Neutral Citation Number: [2010] EWCA Civ 718

Case No: A3/2009/1403

IN THE HIGH COURT OF JUSTICE
COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE CHANCERY DIVISION
MR JUSTICE KITCHIN
HC08C00934

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 28 June 2010

Before :

LORD JUSTICE JACOB
LORD JUSTICE MOORE-BICK
and
LORD JUSTICE ETHERTON

- -

Between :

COOK BIOTECH INCORPORATED **(a company incorporated under the laws of Switzerland)**	**Appellant**
- and -	
EDWARDS LIFESCIENCES AG **(a company incorporated under the laws of the State of Indiana, USA)**	**Respondent**

- -

Mr Simon Thorley QC and Mr Adrian Speck (instructed by **Marks & Clerk Solicitors LLP**) for the **Appellant**
Mr Roger Wyand QC and Mr Piers Acland QC (instructed by **Bird & Bird LLP**) for the **Respondent**

Hearing date : 9th June 2010

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Judgment

Lord Justice Etherton :

Introduction

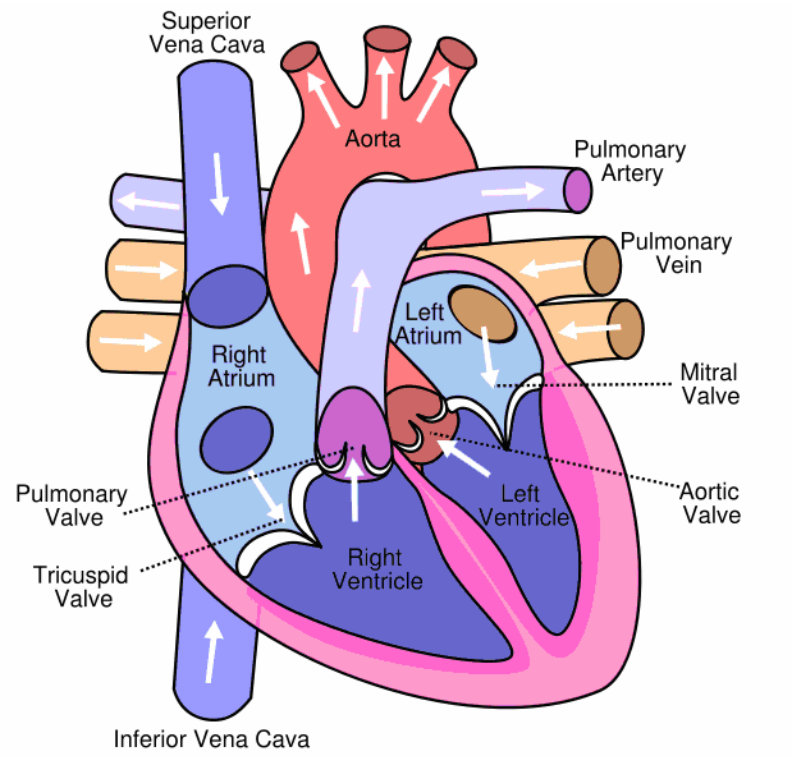
1. This appeal concerns the validity of European Patent (UK) 1 255 510 ("the Patent"), which was filed on 31 January 2001. The Patent is called "stent" valves", and is for an artificial heart valve within a radially expandable stent which can be delivered through a catheter. The appellant, Cook Biotech Incorporated ("Cook"), is the proprietor of the Patent. The respondent, Edwards Lifesciences AG ("Edwards"), brought these proceedings for revocation, and Cook counterclaimed for infringement. By order dated 12 June 2009 Mr Justice Kitchin revoked the Patent. This is the appeal by Cook from that order.

2. The Judge held that the Patent was invalid for obviousness in the light of US Patent 5,411,552 published on 2 May 1995 ("Andersen") and was not infringed. In the course of his judgment, the Judge had to resolve a dispute over the priority date enjoyed by the Patent, if valid, because that had a bearing on what Edwards contended was relevant prior art other than Andersen. That issue turned on, among other things, the provisions of section 5 of the Patents Act 1997 and the Paris Convention. Cook's appeal is in respect of the various matters of law on which the Judge decided against Cook - on construction of the Patent, on obviousness and infringement, and on the priority date of the Patent - and also in respect of findings of fact by the Judge in relation to claims 15 and 22 of the Patent. Edwards has filed a Respondent's Notice seeking to uphold the Judge's findings on additional grounds.

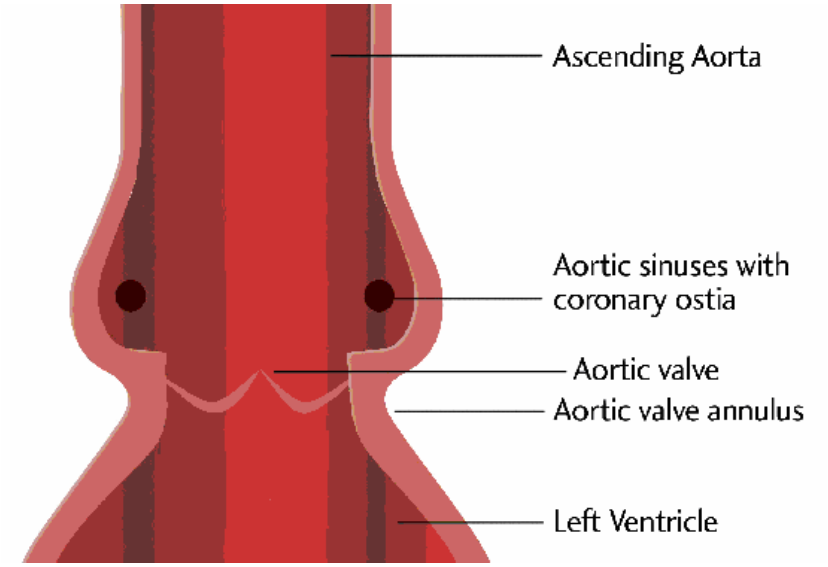
3. The appeal was listed for a 3 day hearing. At the outset of the hearing, it was agreed by the parties that the most efficient way forward was for the Court first to hear the appeal on the Judge's conclusion that the claims of the Patent were obvious over Andersen, including the attack on his findings of fact in relation to claims 15 and 22, since, if those parts of the appeal failed, all the other aspects of the appeal would fall away. In the event, having heard succinct oral arguments and having had the benefit of reading the excellent skeleton arguments of both sides, the Court was of the clear view that the Judge's findings of fact on claims 15 and 22 could not be impugned and his decision on obviousness was correct, and so the appeal should be dismissed. The Court informed the parties immediately of its conclusion and that reasons would be given in reserved judgments. It was not necessary, therefore, to hear submissions on the other matters raised on the appeal, and we did not do so. In this judgment, I set out my reasons for dismissal of the appeal.

The background

4. In paragraphs [17] to [41] of his thorough and lucid judgment, the Judge set out the common general knowledge at the time of the Patent. Neither side criticises what he says. There is no need to set it all out here. What is of particular relevance in the case is the aortic valve. Its place within the heart is shown in the following diagram.



5. The following is an enlarged section of the aortic valve.



6. The Judge described the location and functioning of the aortic valve as follows:

> "22 … [T]he 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

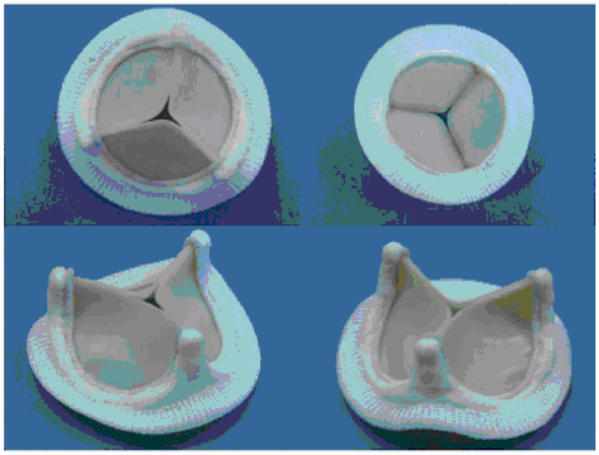
> the ventricle increases until it is greater than in the aorta, at which point the aortic valve opens. When the ventricular contraction ends, pressure in the left ventricle rapidly drops. When it falls below the pressure in the aorta, the leaflets of the aortic valve collapse and come together along 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."

7. In paragraphs [24] to [31] of his judgment the Judge described the replacement of diseased heart valves by surgery. He said as follows.

> "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.

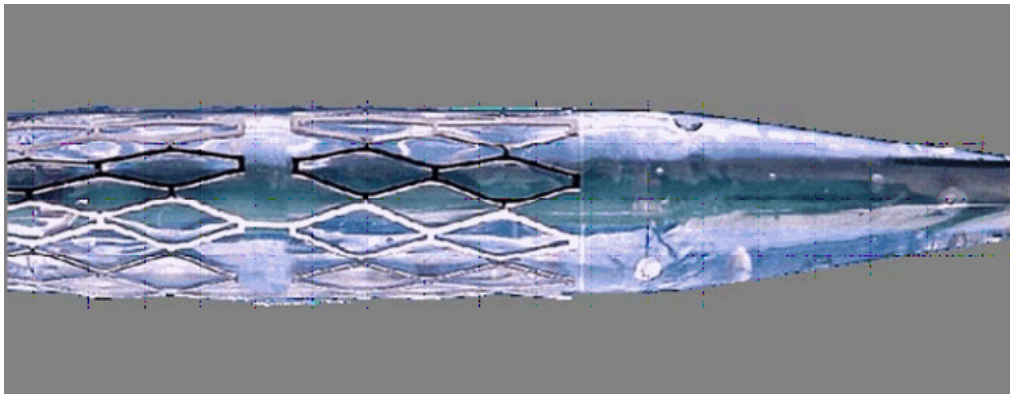
> 31. As Professor Williams [Cook's bioengineering expert] explained, by 2000, attempts had been made to develop a surgically implantable polymer leaflet heart valve which was seen as having the potential to avoid the difficulties of thrombosis caused by the mechanical valves and calcification which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

8. In paragraphs [32] to [41] of his judgment the Judge described as follows the role of "interventional cardiology".

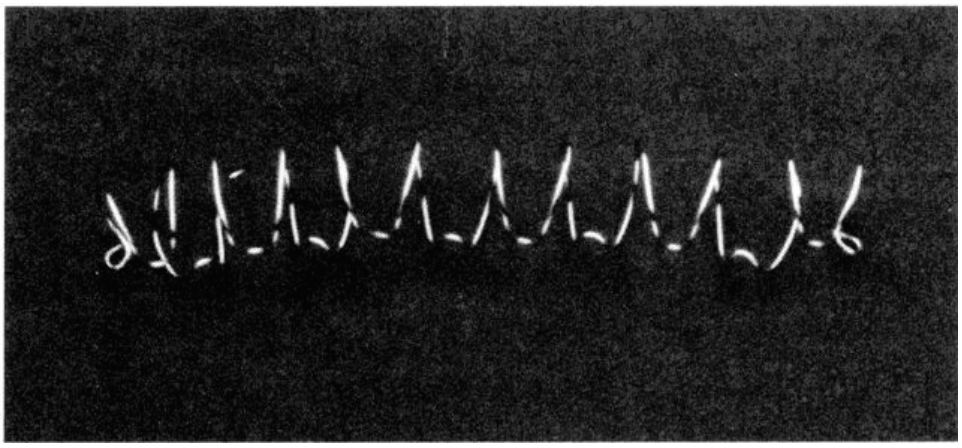
> "32. Surgical heart valve replacement involves a major operation and is not suitable for all patients. However, from the 1960s a new branch of medicine emerged known as interventional cardiology. This is the practice of percutaneously treating problems within the heart and associated vessels and is 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 [Cook's expert interventional cardiologist] 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.

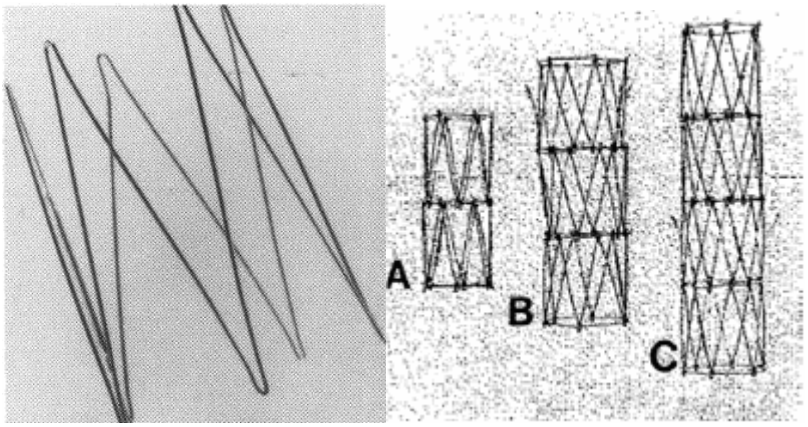
36. Stents essentially fall into two categories, those which are balloon expandable and those which are self-expanding. Balloon expandable stents are compressed around a balloon and inserted into a peripheral vessel by catheter. Once the balloon expandable stent reaches its destination the balloon is 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

9. The Judge described the Patent in paragraphs [42] to [58] of his judgment. Again, the parties make no criticism of what he says there. So far as relevant to the determination of this appeal, he said as follows.

> "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:

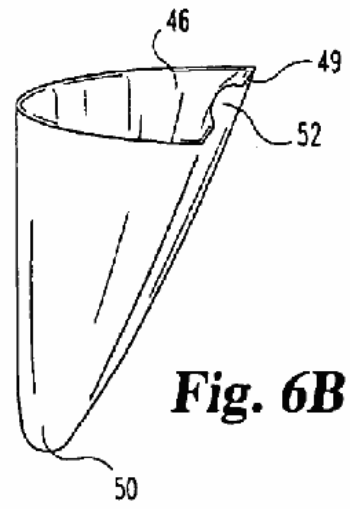


Fig. 6B

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):

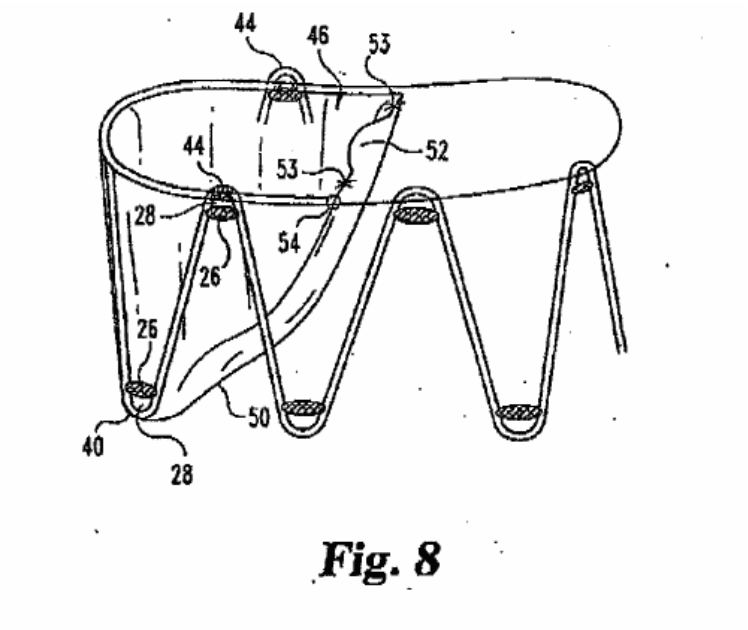


Fig. 8

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:

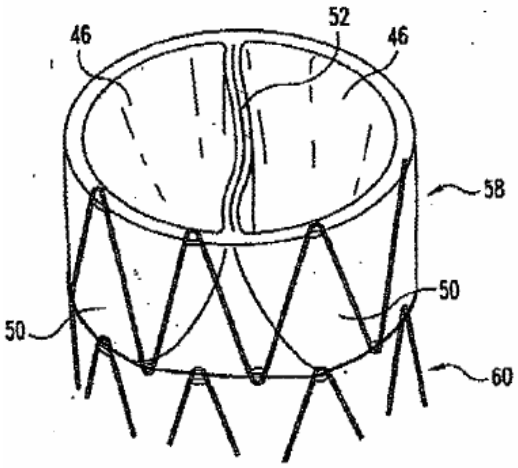


Fig. 12

54. As is figure 17:

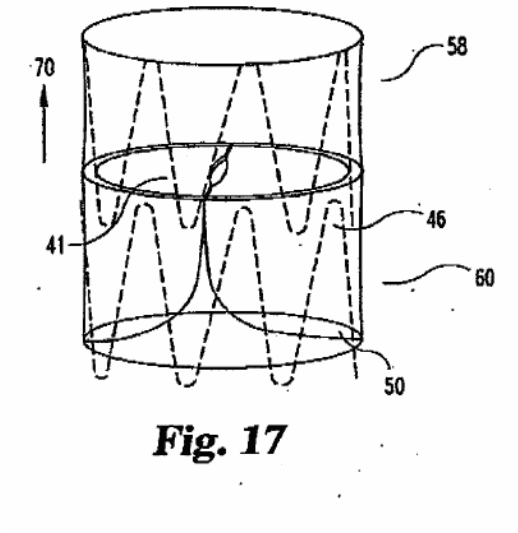


Fig. 17

….

55. 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."

10. The parties have agreed a breakdown of the integers of claim 1 as follows.

> [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).

11. For the purpose of this appeal, the only relevant subsidiary claims are 15 and 22, as follows.

> "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)."

Andersen

12. Andersen discloses a replacement heart valve comprising a heart valve from a slaughtered pig attached to an expandable frame constructed from two surgical steel wires. I gratefully adopt the following description of Andersen in the judgment.

> "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:

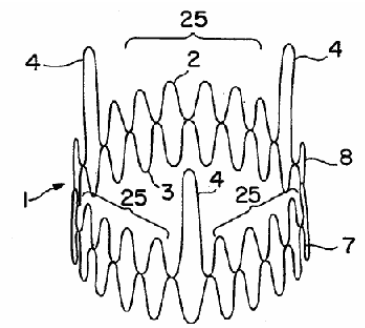


FIG. 1

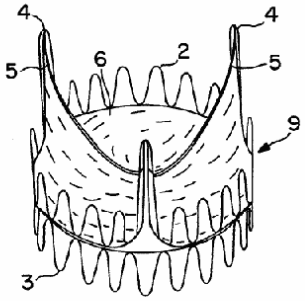


FIG. 2

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):

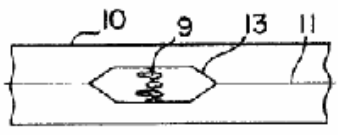


FIG. 5

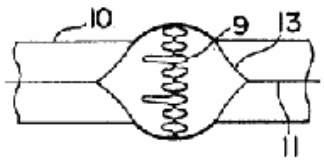


FIG. 6

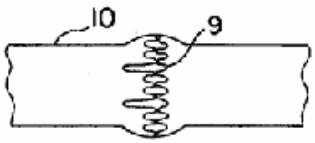


FIG. 7

> 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."

The judgment

13. In paragraphs [111] and [112] of the judgment the Judge set out the "obviousness" test as explained and reformulated by Jacob LJ (with whom the other members of the Court agreed) in *Pozzoli Spa* v *BDMO SA* [2007] EWCA Civ 588; [2007] FSR 37, namely:

> (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?

14. The Judge then added:

> "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."

15. No criticism has been made by either of the parties of that observation, with which I agree.

16. The Judge described the skilled persons to whom the Patent is addressed as being a 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. The team would also have included or at least would have consulted a cardiac surgeon to provide experience of contemporary work with surgically implantable replacement heart valves and a person familiar with the design of implantable surgical heart valves. The Judge considered that in practice a number of engineers might be involved in the team, depending on their specific areas of expertise. Neither side criticises those findings by the Judge.

17. It was common ground that Anderson 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 contended before the Judge that Andersen also does not disclose integers [B] [H] [J] and [K] because (a) the proximal end of the radially expandable stent is the top of the small loops of the upper ring at the point marked (2); (b) the apices of the higher loops (4) extend beyond its end and do not form part of it; and so (c) the valve is connected to and extends from three points outside the proximal end of the stent; and (d) the loops do not themselves expand in a radial direction. In rejecting those contentions, the Judge said:

> "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

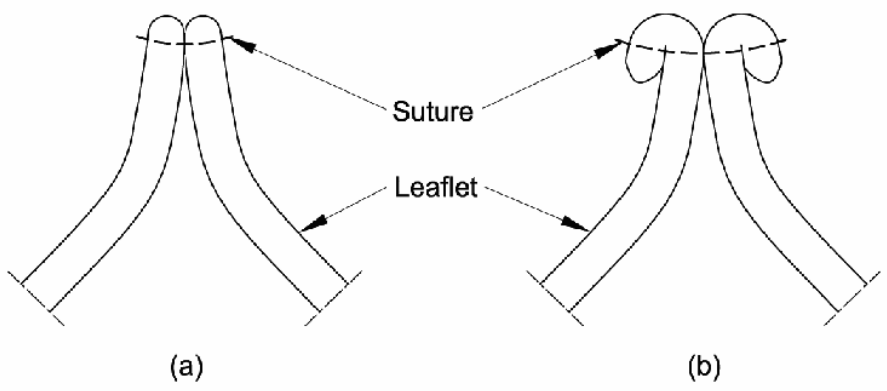
> stent. Fourth, and entirely consistently, Andersen itself describes them as forming part of the stent (see, for example, column 5, lines 9 to 28). Fifth, whilst I accept that the loops do not themselves open out as the stent is expanded, they do move radially outwards together with the rest of the stent as the intervening sections (25) open out."

18. Accordingly, the Judge concluded 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.

19. The Judge then rejected Cook's argument that the skilled person would consider the Andersen device to be a single composite stent comprising the two rings (7) and (8) with the consequence that the valve does not extend to the distal stent end as called for by integers [H] and [J]. The Judge considered that what was important, in this connection, was not so much how the skilled person would understand Andersen, but rather how that person would understand the term "stent" to be used in the Patent. He concluded that the Patent contemplates a device which comprises a number of individual stents joined together, and that it uses the term "stent" to describe a recognisable distinct structure which has the appearance of and performs at least some of the functions of a stent. Applying that approach to Andersen, he observed that each of the two rings (7) and (8) has the appearance of a stent and each performs some of the functions of a stent in assisting in holding the lumen open and keeping the device in position. Accordingly, applying the terminology of the Patent, he concluded that Andersen comprises two stents, and the valve does extend to the distal end of the upper stent. He also observed 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].

20. The Judge then addressed 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. He answered that question in the affirmative, holding, in the light of the evidence, that it was obvious to replace the porcine valve with a fabricated valve made of pericardium, and 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.

21. The Judge then turned to claims 15 and 22, which were the only subsidiary claims said by Cook by the end of the trial to have independent validity over Andersen. Those claims specify that the valve opening terminates at least 1mm from a stent perimeter. The Judge referred to Cook's acceptance 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. He then referred to the evidence of Professor Rothman in his written report that it was obvious to tie the leaflets to the stent with sutures and to buttress their edges in the following arrangements, with the buttresses shown in figure (b):



22. The Judge also referred to Professor Rothman's oral evidence in which he recognised both the need to reinforce the edges of the leaflets and the benefit of keeping the leaflets away from the stent wall. He said that Professor Rothman was unable to say how close to the stent the sutures would be. The Judge also referred to the evidence of Professor Williams that the skilled person would have wished to ensure that the leaflets were directed towards the centre of the valve and did not come into contact with the stent wall or the lumen wall, and that it was obvious, for that purpose, to stitch them together through their faces.

23. The Judge concluded, in the light of all the evidence, 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 permimeter, and so also might buttressing or reinforcing their edges. He considered that there was nothing significant in the figure of 1mm, and so the claims added nothing by way of invention over claim 1.

Cook's appeal on obviousness, including claims 15 and 22

24. At the heart of Cook's complaint about the judgment on obviousness, in the light of Andersen, is the criticism that the Judge interpreted incorrectly the expression "radially expandable stent" in claim 1 of the Patent and the word "stent" in the Patent and in Andersen. It is said that he failed to draw a proper distinction between the prior art function of a radially expandable stent, as known and used by interventional cardiologists at the priority date of the Patent, and the additional function that was to be achieved by such a stent as a result of the invention of claim 1.

25. In his oral submissions Mr Simon Thorley QC, for Cook, presented the argument as follows. His starting point was that, as at 2000, there was no single meaning of the word "stent": it all depended upon context. To the cardiac surgeon, the word meant something like the Perimount valve. It was the frame or structure which supported a mechanical or bioprosthetic valve. The cardiac surgeon had no need to use any form of collapsible device for insertion by catheterisation. Such a device was, however, well known to and used by an interventional cardiologist. For that person, it was invariably a tubular structure used to expand the lumen of a vessel and to provide a scaffolding structure to hold the vessel open and to keep the device in position. It was not used, at that stage, by the interventional cardiologist to support a replacement valve. The Patent was addressed to the interventional cardiologist, and not the cardiac surgeon since the Patent envisaged that the radially expandable stent described in the Patent could be delivered by catheter.

26. The Judge was wrong, therefore, Cook submits, in saying in paragraph [67] of the Judgment: "I consider that 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". Prior to the Patent, the interventional cardiologist would not have regarded the latter function as one performed by an expandable stent. For an interventional cardiologist, the proximal and distal ends of the stent were the top and bottom of the expandable stent which performed the other two functions (holding the lumen open and keeping the device in position). The importance of the invention, reflected in integers [H] [J] and [K], was that the valve was surrounded by, and wholly within and supported and protected by the expandable stent throughout its length.

27. In summary, Cook's case is that the Patent discloses the inventive adaptation of the expandable stent, as previously known to the interventional cardiologist, to carry a pericardium (or other collagen biomaterial) valve wholly within its structure.

28. Cook submits that, applying to Andersen that (interventional cardiologist's) meaning of "stent" in the Patent, the Andersen device comprises, first, as to the two rings of loops (7) and (8), a stent in the sense used in the Patent, and second, as to the taller loops (4) rising above (8) and intended to secure the commissural points, a means of holding the valve. In support of that interpretation, Mr Thorley drew attention to, and relied upon, the observation of the Judge in paragraph [126] of the judgment that the commissural posts on the Andersen device do not move out in line with the rest of the stent: that is the effect of being attached to the valve. In short, Cook's case is that the commissural posts on the Andersen device are an addition to, and not part of, the radially expandable stent, in the sense it bears in the Patent and in the understanding of the interventional cardiologist to whom Andersen is addressed. On that footing, the Andersen device does not satisfy integers [H] [J] and [K]. Mr Roger Wyand QC, for Edwards, agreed that, if that is correct, the Judge's reasons for holding the Patent invalid for obviousness over Andersen would be wrong and the judgment cannot stand.

29. Turning to claims 15 and 22, Cook's criticism is that the Judge was plainly wrong on the evidence to reject as inventive the requirement that the slit forming the valve should terminate at least 1mm from a stent perimeter. As Mr Thorley observed that would be a restriction of 2mm in the case of a bicuspid valve. I have already referred to the evidence relied upon by the Judge in reaching his conclusion on this point. Mr Thorley submitted that the Judge misunderstood that evidence, namely answers given by Professor Rothman on the second day of the trial. In that evidence, as the Judge correctly recorded, Professor Rothman said that it is appropriate to buttress or reinforce the edges and reduce the lumen a little to keep the leaflets away from the wall and so prevent the valve material tearing. Cook's complaint, however, is that neither that nor any other evidence supported the Judge's conclusion in paragraph [144] of his judgment that: "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".

30. Mr Thorley submitted that Professor Rothman's evidence, far from being consistent with termination of the valve at least 1mm from a stent perimeter, was to the effect that 1mm is much greater than is naturally required for that purpose. Professor Rothman said, with reference to figure 7, that it was "a massive reduction", and that,

"you do not get to a millimetre just by doing the stitch in (a) or (b)". Cook's case is that the 1mm minimum requirement was inventive because it went beyond what was obviously to be obtained as a mere matter of fixing; it was intended to ensure the inventive benefit of putting the valve inside the stent, which had never previously been done, in such a way as not to damage the valve.

Discussion

Claim 1

31. Despite Mr Thorley's skilful advocacy, I unhesitatingly reject Cook's attack on the Judge's conclusion on claim 1 on the basis of the proper meaning of the expression "radially expandable stent" in the Patent and the word "stent" in the Patent and in Andersen. Fundamental to Cook's argument is the difference between the functions performed at the relevant date by interventional cardiologists, on the one hand, and cardiac surgeons, on the other hand, reflected in the different types of stent used by them. The Patent, it is said, was directed to the interventional cardiologist, and so should be interpreted in a manner consistent with the knowledge, functions and expectations of that skilled person: hence "radially expandable stent" and "stent" in the Patent and in Andersen should be restricted to the type of stent used by the interventional cardiologist. The fundamental flaw in that argument is that, as the Judge held and is not challenged, the Patent and Andersen were notionally addressed at the relevant time not just to an interventional cardiologist but to a team which included or would have consulted a cardiac surgeon and someone familiar with the design of implantable surgical heart valves. They would have pooled their joint knowledge and experience when interpreting the Patent and Andersen. The interventional cardiologist was working with the cardiac surgeon and a person familiar with the design of implantable surgical valves to adapt the expandable stent so as to be able to carry a valve.

32. Secondly, the Judge rightly placed weight on the fact that the device in Andersen is structurally designed as a single stent, the taller loops for the commissural points (4) forming an integral part of the upper ring (8). They could not be detached from the stent without destroying the integrity of the whole. Unsurprisingly, the entire wire structure is expressly stated in Andersen to be a stent. It is artificial, and counter-intuitive, to seek to make a clear division between different parts of such a stent on the basis of functionality, and there is no reason to think that the skilled team as a whole, or the interventional cardiologist in particular, would have taken a different view.

33. Thirdly, as Mr Wyand pointed out, the description of the device in Andersen (col. 3 ll 22-28) reinforces the concept of a single stent, without meaningful differentiation according to the different functions it was performing:

> "The lower ring is circumferentially expandable at least along sections thereof which correspond to the circumferentially expandable sections 25. By using a substantially cylindrical thread structure with projecting apices, a reduction in weight is obtained as compared to a stent which is exclusively with the same loop heights for all the loops."

34. Mr Thorley submitted, to the contrary, that those words support Cook's argument by making clear that the part above the second ring was not necessary for the purposes for which an expandable stent was used by the interventional cardiologist. I do not agree. The explanation in the description says nothing about different functions, but would have reinforced the skilled team's understanding that the stent is a single expandable stent, which can be designed so as to be as light as possible.

35. Indeed, fourthly, Cook's argument proceeds on the premise that the part of the Andersen device above the second ring does not perform any function for which the interventional cardiologist was responsible; but that premise is contrary to the evidence and the findings of the Judge. The Judge held in paragraph [126] of his judgment (quoted above) both that the loops for the commissural points may well contact the lumen (thereby performing the objectives of the cardiologist to support the lumen and to hold the device in place), and also that they move radially outwards with the rest of the stent, albeit not to the same extent.

Claims 15 and 22

36. The Judge was plainly entitled to conclude on the evidence that it was obvious that there was a need to reinforce the edges of the leaflets and to keep the leaflets away from the stent wall so as to prevent tearing of the valve material. Mr Thorley did not submit the contrary. What Cook criticises is the Judge's finding in paragraph [144] of the judgment that such obvious need "might easily lead to a restriction of the valve opening of 1mm from the stent perimeter" and that "[t]here is nothing significant in the figure of 1mm". Mr Thorley accepts, and indeed relies on, the fact that the minimal 1mm requirement in claims 15 and 22 is arbitrary. What Cook says is that it was inventive precisely because it was an arbitrary requirement in excess of what was required to secure and reinforce the edges of the valve, and there was no prior art which contained any such restriction of the width of the aperture of the valve.

37. In my judgment, Cook fails on this argument for two reasons. First, I do not accept that the Judge was "plainly wrong" to reach the conclusion that there might be a need to restrict the opening by as much as 1mm from a stent perimeter. I do not accept that Professor Rothman's evidence in cross-examination quoted in paragraph [30] above (transcript Day 2 p. 245 at lines 22-24, and p. 246 lines 19-21) amounted to an assertion by him that the opening of the valve would never be as much as 1mm. I agree with Mr Wyand that Professor Rothman's cross-examination goes no further than that the necessary distance from the stent perimeter depends on a number of factors. It depends on achieving an appropriate balance between, on the one hand, retaining a desirable width of opening of the valve for blood flow, and, on the other hand, securing as strong and secure an opening as possible in the light of, for example, the strength and thickness of the valve material and the thickness of the suture. Exchanges with counsel during the hearing of the appeal established no difficulty in arriving at a figure of .7mm from the stent perimeter, and I consider that it was well within a proper determination of the facts by the Judge to conclude that it might be as much as 1mm.

38. Even if that is not correct, the Judge was nevertheless right to say that the 1mm requirement has no significance. That was the evidence of Professor Rothman, who considered the requirement as being so great a reduction of the valve opening that it

should not be read literally but rather as a general indication of the need to reinforce the edges of the valve. He said (transcript Day 2 p.245 line 24-p.246 line 3):

> "The example is a massive reduction, so I think it is just an example of showing how you might buttress or reinforce the edges. I think that … it throws up the issue that you do need to reinforce the edges in some way otherwise you will end up potentially with an Ionescu-Shiley problem."

39. In other words, the arbitrary minimum 1mm requirement in claims 15 and 22 was not intended to, and would not at the priority date have been understood by the skilled reader to, add anything inventive to claim 1, but was merely there as a reflection of the obvious general need to secure and strengthen the edges of the valve and to prevent tearing.

Conclusion

40. For those reasons I would dismiss this appeal.

Lord Justice Moore-Bick

41. I agree.

Lord Justice Jacob

42. I also agree.