Neutral Citation Number: [2010] EWCA Civ 704

Case No: A3/2009/0917 and 0921

IN THE HIGH COURT OF JUSTICE
COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE HIGH COURT OF JUSTICE
CHANCERY DIVISION (PATENTS COURT)
Peter Prescott QC
HC 07 CO1243

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 30/06/2010

Before :

THE RT HON LORD JUSTICE JACOB
THE RT HON LORD JUSTICE MOORE-BICK
and
THE RT HON LORD JUSTICE ETHERTON

- -

Between:

Medtronic CoreValve LLC (formerly CoreValve Inc)	**Appellants/ Respond-ents**
- and -	
(1) Edwards Lifesciences AG **(2) Edwards Lifesciences PVT Inc**	**Respond-ents/ Appellants**

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- -

Antony Watson QC and Tom Mitcheson (instructed by Simmons & Simmons)
for Medtronic CoreValve

Henry Carr QC and Piers Acland QC (instructed by Bird & Bird LLP)
for Edwards Lifesciences

Hearing date: 11 May 2010

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Judgment

Lord Justice Jacob:

1. The patentee (Edwards) appeals the decision, [2009] EWHC 6 (Pat), of Peter Prescott QC (sitting as a Deputy Judge of the Chancery Division). He held that the claimant's (CoreValve as I shall call it) heart valve device did not infringe Edwards' EP (UK) No. 0592410 but the Patent is valid. CoreValve cross-appealed his decision on validity, but only contingently so: if we decided that its product does not infringe, then it was not concerned with validity.

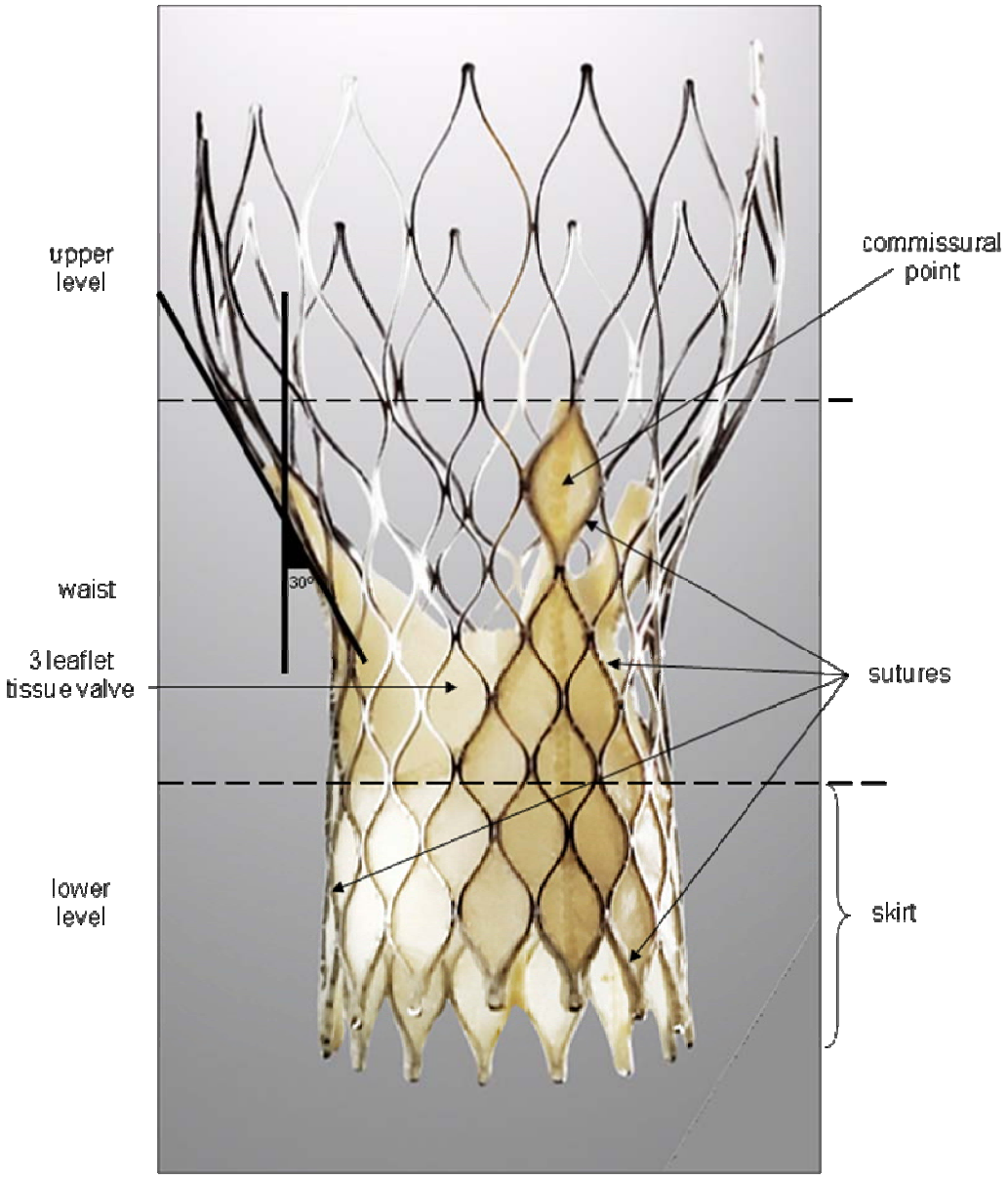
2. This was not one of those cases where the issue of infringement is interlinked and overlapped with that of validity – the validity and infringement points were independent of each other. So, with the parties' agreement, we decided to "bifurcate" the appeal by hearing all the argument on the issue of infringement first. Only if we concluded that the product infringed (or were not yet sure one way or the other) would it be necessary to hear the appeal about validity. In the event, following argument, we were able to form a clear conclusion to the effect that the CoreValve product did not infringe. We so informed the parties at the time. They were able to agree the consequential order.

3. I turn, therefore, to my reasons for the conclusion.

4. Claim 1 (the only claim which matters) reads (omitting the numbers):

> A valve prosthesis, preferably a cardiac valve prosthesis, for implantation in the body and comprising a collapsible elastical valve which is mounted on an elastical stent wherein the commissural points of the elastical collapsible valve are mounted on *the cylindrical surface* of the elastical stent **characterized** in that the stent is made from a radially collapsible and re-expandable *cylindrical support means* for folding and expanding together with the collapsible valve for implantation in the body by means of a technique of catheterization.

5. I have italicised the words over which the dispute rages. It is now being accepted that apart from these aspects of the claim the CoreValve product falls within it. One can see the reason for the dispute by looking at the accused product:



6. The commissural points of the valve, says CoreValve, are not mounted on a *cylindrical* surface of the stent. Nor is the support means *cylindrical.* "Oh yes they are when you construe the claim properly", retorts Edwards.

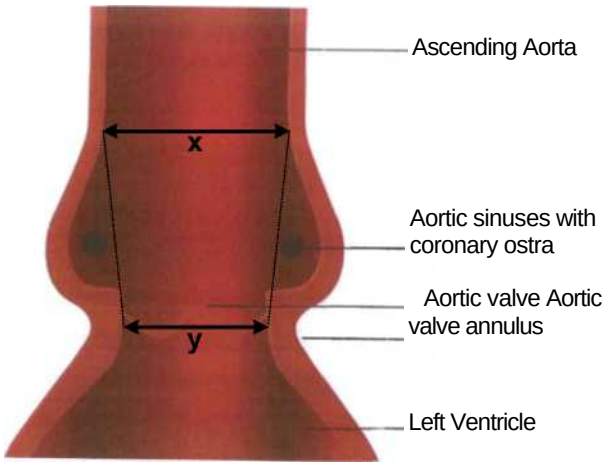
7. There was no dispute as to the applicable principles of construction. "The question is always what the person skilled in the art would have understood the patentee to be using the language of the claim to mean" *per* Lord Hoffmann in *Kirin-Amgen* ([2004] UKHL 46 at [35].

8. Before considering the disputed language further, I must record the other issues of construction which were resolved by the Judge and not resurrected on the appeal. First is that the claim is to a device as manufactured, not as compressed and ready to be introduced via a catheter. And second that the claim is limited to a device which can be introduced by a catheter without having to open the thoracic cavity.

9. The Judge describes the heart, its valves and main blood vessels uncontroversially at [8-16]. I do not repeat it: it is on the Bailii website (www.bailii.org). The skilled reader would know all this.

10. He would also be familiar with stents for implantation into arteries by catheterisation. All the stents of this sort at the date of the Patent were cylindrical in the ordinary meaning of the word: of uniform circular cross-section at right angles to the axis of the circular cross-section. He would also know that they were implanted in lumens of approximately uniform cross section: in layman's language the prior art stents were cylindrical and went into roughly cylindrical "pipes."

11. A particular matter on which Mr Carr QC (counsel for Edwards) places considerable reliance is that the skilled reader would also know the basic structure of the aortic valve and its surrounds. Schematically it looks like this:



12. Mr Carr draws attention to the fact that the diameter of the aortic valve annulus (y) is less than x, the diameter of the ascending aorta. Any stent reaching from the annulus to the aorta in vivo and "gripping" at both places will not be of substantially constant diameter – it will be wider at x than y.

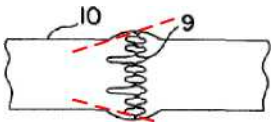
13. What then does Mr Carr contend the patentee's limitations *cylindrical surface* and *cylindrical support means* would convey to the skilled reader? We put it to him directly. His answer was this: "cylindrical means a shape which has a generally circular cross-section. It needs to have some length to hold it in place, but it does not have to have a substantially constant diameter. It has to be sufficiently cylindrical to mirror the place of implantation but no more."

14. As I see it, before the argument can get off the ground, it is necessary for Mr Carr to show that the skilled reader would learn from the Patent the idea that his stent should "mirror the place of implantation".

15. Mr Carr submits that is obviously technically necessary – otherwise there is a danger of migration. But the Patent does not say that or anything like it. The general idea of the Patent is to put a valve onto a stent. Known stents were truly cylindrical and radially expandable (either by a balloon or by natural expansion of a material such as nitinol). The patentee had got no further than the idea of a valve on a stent – he had not thought of (or more accurately had not disclosed) the idea of changing the shape of the stent itself depending on the place of intended implantation.

16. Mr Carr contended otherwise. His main argument depended on some of the figures and on a passage at col. $8_{2\text{-}22}$. The figures relied on are 7 showing a stent implanted in the aorta, and fig. 9 showing the stent implanted in a position immediately after the mouth of the coronary arteries in the ascending aorta.

17. Figure 7 is as follows:



And figure 9:

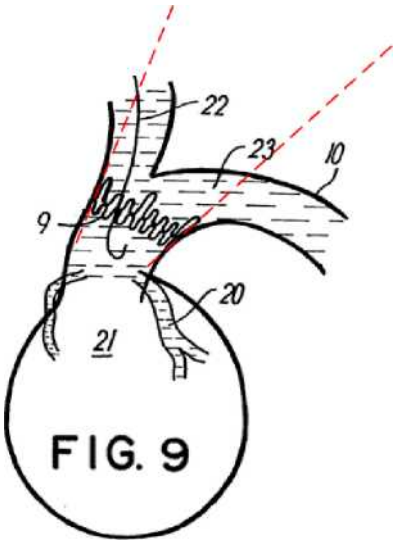


FIG. 9

18. To both of these figures Mr Carr has added dotted lines. He says that the skilled man would realise that when implanted the stent will not be cylindrical but will follow the shape of the place of implantation.

19. That may be so, but it does not follow that the patentee had disclosed the idea of shaping the stent to mirror that place. Thus all he says in his discussion of fig. 7 is this (col.$7_{45\text{-}48}$):

> To obtain an effective fastening in the aorta the outer dimension of the cardiac valve prosthesis is greater than the diameter of the aorta. This means that the prosthesis is right against the inner wall of the aorta.

To speak of "the outer dimension" is not suggesting a dimension which varies.

20. The passage relied on reads:

> Figs. 8-10 show the positioning of the valve prosthesis 9 as cardiac valve prosthesis in the aorta 10 in three different positions. In a position between the coronary arteries 20 and the left ventricle of the heart 21 (Fig. 8). In a position immediately after the mouth of the coronary arteries in the ascending part of the aorta (Fig. 9). In a position in the descending part of the aorta 10. The positioning of the valve prosthesis is chosen in accordance with the diagnose(sic) of the illness of the patient. By placing the cardiac valve prosthesis as shown in Fig. 8 there is a risk of detachment and/or covering the mouth of the coronay (sic) arteries, and therefore it is preferred to use a higher stent which for instance comprises several rings 7,8 placed on top of each other. This allows a fixation of the prosthesis at a

> place after the mouth of coronary arteries even though the valve itself is in the position between the coronary arteries and the left ventricle.

21. Fig 1 of the Patent shows the rings 7,8 which are referred to:

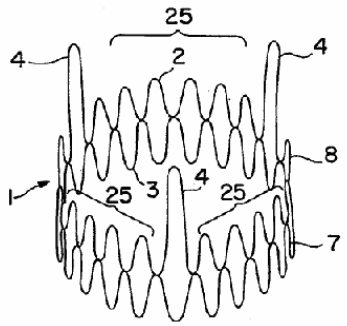
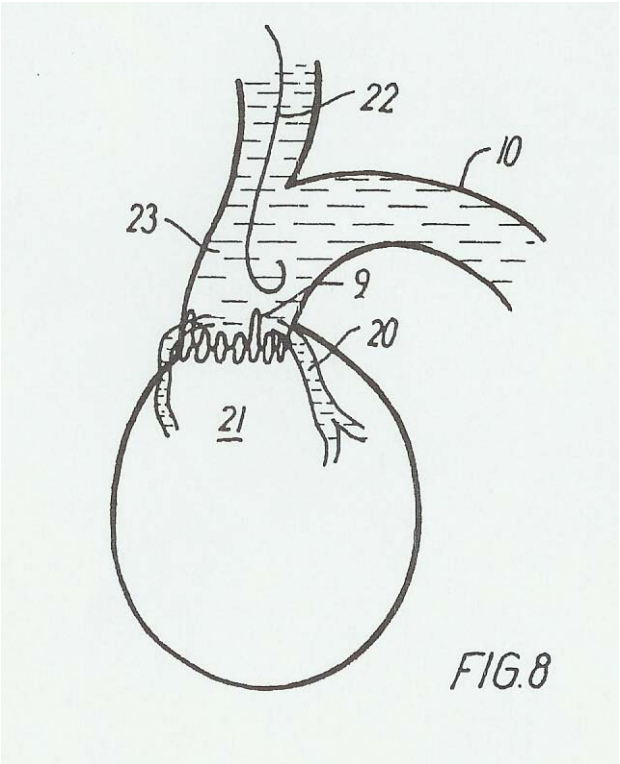


FIG. 1

And fig. 8 looks like this:



22. Mr Carr relies on the reference to the "higher stent". The Patent suggests "several rings, 7, 8 placed on top of each other" Mr Carr submits this would be understood by the skilled person as rings of *different diameter* fixed together. He says that is the only way one could get better fixation at the position shown in fig. 8. By using a longer stent one can get a second fixation point in the ascending aorta. That has a larger diameter than the aortic valve annulus. It follows, he says, that the Patent teaches a stent which has differing diameters along its length when implanted. Hence the reader would learn that the stent

should have different diameters before implantation; to mirror the place of implantation.

23. He further submits that Prof. Rothman was wrong to suppose that the patentee by the use of the "higher stent" was contemplating moving the stent to the fig.9 position.

24. And, he says, to confine *cylindrical* to that which is approximately geometrically cylindrical is to give the claim a purposeless limitation.

25. I cannot accept these arguments. They put far too great a strain on the word "cylindrical" – they indeed amount to striking it out altogether. Of course in some cases a patentee by the use of a particular geometric term may not have intended mathematical precision (the classic is "vertical" in *Catnic* [1982] RPC 183). But it is quite another thing to strike a limitation out altogether which is the effect of Mr Carr's suggested meaning of *cylindrical*. As Hoffmann LJ observed in *STEP v Emson* [1993] RPC 513 at 523:

> The well known principle that patent claims are given a purposive construction does not mean that an integer can be treated as struck out if it does not appear to make any difference to the inventive concept. It may have some other purpose buried in the prior art and even if this is not discernible, the patentee may have had some reason of his own for introducing it.

26. Further Mr Carr's arguments ignore the basic theme of the Patent – which was just to put a valve onto a known type of stent which is cylindrical. Re-shaping the stent is simply not mentioned. I cannot envisage a skilled man getting that notion out of the short, cryptic, passage relied upon.

27. Quite what it would convey I am not sure. Perhaps that a longer stent would, when expanded, achieve sufficient fixation from the second fixation point. Or perhaps that it should simply be placed as suggested by Prof. Rothman. This kind of complicated speculation about a cryptic bit of teaching is surely not enough to convey to the skilled reader that the Patent is using *cylindrical* in a very special way - to teach a shape which varied along its length. There is simply not enough there for the skilled reader to understand that the word was being used other than in its ordinary acontextual sense, a sense which would accord with his own knowledge of stents used for implantation by catheterisation.

28. In the end I agree with the Judge. He said this:

> [58] But, said Mr Wyand [then counsel for Edwards] the cross-section of that part of the aorta is not uniform. Therefore, said Mr Wyand, the description in the patent implies that the cross-section of the stent need not be uniform. In my judgment, that is to place more inferential weight on the above-quoted passage than it can bear, the more so since it is not all that clear

> in the first place. In my judgment it probably means no more than this, that a taller stent can be used.

29. Mr Carr had an alternative argument. This was that the accused stent should be regarded as two-part, a lower part from the waist down which was essentially truly cylindrical and an upper, widening out part. He said the claim was satisfied by the lower part alone. That being so, the "extra" upper part could not turn that which was an infringement into a non-infringement. I reject that for two reasons. First I do not think the skilled reader would regard the accused device as a stent in two parts: to him or her it is a unitary article. Secondly the commissural points of the accused stent are in any event not mounted on a cylindrical surface – they are above the waist, being mounted where the angle of flare is about 30^0.

30. I am gratified to find that I reach the same conclusion as the Oberlandsgericht in Düsseldorf. By a Judgment of 11th February 2010 it upheld a finding of non-infringement of the Landsgericht. It too thought that Edwards' construction of *cylindrical* meant it had no meaning (the translation says "obsolete" but clearly in context means redundant). And it too was not impressed by the "two-part" argument.

Lord Justice Moore-Bick:

31. I agree.

Lord Justice Etherton:

32. I also agree.