Case No: A3/2017/1080
A3/2017/1090

Neutral Citation Number: [2018] EWCA Civ 673
IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT
HHJ Hacon (sitting as a judge of the High Court)
[2017] EWHC 405 (Pat)

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 28/03/2018

Before:

LORD JUSTICE KITCHIN
LORD JUSTICE MCCOMBE
and
LORD JUSTICE FLOYD

- -

Between:

(1) EDWARDS LIFESCIENCES LLC **(2) EDWARDS LIFESCIENCES CORPORATION** **(3) EDWARDS LIFESCIENCES AG (also known as EDWARDS LIFESCIENCES SA)** **(4) EDWARDS LIFESCIENCES LIMITED**	**Appellants/ Respondents**
- and - **BOSTON SCIENTIFIC SCIMED INC**	**Respondents/ Appellants**

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Iain Purvis QC and **Piers Acland QC** (instructed by **Powell Gilbert LLP**) for the **Appellants**
Richard Meade QC and **Kathryn Pickard** (instructed by **Simmons & Simmons LLP**) for the **Respondent**

Hearing dates: 30-31 January 2018

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Judgment

Lord Justice Floyd:

1. These appeals concern two patents owned by one of the parties, Boston Scientific Scimed Inc ("Boston"), which relate to replacement heart valves known as transcatheter heart valves or THVs. The other parties, four Edwards Lifesciences companies (there is no need to distinguish between them and I will refer to them as "Edwards") brought these proceedings to obtain revocation of the two patents. In return, Boston sued for infringement of both patents by Edwards' Sapien 3 model of THV. Neither party was wholly successful before HHJ Hacon sitting as a judge of the High Court. In his judgment handed down on 3 March 2017 after a 7 day witness hearing, he held that one of the patents, European Patent (UK) No 2 749 254 ("254") was obvious over a prior art document called Thornton, but found that the other patent, European Patent (UK) No 2 926 766 ("766") was valid and that claims 1-4, 6-7 and 17 were infringed by the Sapien 3. Both parties now appeal to this court against that judgment and the orders which the judge made in consequence on 24 March and 31 August 2017.

2. Edwards' sole ground of appeal in relation to 766 is, in essence, that if the judge's finding of obviousness of 254 over Thornton is correct, it follows that 766 is invalid for obviousness over Thornton as well. That conclusion follows, so they contend, because claim 1 of 766, properly construed, covers the very thing which the judge held to be obvious in the context of 254. Boston disputes this, but submits that if it loses on that point it is nevertheless entitled to rely on claims 4 and 7 of 766, which the judge also found to be infringed by the Sapien 3, and which are contended by Boston to be independently valid. The judge made no findings about the independent validity of these claims, but the parties agreed that, if we came to the conclusion that claim 1 was invalid, we could decide upon the validity of claims 4 and 7 over Thornton on the basis of the existing record, and without the need to remit those issues to the judge.

3. Boston's appeal is against the judge's finding of obviousness of 254. Boston contends that the judge made an error of principle in declining to accept unchallenged evidence given by one of their expert witnesses, Prof Georg Lutter. Boston contends that, had the judge accepted Professor Lutter's evidence as he was bound to do, he ought not to have found the invention of 254 to be obvious.

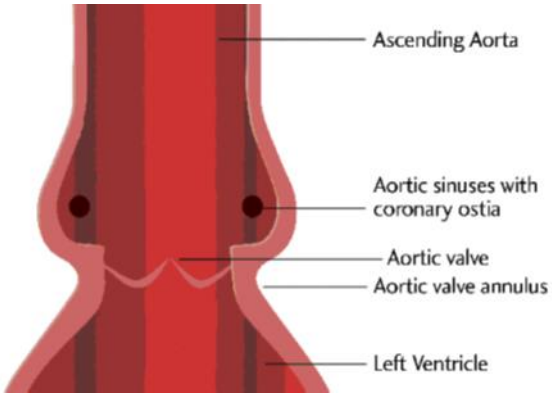
4. The judge held that the patents in the present case were directed to a team consisting of an interventional cardiologist (i.e. a clinician who might implant a replacement heart valve) and a bio-medical engineer (i.e. an engineer who might design one). There is no challenge to that conclusion, and it follows that the patents are to be read and understood from the perspective of such a team, armed with their collective common general knowledge, and that the evidence of both the clinician and the engineer may have a potential impact on the issue of obviousness.

5. To assist the judge with these issues, both sides called distinguished expert witnesses. Boston called Prof Georg Lutter, Professor of Cardiac Surgery at the University of Kiel and Head of the Department of Experimental Cardiac Surgery and Heart Valve Replacement there. He was a clinician who had carried out many procedures using Edwards' Sapien valves. In addition, Boston called Prof James Moore, who was Professor of Biomedical Engineering at Imperial College London. Edwards, for their part, called Dr Nigel Buller, a retired consultant cardiologist, who had been Head of

Interventional Cardiology at Queen Elizabeth Hospital, Birmingham and the lead clinician for its cardiac catheterisation laboratories. Edwards' expert on biomechanical engineering was Prof John Fisher, who has been Professor of Mechanical Engineering at the University of Leeds since 1993 and is currently Pro-Vice-Chancellor for Research there.

6. Before coming in more detail to the issues, it is necessary to set out some of the technical background which the judge held to be part of the common general knowledge of such a skilled team. The parties agreed a helpful Technical Primer and the judge extracted the essentials from it at paragraphs 9 to 31 of his judgment. For our purposes it is sufficient to set out the matters which I summarise below.

7. THVs are used to treat patients whose aortic valve has ceased to operate effectively. The aortic valve is situated between the left ventricle and the aorta. The rhythmic contractions of the left ventricle are responsible for maintaining the systemic circulation of blood in the body. When the left ventricle contracts, blood flows under high pressure into the main artery of the systemic circulation, the aorta. This phase is called "systole". The following phase, in which the left ventricle expands, is called "diastole". When the diastole begins, pressure inside the ventricle drops and causes the aortic valve to close. A diagrammatic representation of the location of the aortic valve between the left ventricle and the aorta is shown below:



8. As shown, the aortic valve comprises two or three "leaflets", which are flaps of tissue. When the ventricle contracts, the pressure of blood forces the leaflets apart. The pressure change at the beginning of the diastole causes the leaflets to close and prevent the back-flow of blood. Disease of the aortic valve is characterised by degenerative calcification of the leaflets and parts of the heart surrounding the valve. Calcium carbonate nodules are formed which prevent the leaflets from opening or closing fully.

9. Defective heart valves can be replaced by open heart surgery, in which the patient's chest is opened, the defective valve cut out and replaced by an artificial one. The present case is concerned with a different approach, known generally as interventional cardiology. In interventional cardiology the patient with heart problems is treated percutaneously.

10. THVs for use in animals were developed in the late 1980s. In 2002 a team led by Dr Alain Cribier in Rouen performed the first implantation of a THV in a human. This was recognised as a considerable breakthrough in heart surgery. The Cribier THV

consisted of three bovine pericardial leaflets mounted within a balloon-expandable metallic frame or stent, also sometimes called an anchor. The leaflets were attached to a lining on the inside of the bottom part of the frame, referred to as a skirt. The Cribier THV is illustrated below:

11. The valve is inserted in compressed form through an artery by means of a catheter. The technique of replacing an aortic valve percutaneously has become known as "transcatheter aortic valve implantation" or TAVI.

12. The problem addressed by the patents in suit is that, when the THV is installed, the contact between the frame and the annulus of the natural aortic valve is not perfect and there can be leakage of blood around the outside of the frame. This phenomenon is referred to as paravalvular leakage or PVL. PVL was generally appreciated to be undesirable at the priority date of the two patents, although it was not until later that it was discovered to carry more serious, and potentially fatal consequences. The gaps where the frame does not meet the annulus, which are responsible for PVL, are exacerbated by the presence of calcium nodules, or the presence of the native leaflets (which are not removed in the implantation procedure).

The patents in suit

13. Both patents are based on divisional applications from a common parent application. The disclosure of the two patents is for present purposes the same. In summary, the patents propose a Cribier type valve with the addition of a fabric skirt on the outside of the lower part of the frame. The outer skirt provides a fabric seal between the outside of the valve and the annulus, preventing PVL. The difference between the main claims of the two patents is that in 254 the seal is required to be "bunched up" in the deployed configuration, whereas in 766 the seal is to comprise "at least one sac".

14. A bunched up configuration is illustrated in Figure 23 of 254:

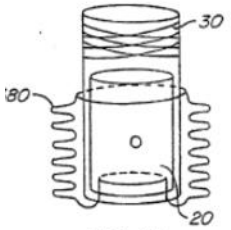


FIG. 23

15. In this particular configuration the bunched up configuration is arrived at by reducing the axial length of the device, in a process referred to as foreshortening. Claim 1 of 254, divided into integers, and with emphasis showing the critical words is:

    i) Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

    ii) an expandable anchor

    iii) supporting a replacement valve,

    iv) the anchor having a delivery configuration and a deployed configuration,

    v) characterized by

    vi) a fabric seal

    vii) extending from the distal end of the valve

    viii) proximally over the anchor in the delivery configuration

    ix) wherein the seal **is bunched up** in the deployed configuration.

16. The distal end of the valve would be the bottom end in the Cribier valve I have illustrated above.

17. In the invention claimed in the 766 Patent the seal is created by "at least one sac" disposed around the exterior of the anchor (i.e. frame) of the THV. The specification explains the problem of PVL at paragraph [0064] by reference to Figure 13:

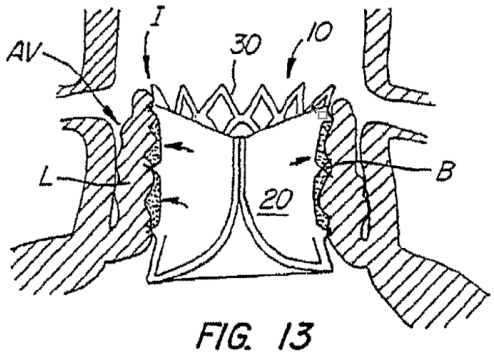
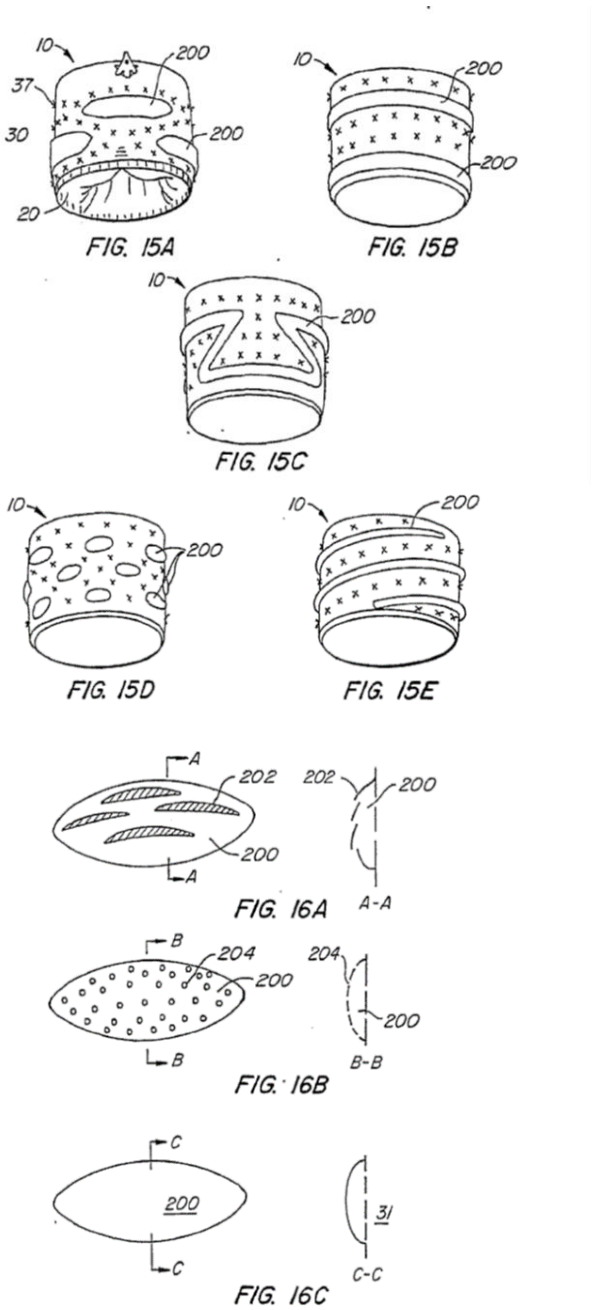


FIG. 13

18. In Figure 13 the native leaflets are identified by the letter L. It is explained that the surface of the leaflets is irregular and, in the absence of a seal, the interface I between leaflets L and the anchor 30 may comprise gaps where blood, denoted by the letter B, may seep through, and pose a risk of clot formation or insufficient blood flow.

19. The specification goes on to explain that "compliant sacs" may be included to reduce regurgitation or leakage. Such sacs provide a more efficient seal along interface I, and may be filled with an appropriate material such as water, blood, foam or a hydrogel. Figure 14 illustrates enclosed, lozenge-shaped sacs.

20. The remaining disclosure about the sac is at column 17 paragraphs [0066] to [0067], which needs to be read together with Figures 15 and 16:



"[0066] With reference to Figures 15, illustrative arrangements for sacs 200 are provided. In Figure 15A, Sacs 200 are provided as discrete sacs at different positions along the height of anchor 30. In Figure 15B, the sacs are provided as continuous cylinders at various heights. In Figure 15C, a single sac is provided with a cylindrical shape that spans multiple heights. The sacs of Figure 15D are discreet, smaller and provided in larger quantities. Figure 15E provides a spiral sac. Alternative sac configurations will be apparent to those of skill in the art.

> [0067] With reference to Figures 16, exemplary techniques for fabricating sacs 200 are provided. In Figure 16A, sacs 20[0] comprise 'fish-scale' slots to go to that may be back-filled, for example, with ambient blood passing through replacement valve 20. In Figure 16B, the sacs comprised pores 204 that may be used to fill the sacs. In Figure 16C, the sacs open to lumen 31 of anchor 30 and are filled by blood washing past the sacs as the blood moves through apparatus 10."

21. Claim 1 of 766, set out as before, reads:

    i) Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

    ii) an expandable cylindrical anchor

    iii) supporting a replacement valve,

    iv) the anchor having a delivery configuration and a deployed configuration,

    v) and **at least one sac** disposed about the exterior of the anchor to provide a seal.

The prior art – Thornton

22. US patent No 6 015 431 (Thornton) is for an invention entitled "Endolumenal stent-graft with leak-resistant seal". It is dated 18 January 2000. It specifically discloses a device known as an endograft, which is used to treat an abdominal aortic aneurysm ("AAA"). An AAA is an enlargement of the abdominal section of the aorta. As the diameter of the aorta enlarges, its wall becomes thinner. If left untreated the wall may burst and lead to the patient's death. The judge described the function of an endograft as follows:

> "An endograft is a stent covered with graft material on the internal or external surface. It can be introduced percutaneously into the aorta at the site of the aneurysm. Once securely anchored at either end of the aneurysm, it replaces that part of the artery so that the blood flowing within it exerts no radial pressure on the weakened section of the artery wall. Relieving the aneurysm of pressure will happen only if the endograft is sufficiently well sealed at either end so that it does not migrate and, importantly, so that blood does not leak into the part of the artery with the weakened wall."

23. Figure 1 of Thornton is reproduced below:

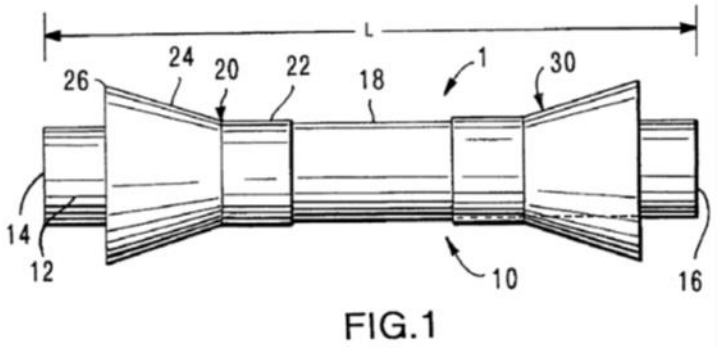


FIG.1

24. The specification explains:

> "More particularly in FIG. 1, flange (26) is shown in a flared condition, which condition may be its relaxed geometry or may be a geometry imparted thereto by flow in the occluded direction. In the case where the flared shape of flange (26) is its relaxed geometry, flange (26) may include an outward bias to that shape, such that when tubular member (10) is deployed into an endolumenal space (not shown in FIG. 1), flange (26) may engage a radially confining endolumenal wall defining that space (not shown) and thereby enhance the reduction of flow around tubular member (10) between outer surface (18) and the endolumenal wall."

25. Although the description is primarily of an endograft there are passages which suggest utility for seal members more generally. Thus at column 6 line 66 to column 7 line 9 Thornton says:

> "It is believed that this invention is particularly useful when the seal member is secured to the outer surface of a stent-graft as the tubular member. This variation is particularly useful in the treatment of intravascular aneurysms, wherein the seal member includes leakage flow around the stent-graft and substantially isolates that flow from the dangerous, abnormal aneurysmal wall. It is further believed that the broader aspects of tubular member-seal member combination of the invention has utility in the prevention of leakage flow around the outer surfaces of implantable endolumenal medical devices."

26. The flange may be made of collagen or Dacron (PET), but a thin-walled ePTFE tape is also proposed as a material for the seal member. It is said that such a tape should be as thin as possible (col. 29, lines 17-67). The overall idea is that the tape provides a one-way flange-type valve function.

27. Figure 3 of Thornton shows the device when deployed in the vessel:

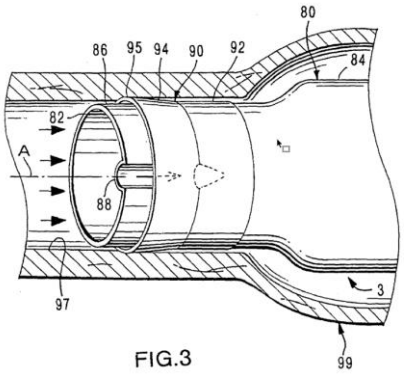


FIG.3

28. At column 8 line 42 of Thornton it is explained that "clinical limitations such as profile, lubricity, traumaticity, or toxicity may dictate the utility of a particular seal member when it is intended to be combined with a tubular member which is designed for a particular application."

29. Edwards' argument was that it would have been obvious to the skilled team to use a flange seal of the type disclosed in Thornton to prevent leakage around a Cribier type THV. Such a flange would, in its deployed state, have taken the form of a bunched up fabric seal as required by claim 1 of the 254 patent, and also have comprised one or more sacs as required by claim 1 of 766.

30. Edwards' clinical expert, Dr Buller, explained in his report how he thought the skilled team would implement Thornton's idea in a THV. He provided a diagram in Figure 32 of his report to show what he meant:

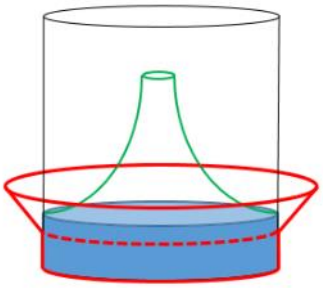


Figure 32: Example of a Thornton seal combined with a THV, showing the seal (red), skirt (blue), stent (black) and valve (green)

31. Dr Buller gave evidence in cross-examination as to how his Figure 32 would operate in the deployed configuration. The reduction in diameter by being pressed against the walls of the annulus would cause the flange to have excess material which would bunch up.

The judgment of HHJ Hacon

32. On the 254 patent, the judge had to resolve a dispute on the evidence over whether one would arrive at Dr Buller's Figure 32 starting from Thornton and the common general knowledge of the Cribier device. He explained that Profs Lutter and Moore

(Boston's clinician and bio-medical engineer respectively) had raised a number of obstacles in the way of using Thornton's seal on a THV. These were seven in number:

i) The skilled team interested in TAVI devices would not expect to find useful ideas in a patent about endografts.

ii) Stents as specifically described in Thornton are anchored against healthy, elastic parts of the aorta rather than having to cope with calcified walls and native leaflets.

iii) The Thornton flange appears to be stiff where it is shown in figure 1 of Thornton.

iv) The Thornton flange would have taken up a lot of space, and compromised the delivery profile.

v) A soft material would not press firmly against the artery wall to form a seal.

vi) Thornton teaches that wrinkles cause leaks, which is the opposite of the wrinkling and bunching of the seal taught in the 254 patent.

vii) There was a risk that a flange might obstruct the coronary ostia.

33. The judge explained that Dr Buller had provided answers to each of these points which he had maintained convincingly in cross examination. As to each of the points identified above, these answers were:

i) The skilled team would expect to find useful ideas about TAVI devices in Thornton. Teachings about TAVI devices had often referred to as an extension of endograft concepts.

ii) It was well known that the points of attachment of a stent proximal and distal of the aneurysm could be irregular and calcified.

iii) The appearance of the flange in the figures of Thornton was only diagrammatic; ePTFE would not maintain a stiff conical shape in use.

iv) ePTFE tape is 0.1 mm thick or less, so even in its delivery configuration would not take up significant space.

v) The ePTFE would consist of excess material in the delivery mode, which would expand into a flange when blood was caught in it and be forced against the vessel wall.

vi) The wrinkling warned against in Thornton concerns the tubular cover of the stent, where wrinkling may be caused by under-expansion of the stent. The flange will seal leaks due to such wrinkles by bulging outwards and conforming to the irregularities in the surrounding tissue.

vii) If the Thornton seal were placed at the bottom of the stent, as shown in Dr Buller's diagram, it would not block the coronary ostia.

34. The judge then pointed out that it was Prof Moore rather than Prof Lutter who had been cross-examined on these points. Having summarised the effect of Professor Moore's cross-examination, the judge said that he preferred the evidence of Dr Buller. He expressed his conclusions in the following way at paragraph 208:

> "The skilled team would have been interested in a general way in anything that might improve the performance of Dr Cribier's THV, which was part of their common general knowledge. Reducing PVL would be only one of several means of making such an improvement, but it would nonetheless have been in the mind of the skilled team in December 2003. The hypothesis is that the team was given a copy of Thornton and read it with interest. They would have regarded it as having come from a field related to TAVI. They would have been aware that the seals used for endografts treating AAA must be particularly effective because a leak in the endograft is liable to be fatal. The flange in Thornton is clearly shown in figure 1 and discussed as a seal in some detail in the specification. In my view the skilled team would have thought it obvious to try using the Thornton flange as a seal on a THV in the manner described by Dr Buller, with a reasonable expectation of success – by which I mean an expectation of reducing PVL to a significant extent. Had that been done, the excess of fabric towards the unattached end of the seal would have caused it to fold in deployment and consequently to become bunched up according to the construction of that term I have reached above. The blood flow would have caused the fabric to bulge out and lie adjacent to the vessel wall, conforming with its contours, thus preventing blood flow past the THV to a significant extent."

35. The judge then recorded the submission made by counsel for Boston based on the fact that Prof Lutter had not been cross-examined on the prior art. It was submitted that if an invention was not obvious to one member of the skilled team the invention was not obvious. The judge dealt with this submission at paragraph 210:

> "I think this was putting the matter too simply. The present case is an example of the frequent circumstance in which there is overlap between the circles of expertise of the members of the skilled team, to use a Venn diagram image. Mr Meade's point would have been a good one if Professor Lutter had raised a reason why the invention in the 254 Patent would not have been regarded as obvious to a skilled interventional cardiologist and that reason was plainly solely within the latter's circle of expertise. In my view that did not apply to the present case."

36. Accordingly, the judge concluded that the invention claimed in 254 was obvious over Thornton.

37. On the validity of the 766 patent, the judge considered the interpretation of "sac" in the course of a long passage at paragraphs 111 to 119 of his judgment. He began by quoting two definitions from the Shorter Oxford English Dictionary:

> "**sac** noun
>
> 1 BIOLOGY. A natural baglike cavity in an organism; the membrane or other structure enclosing this.
>
> 2 MEDICINE. A pouch formed by the pathological dilation or protrusion of a part; the membranous envelope of a hernia, cyst, tumour, etc."

38. In this passage, the judge goes on to consider a separate point, no longer live on this appeal, as to whether the requirement in claim 1 that the sac be "disposed about the exterior of the anchor" meant that both walls of the sac had to be outside the anchor, or whether it sufficed for one wall to be outside and the other inside. He resolved this dispute by saying that the inner wall could be inside or outside the anchor. As to the meaning of "sac" itself he said at 116:

> "… it seems to me that the skilled person would understand the sac to consist of the cavity and also its walls. Also, it is a sac and therefore must have ends which, at the minimum, are broadly perceptible. So the walls must at least approximately meet at each of the two ends."

39. He concluded at paragraph 119:

> "A sac consists of a cavity created between the fabric of the inner and outer skirt, together with its fabric walls which at least approximately meet at its two ends. The inner fabric may be inside or outside the frame. The outer fabric must be adapted to move freely enough to lie sufficiently closely against the adjacent vessel wall, such as to reduce leakage to a significant extent."

40. The judge had thus concluded that a sac connotes (i) a cavity, (ii) with walls, (iii) perceptible ends, and (iv) the walls at least approximately meeting at the ends. I understand the judge to mean that the remaining feature "adapted to move freely enough to lie sufficiently closely against the adjacent vessel wall, such as to reduce leakage to a significant extent" was intended to reflect the remaining words of the claim, ("to provide a seal"), rather than to be an inherent feature of a sac.

41. The judge stated his conclusion on the issue of whether claim 1 of 766 was obvious over Thornton at paragraph 215:

> "I have found that that the invention claimed in the 254 Patent is obvious over Thornton. The important difference between that invention and the one claimed in the 766 Patent is that the latter requires a sac and therefore a cavity with two walls. Nothing in Thornton teaches the further step of creating a sac

> and nothing in the skilled team's common general knowledge would have led the team towards using a sac as a seal. The 766 Patent is not obvious over Thornton."

42. It follows that the judge must have considered that, of the four features I have identified in paragraph 41 above, features (i) and/or (ii) were missing from Dr Buller's Figure 32. In other words, whilst it would be obvious to the skilled team to make something like Figure 32, the flange seal arrangement would not meet the description "cavity with two walls". The judge does not expressly mention features (iii) and (iv), but it seems likely that he was also relying on at least feature (iv), that the walls should at least approximately meet at the ends, so as to distinguish and exclude the open conical shape of the Thornton flange in the undeployed state.

Edwards' appeal on 766

43. The first issue on this appeal is whether Dr Buller's Figure 32 falls within the scope of claim 1 of the 766 patent. Its resolution depends on the proper interpretation of the words "one or more sacs".

Edwards' submissions

44. Mr Iain Purvis QC, who appeared on behalf of Edwards with Mr Piers Acland QC, submitted that, in the specification of 766, the patentee has made it clear that the precise structure of the sac can vary within wide limits. In the end, all that was required was a cavity with walls and which could be filled, either with flowing blood or with gel, so as to provide a seal between the frame and the inner wall of the annulus. The judge's findings in relation to how Buller Figure 32 would work were adequate to establish that it fell within the claims on that construction. There was a cavity in the hollow volume created by the flange. The cavity had two walls: the flange and the inner skirt. The judge's further limitation based on the walls of the sac having to meet was wrong. A bag, which is what in essence a sac was, had to have an opening if it was to function as a bag.

Boston's submissions

45. Mr Richard Meade QC who appeared for Boston with Ms Kathryn Pickard, explained that the argument about whether Thornton disclosed a sac had been deployed at the trial by Edwards as a patent lawyer's "squeeze" on construction. He meant by this that Edwards were not really arguing that Buller Figure 32 had a sac as a matter of ordinary language. Rather it was their case that Boston could not maintain that the Sapien 3 was an infringement whilst at the same time arguing that Buller Figure 32 was outside the scope of the claim. He drew attention to certain differences between the Sapien 3 and Buller Figure 32 with the objective of demonstrating that the answer to the dilemma posed was that the Sapien 3 truly did have a sac, whereas Buller Figure 32 did not.

46. Mr Meade submitted that the correct construction of "sac" was that it was a cavity with a degree of enclosure. This did not mean that you could not have an opening in the sac, as the patent showed. The judge had expressed this notion in terms of requiring the ends of the bag to meet, but both meanings were driving at the same thing. Figures 14 to 16 all shared the feature of a substantial degree of enclosure,

albeit with limited openings. The purpose was to fill the enclosure with blood or gel so as to make a bumper-like feature for improving the seal. Mr Meade drew attention to Edwards' closing submission at trial, with which Boston agreed, where they had said:

> "Whether sealed or open to the bloodstream via slots, pores or otherwise, the skilled person will nevertheless understand the patentee to be using the word sac in accordance with its ordinary English meaning, referring to a baglike cavity or pouch. In other words, a structure with walls of some description that is substantially (if not wholly) enclosed so that it can fill."

47. Buller Figure 32 did not have the requisite degree of enclosure to amount to a sac, whether in the undeployed or deployed configuration. Before use it was not enclosed at all. When deployed, the evidence was not sufficiently clear as to what configuration the Thornton flange would adopt, and there had been no attempt to elucidate it at the trial.

Discussion and conclusion

48. There is an initial question as to whether claim 1 of 766 requires the presence of a sac in both the undeployed and deployed configurations. It might be said, on the one hand, that what matters, on a purposive basis, is that the sac should be present in the deployed configuration, where it is required to form a seal. The fact that a sac is not present in the undeployed configuration would not be considered important to the skilled team. On the other hand, a more literal construction would be to say that all the features of the claimed apparatus are required to be present both in the undeployed and deployed configurations. As will appear, I do not consider that it was established that Buller Figure 32 comprised a sac in either configuration, and so it is not it necessary to resolve this issue.

49. In my judgment, Boston is correct that the requirement for a sac in claim 1 is not so broad as to encompass any cavity which is capable of receiving blood or other material so as to form a seal. The term "sac" has been chosen by the patentee in preference to such general language. It means a bag-like cavity providing a substantial degree of enclosure, as the dictionary definition cited by the judge implies. Edwards' submission at trial also recognised that the term implied that the cavity had a substantial degree of enclosure. That is the concept illustrated in all the relevant figures. These allow a degree of freedom in the design of the sac, but not so much freedom as to encompass any cavity, however open. Plainly, as the figures show, the sac can have openings. There is also no reason why the sac cannot have an opening at the upper (proximal) end to allow the blood to enter. Nevertheless, the openings must not be such as to cause it to lose its bag-like, substantially enclosed character.

50. It follows that I do not consider that Buller Figure 32 shows a sac in the undeployed condition. It would be better described as having a flange- or dish-like structure. The structure does not provide any real enclosure: it is wide open.

51. I also need to consider the structure that Buller Figure 32 would adopt in the deployed configuration. The judge's finding here was that the fabric of the flange would be

caused to bunch up, and that "the blood flow would have caused the fabric to bulge out and lie adjacent to the vessel wall, conforming with its contours thus preventing blood flow past the THV to a significant extent." To my mind, that finding is not sufficiently precise to allow the conclusion that the flange will create one or more sacs. It leaves room to speculate as to the degree to which the bunched up fabric will form enclosures which can be described as bag-like. I agree with the judge that one would not get the idea of a sac forming a seal in the deployed configuration from Thornton. His depiction of the flange in the deployed configuration, albeit diagrammatic, gives no hint that this is how it would operate. I accept Mr Meade's submission that there was insufficient investigation at trial as to how Dr Buller's implementation of Thornton would behave in the deployed state to conclude that there would necessarily be created a sac functioning as a seal.

52. It follows that the issues on claims 4 and 7 are not necessary for our decision. Given that the judge made no findings on these issues, I prefer not to express a conclusion on them.

53. I would therefore dismiss Edwards' appeal against the finding of validity of claim 1 of 766.

Boston's appeal on 254

Boston's submissions

54. Mr Meade submitted that the judge made five fundamental errors. Firstly, he wrongly treated the evidence of Boston's two experts as overlapping because they covered the same topics. In fact, their evidence was separate and distinct because they came from different disciplines. Secondly, he wrongly held that it was for Boston to show that Prof Lutter could have said something which was solely within the expertise of the clinician. Instead, he should have asked whether he could be confident that there would not have been anything material to be contributed by the clinician, had the matters been put to him as they should have been. Thirdly, he wrongly applied those principles here, because there were issues which plainly needed to be put to Prof Lutter, such as delivery profile and whether Buller Figure 32 would work. Indeed there were some matters where Prof Moore had expressly said that the clinician would need to comment. Fourthly, the matter was not handled correctly from the procedural point of view: the decision not to cross-examine Prof Lutter was not raised with the judge in advance, the cross-examiner did not ask Prof Lutter whether there was anything he could add, and Edwards had given the clear impression that they intended to cross-examine both experts on the prior art. Finally, Prof Lutter had been an important witness because he was the only expert with practical experience of TAVI devices at the priority date.

55. Mr Meade stressed the collaborative nature of the skilled team. The question of whether a Thornton type flange would be worth trying as a seal in a THV was not a question exclusively for the engineer or the clinician. Whether it would be likely to work was a matter on which the views of the clinician would be canvassed.

56. There were three areas on which Professor Lutter's views were material. Firstly, Prof Lutter had said in paragraph 138 of his first report:

> "It is difficult to envisage how the concept of a flange, as shown in Figure 1 in Thornton, would work well in a TAVI device. A stiff material would not create a seal with an irregular surface, although it may seal against a calcium free, regular section of the aorta. A soft material would not function as a flange: it would not press firmly against the wall of the vessel of the unsecured end, unless squeezed between the wall and the stent, in which case it would not operate as a flange and will not serve a useful function. I cannot therefore see how a flange would work to prevent leakage in an aortic heart valve to any useful extent."

57. I will call the first point "the weak flange point." Secondly, Prof Lutter had pointed out as a fact that Thornton's flange proposal had never been implemented even in an endograft device ("the Thornton implementation point"). Thirdly, during the course of the cross-examination of Prof Moore in relation to Thornton, Prof Moore had said that the question of whether the flange would be worth including in a heart valve system in the light of the increased delivery profile that would be created ("the delivery profile point") would be a question for discussion (i.e. between the engineer and the clinician). The cross-examiner had recognised in this passage that he would have to take the delivery profile point up with Prof Lutter.

58. Mr Meade's primary submission as to the consequences of the failure to cross-examine Prof Lutter, was that the court was bound to accept his evidence and reject the allegation of obviousness. Alternatively, and perhaps more realistically, he submitted that this court would have to look at the issue again, and if persuaded that cross-examination could have made a difference to the outcome on this issue, set aside the judge's conclusion.

Edwards' submissions

59. Mr Purvis submitted that the rules about what must be put in cross-examination were not to be rigidly applied in relation to expert evidence. Where the issue for the judge was obviousness, it was the expert's reasons which were important, and these had already been laid out in their reports for the judge to evaluate. It did not matter that the expert had not been challenged head-on in relation to each reason, particularly when each of the reasons had been advanced independently by both experts. Moreover, in the present case, two fundamental planks of Prof Lutter's reasoning had been undermined by cross-examination. Firstly, Prof Lutter had said that he would not have been interested in transferring technology from the field of endografts to that of replacement heart valves. Secondly, he had argued that the skilled team would not have been aware of the problem of PVL. That was enough to reduce the effect of his overall opinion of non-obviousness.

60. Each of Prof Lutter and Dr Moore had given evidence on each of the points which the judge identified as purported obstacles on taking Thornton's idea and coming up with the Buller Figure 32 configuration. Dr Buller had challenged each of these reasons in his report in reply. It was therefore significant that Boston chose to adduce evidence in rejoinder on these points only from Prof Moore, and reasonable to assume that it was Prof Moore who was the main witness to cross-examine on these obstacles, not Prof Lutter.

61. Of the three points advanced by Mr Meade on which it was suggested Prof Lutter should have been challenged, the delivery profile point was not one which Prof Lutter had made once he saw Figure 32 of Buller. It had rightly been pursued in cross-examination with Prof Moore, given that he had expressed competence to deal with it, and it was essentially a bio-engineering issue. The weak flange point was also a bio-engineering point concerned with the strength of materials. Consistently with that, it had been dealt with by Prof Moore in his rejoinder report. The Thornton implementation point was simply a factual point on which there was indeed no contrary evidence. However there was no basis for supposing that the judge did not take this point on board in his overall evaluation of obviousness.

Discussion and conclusion

62. Phipson on Evidence (19th Edn. 2016) summarises the obligation to cross-examine a witness in the following way at paragraph 12-12:

> "In general a party is required to challenge in cross-examination the evidence of any witness of the opposing party if he wishes to submit to the court that the evidence should not be accepted on that point. The rule applies in civil cases as it does in criminal. In general the CPR does not alter that position. This rule serves the important function of giving the witness the opportunity of explaining any contradiction or alleged problem with his evidence. If a party has decided not to cross-examine on a particular important point, he will be in difficulty in submitting that the evidence should be rejected. However, the rule is not an inflexible one. For example, if there is a time-limit imposed by the judge on cross-examination it may not be practicable to cross-examine on every minor point, particularly where a lengthy witness statement has been served and treated as evidence-in-chief. Thus, in practice there is bound to be at least some relaxation of the rule. Failure to put a relevant matter to a witness may be most appropriately remedied by the court permitting the recall of that witness to have the matter put to him.

63. As made clear by cases from *Browne v Dunn* (1894) 6 R. 67 HL to *Markem v Zipher* [2005] EWCA Civ 267; [2005] R.P.C. 31, the rule is an important one. However, it is not an inflexible one. Procedural rules such as this are the servants of justice and not the other way round.

64. I would start by accepting two of the points on which Mr Meade relies. In a case where it is proposed to save time by not cross-examining two witnesses in relation to the same or similar subject matter, it is good practice for the matter to be raised with the judge beforehand so that he can give directions in the light of the parties' submissions. The judge should in general give directions so as to ensure fairness to the parties without incurring unnecessary costs by extending the length of the trial. However, the fact that such a direction is not sought or given does not automatically require the judge to accept an unchallenged reason given by one expert.

65. Secondly I would agree, as a general matter, that the rule requiring important positive evidence to be challenged is a rule which is not simply for the benefit of the witness (whose honesty or professional reliability is challenged) but is also designed to ensure the overall fairness of the proceedings for the parties. In *Markem* Jacob LJ, giving the judgment of the Court of Appeal, with which Mummery and Kennedy LJJ agreed, put it this way at [56]:

> "… procedural fairness **not only to the parties but to the witnesses** requires that if their evidence were to be disbelieved they must be given a fair opportunity to deal with the allegation." (emphasis supplied).

66. The rule applies with particular force where a witness gives direct evidence of a fact of which he has knowledge and which it is proposed to invite the court to disbelieve. Fairness to the witness and to the parties demands that the witness should be challenged on his factual evidence so as to give him the opportunity of affirming or commenting on the challenge, or on a positive matter which it is proposed to set against his evidence.

67. Not every situation however calls for a rigid application of the rule. At least part of the unfairness which the rule is intended to address is the lack of any opportunity for a witness to respond to a challenge to his evidence. In the present case there was more than one round of expert evidence. Boston put in three rounds, so each expert had more than ample opportunity to comment on the views of the other. The battle lines between the experts were clearly drawn in the pre-trial exchange of reports. The potential for unfairness to the witness in such circumstances is much reduced.

68. Even in the case of evidence of fact, it is no longer the law that every aspect of a witness' evidence needs to be challenged head-on. Foskett J expressed this in terms with which I agree in *Various Claimants v Giambrone & Young* [2015] EWHC 1946 at [21].:

> "I do not accept that merely because the suggestion that what he said in his witness statement was untrue (or simply misguided) was not put specifically to him (a proposition that inevitably he would deny) means that I am bound to accept his position. It is, of course, important to be fair to a witness, particularly if serious imputations as to the witness' honesty and integrity are being made, and there may be other areas of a witness' evidence that need to be challenged head-on, but the days of the "I put it to you" cross-examination on other matters have long since gone."

69. On an appeal to this court the question must be whether the decision not to cross-examine has led to unfairness to the extent that the judge's decision on the relevant issue is thereby undermined.

70. I am wholly unpersuaded that the judge's decision in the present case is rendered in any way unsafe by the fact that Prof Lutter was not individually challenged in cross-examination on the points to which Mr Meade has drawn attention. My reasons in summary are the following:

i) It is not entirely accurate to regard Prof Lutter's evidence as "unchallenged". By the time Prof Lutter went into the witness box he had seen and had the ability to comment on the contrary technical opinion of Dr Buller and, in addition, seen the challenges put to the self-same points being put to Prof Moore. This is a wholly different situation to one where a witness has had no notice of the nature of the challenge to his evidence and no fair opportunity to comment on it. To use Jacob LJ's phrase, Prof Lutter had had a "fair opportunity" to comment on the conflicting evidence of Dr Buller.

ii) Ultimately it was each expert witness' overall reasoning which the judge was examining. The cross-examiner did challenge Prof Lutter's opinion that the invention was obvious in the light of Thornton in the sense that he attacked Prof Lutter's twin suggestions that PVL was not a problem that needed solving and that one would not transfer ideas from endografts to heart valves. The judge made findings adverse to Prof Lutter on both these points, and it was accordingly open to Edwards to submit that two of the basic planks in Prof Lutter's reasoning had been knocked away, and that Prof Lutter had not approached his task from the correct perspective. In those circumstances I do not see why the judge would be bound to accept Prof Lutter's further reasoning, particularly when he had heard evidence to the opposite effect from Dr Buller, whose evidence did not suffer from the same drawback.

iii) Although Prof Moore and Prof Lutter had different expertise, they were both giving evidence on how a collaborative skilled team would have undertaken a hypothetical design project. They were qualified to do so because they would both be in a position to know how such a team would react to a document such as Thornton. Consistently with that Prof Lutter had expressed himself in terms which showed he considered he was able to speak on behalf of the whole team, when he said in his first report "*I doubt whether a team working on the design of a TAVI device would have been very interested in Thornton or found anything useful in it. I do not consider it would have been obvious to such a team to modify the endograft described in Thornton*……".

iv) For that last reason there was a genuine overlap between the evidence of the two experts. That overlap was the more extensive because both were making, as Mr Meade accepts, exactly the same technical points. The judge was right, therefore, to focus on whether Boston could identify any point which was exclusively for the clinician. The judge was justified in thinking that Boston would not be able to identify such a point as each expert had claimed the ability to make the same points.

v) The weak flange and delivery profile points were plainly points principally within the expertise of the biomedical engineer, whose job includes understanding how a given device will interact with living tissue. Prof Lutter had not given any positive evidence which went beyond discussing the properties of the materials and their interaction with tissue, and did not take the several opportunities which were open to him to make some further point in writing from the point of view of the clinician.

vi) Accordingly, if the overlap had been raised with the judge by counsel for Edwards, the judge should not have required both experts to be cross-

examined on these points. To do so would have increased the length of the trial for no good reason. It seems to me that he would inevitably have considered that Prof Moore was the witness to choose to be cross-examined on the weak flange and delivery profile points, given the way in which these points had been presented in Boston's evidence.

vii) I accept that it was at one stage said to Prof Moore whilst he was in the witness box that an issue would have to be pursued with Prof Lutter. I do not regard that as determinative. If Boston considered that there was something of importance which Prof Lutter could add on that issue (despite the fact that he had not taken the opportunity to make the point in writing) Boston could have led such evidence from Prof Lutter in chief, or, alternatively (and as Phipson suggests), applied to have Prof Lutter recalled before final speeches. It took neither course.

viii) Mr Meade accepted that the "Thornton not implemented" point would not on its own undermine the judgment, but submitted that, taken with his other points, it rendered the judgment unsafe. I would not accord it even that status. It is a point of a quite different character to his other points, which depend on Prof Lutter being denied a further opportunity to give justification for his views. It amounts to no more than a suggestion that the judge ignored this one point, notwithstanding the fact that it was argued by Boston below. It is a point often made in patent cases, and it is most unlikely that the judge did not bear it in mind in his overall evaluation of obviousness.

71. I would therefore uphold the judge's conclusion of obviousness of 254, and dismiss Boston's appeal on the 254 patent. It is not therefore necessary to consider a further ground of invalidity based on added matter raised by Edwards' respondents' notice.

Overall Conclusion

72. If my Lords agree, it follows that both the appeals should be dismissed.

Lord Justice McCombe

73. I agree.

Lord Justice Kitchin

74. I also agree.