by 2000 it had been superseded by the 1999 edition which made no mention of the percutaneous delivery of heart valves. Nor was it established that the work of Andersen was common general knowledge. It is true to say the 1990s saw a great expansion in the use of coronary stents by interventional cardiologists but this of itself did not make it obvious to add a valve. The allegation of obviousness over the common general knowledge therefore fails.

Insufficiency

175. Edwards contends that the Patent is insufficient arising from the use of the word "substantially" in integers [H] and [J] of claim 1. It contends that claim 1 requires the leaflets to extend to the distal end or virtually to the distal end of the stent. Alternatively, the term is meaningless.

176. I have addressed this issue in considering the proper interpretation of claim 1. The word "substantially" is not meaningless or so ambiguous as to prevent the invention from being performed. In context, it means virtually the whole of the length of the stent. This allegation therefore fails.

Added matter

177. The Patent is said to be invalid because the matter disclosed in the specification extends beyond that disclosed in the application for the Patent as filed. The allegation has two limbs.

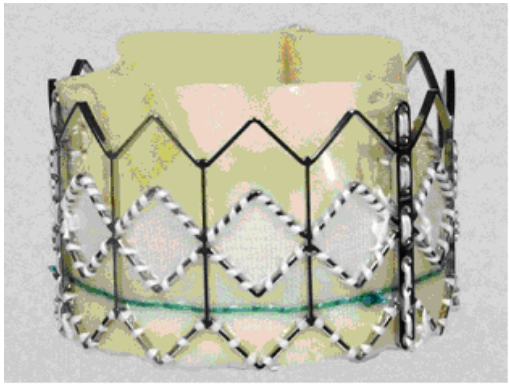
178. The first arises once again from the use of the word "substantially" in integers [H] and [J] of claim 1. Edwards says this did not appear in the application as filed and that if it means anything other than that the leaflets must extend to the distal end or virtually to the distal end of the stent, there is added matter because there is no disclosure in the application of a stent with any other arrangement, with the exception of figure 15. Further, when the word "substantially" was inserted, figure 15 was stated not to be part of the invention.

179. In light of the way I have construed the word "substantially" in claim 1, this objection must be rejected. Had I reached any other conclusion then it would have had substance.

180. The second objection concerns the scope of claim 3. Edwards contends that if and insofar as Cook suggests that the wording of claim 3 of the Patent discloses a stent valve in which the sheath partially covers the *interior* surface of the stent there is added matter. In the course of the trial Cook made it clear that it does not so contend and so this objection falls away.

Infringement

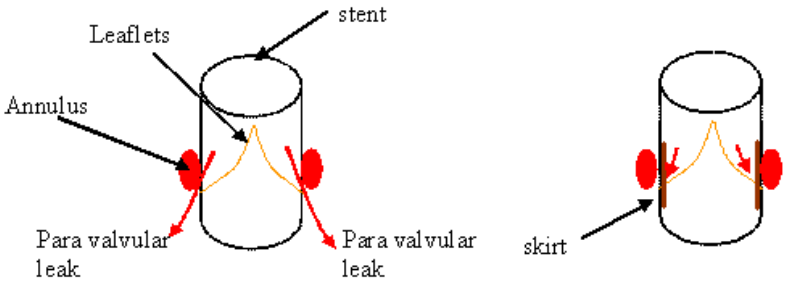
181. The SAPIEN device is described in the amended Product Description. It comes in two sizes, one with a nominal expanded outer diameter of 23mm and a length of 14.5mm and the other with a nominal expanded outer diameter of 26mm and a length of 16.1mm. It looks like this:



182. The SAPIEN is designed to treat patients with aortic stenosis and is delivered translumenally via a catheter through a patient's circulatory system or operatively by a surgical incision between the ribs and through the apex of the heart. Once sited at its desired location, the device is expanded by a balloon to fix it securely in place.

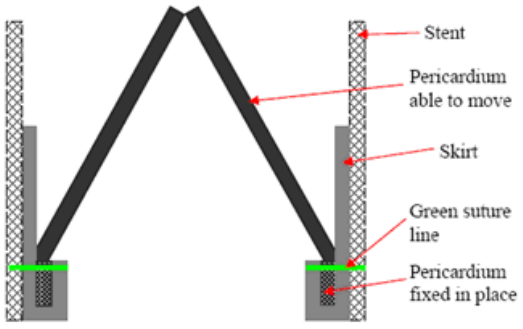
183. The device consists of four serpentine rings joined together with rods and 9 or 10 hole bars. The valve is attached via these bars and a circumferential green suture line which all remain constant in their longitudinal position regardless of any expansion or compression of the device.

184. As I have mentioned, in the native human heart the valve is connected to the annulus and therefore blood flowing in the retrograde direction is captured between the valve leaflet and the annulus so forcing the leaflet closed. However, as Dr Buller explained, it is not possible to ensure that a translumenal replacement valve is placed precisely in the annulus so as to prevent retrograde blood flow around the leaflets, a condition known as "para valvular leakage". In the case of the SAPIEN, para valvular leakage is prevented by the provision of a Dacron skirt as shown below:



185. It is also apparent from this diagram that the top of the stent protrudes above the aortic annulus and into the aortic sinuses. The diameter of the aortic sinuses is larger than the annulus and accordingly, once deployed, the top of the stent is not in contact with the walls of the sinuses and so plays no part in keeping the device in position.

186. The skirt and the leaflets are secured to the stent in the manner shown in this cross sectional diagram:



187. As can be seen, the skirt is located at the inflow end of the pericardium. The majority of the skirt is positioned on the outside of the pericardium but a small quantity is folded over the inflow end of the pericardium and positioned on its inside. These components are connected together by the green suture line. In the smaller size it is 3.69 mm from the inflow end of the pericardium and in the larger 4.05 mm. So in both cases the suture line is 25% of the length of the stent from its end.

188. Edwards disputes infringement of claim 1 on a number of grounds. Its primary submission is that the SAPIEN does not have integer [F] because it is not formed with a collagen containing biomaterial. Part of the valve - the skirt - is made of Dacron.

189. This argument turns on the proper interpretation of the word "valve" in integer [D], a matter I considered in paragraphs [68] to [71], and the expression "formed with a collagen containing biomaterial", which I considered in paragraphs [72] to [73]. For the reasons I have given, I believe the valve of the Patent is not limited to the elements which move and may include other elements extending inside the stent which act as pockets so as to collect blood and force the leaflets to close. On the other hand, I do believe the claim is limited to devices in which the valve is made of collagen containing biomaterial.

190. Professor Williams explained in his first report that the pockets described in the Patent provide greater functionality because they reduce leakage around the stent and provide greater back pressure on the leaflets to effect closure. In the course of cross examination he also accepted that if the pocket is formed on the inside of the stent then it is performing part of the valve function. There can be no doubt that the Dacron skirt of the SAPIEN is on the inside of the stent and does form pockets together with the pericardium. Those pockets assist the valve to close and prevent para valvular leakage. They therefore form part of the valve. But they are not made of collagen containing biomaterial. It follows that integer [F] is not satisfied.

191. Second, Edwards says that the SAPIEN comprises four serpentine rings joined together with rods and bars and that in the eyes of the Patent it is a multi-stent device and does not satisfy integers [H] and [J] because the leaflets extend beyond the length of each of the stents.

192. I reject this submission. It depends upon the proper interpretation of the word stent, a matter I have addressed at paragraphs [62] to [64]. In my judgment the rings of the SAPIEN comprise a single integral stent within the meaning of the Patent and that is how the device would be understood by the interventional cardiologist.

193. This, however, leads to the third contention. On the assumption, which I believe to be correct, that the entire multi-ring structure is to be regarded as a single stent then, says Edwards, the valve and leaflets do not extend substantially from the proximal stent end to the distal stent end, as called for by integers [H] and [J]. Rather, they terminate at the green suture line, approximately 75% of the way down the stent.

194. In my judgment this is a valid point. As I have explained, it is difficult to discern the purpose of this limitation, linked as it is to the length of a stent rather than to any absolute measure of length. However, the skilled person would recognise the benefits of having longer leaflets and these matters, coupled with the figures of the Patent, would lead him to believe the patentee intended the claim to be limited to stents in which the valve and leaflets extend virtually the whole length of the stent. Can it be said that a device in which the valve and leaflets extend for 75% of the length of the stent satisfies the requirements of the claim? I do not believe that it can. Dr Buller explained, and I accept, that the leaflets in the SAPIEN device could have extended much further down the stent, even to its end. It follows that integers [H] and [J] are not present in the SAPIEN.

195. The final ground is a “squeeze” in relation to Andersen. Edwards says that if Cook is right and the projecting apices of Andersen do not form the proximal stent end, the SAPIEN cannot infringe because its proximal end protrudes into the aortic sinuses and plays no part in keeping the device in position. So, it continues, the SAPIEN does not have integers [H] and [J] for this further reason.

196. I have rejected this submission in dealing with Andersen and must reject it here too. The proximal end of the SAPIEN is integral with the rest of the device and does play an important role in supporting the valve. In my judgment it does form part of the stent, just as do the projecting apices of Andersen.

197. I conclude the SAPIEN does not infringe claim 1 of the Patent because the valve is not formed with a collagen containing biomaterial as called for by integer [F] and because the valve and leaflets do not extend substantially from the proximal stent end to the distal stent end as called for by integers [H] and [J].

198. The one further issue in relation to the subsidiary claims is whether the SAPIEN has an opening which “extends across the stent diameter”. I believe it does, for the reasons I have given at paragraphs [78] to [79].

Conclusion

199. The Patent is invalid and not infringed. I will hear argument as to the form of order if it cannot be agreed.