IN THE HIGH COURT OF JUSTICE Claim No. HC-2015-004574
CHANCERY DIVISION
PATENTS COURT

The Rolls Building
7 Rolls Buildings
London EC4A 1NL
Fetter Lane
Friday, 27th January 2017

Before:
HIS HONOUR JUDGE HACON
(Sitting as a Judge of the High Court)

BETWEEN:

EDWARDS LIFESCIENCES LLC
(a company incorporated under the laws of the state of Delaware)
Claimant

- and -

BOSTON SCIENTIFIC SCIMED, INC.
(a company incorporated under the laws of the state of Minnesota)
Defendant

- and -

(1) EDWARDS LIFESCIENCES CORPORATION
(a company incorporated under the laws of the state of Delaware)
Third Party

(2) EDWARDS LIFESCIENCES AG
(also known as EDWARDS LIFESCIENCES SA)
(a company incorporated under the laws of Switzerland)
Fourth Party

(3) EDWARDS LIFESCIENCES LIMITED
Seventh Party

(Computer-aided transcript of the Stenograph Notes of
Marten Walsh Cherer Ltd., 1st Floor, Quality House,
6-9 Quality Court, Chancery Lane, London WC2A 1HP.
Telephone No: 020 7067 2900. Fax No: 020 7831 6864
e-mail: info@martenwalshcherer.com)

DR. PIERS ACLAND QC and MR. MILES COPELAND (instructed by Powell Gilbert LLP) appeared for the Claimant.
MR. RICHARD MEADE QC and MS. KATHRYN PICKARD (instructed by Olswang LLP) appeared for the Defendant.

PROCEEDINGS
DAY 7

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JUDGE HACON: Yes?

MR. ACLAND: Good morning. I have two memory sticks which contain the electronic documents.

JUDGE HACON: Very helpful.

MR. ACLAND: I am sure you do not need them right now. My Lord, I have an hour left and can I tell you how I propose to use that hour.

JUDGE HACON: Yes, please.

MR. ACLAND: We were dealing with construction and what I am going to do is to articulate as concisely as I can what our contentions are on the two patents and what we see are the deficiencies with Boston's construction.

Now, in those circumstances it may not be fruitful to spend any more time debating whether figure 15 in the Sac Patent discloses double layered sacs. I will let Mr. Meade explain why they are necessarily single-walled. But what is clear and if you have the -- I am looking at the Sac Patent.

JUDGE HACON: Yes, do you want me to get that out?

MR. ACLAND: Yes. So it is page 53 is the first part of figure 15 and then the top of page 54 is the second. So figure 15, at least as far as double-walled is concerned, they are the sac that you see in figure 14, or the two sacs one sees in figure 14 are certainly double-walled and the sacs that are

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shown in figure 16 are certainly double-walled -- two layers.

What this really goes to is the construction of the term "disposed about the exterior of the anchor", which now, although you have just been looking at the Sac Patent, is an issue in the Bunched-up Patent. You want to look at the bunched-up claims, claim 1. Sorry, what am I talking about? That is completely off the page. The Sac Patent claims.

JUDGE HACON: We are back to the Sac Patent.

MR. ACLAND: Sorry. So it is the language at the end of claim 1, "at least one sac (200) disposed about the exterior of the anchor (30)." So this is what this is going to. If they are double-walled the double walls both have to be outside the scope of the anchor. We are talking about a sealing function, whereas my learned friend's case is that in so far as double-walled sacs are allowed, they can be both within and without the anchor. Do you remember, fabric, metal, fabric?

JUDGE HACON: Yes. He says the sac presumably need not include both walls.

MR. ACLAND: Well, I think in so far as he says a sac has two walls, because of course his construction is, it does not have to have necessarily two walls, it can just be a volume-filling space.

JUDGE HACON: Well, we leave that. I do not want to take up your time.

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MR. ACLAND: Can I tell you, "disposed around the exterior of the anchor", there are two submissions on that. First of all, as a matter of ordinary English, what is "disposed about the exterior"? It means that whatever is your sac needs to be disposed exterior of the anchor. That is tremendously straightforward. Then as a matter of purpose there is a technical reason for having your sac, whatever it is, disposed outside of the exterior because the sealing that one is seeking to achieve is between the outside of the stent and the annulus.

Now, Dr. Buller was cross-examined on this. The references are given in our skeleton. But I can summarise the point I was making which was, if you had a sac -- I will just find you the references for that in our skeleton. It is page 178. Do you see that? He says it is a sac. He would understand the purpose to be to inflate or fill gaps between the stent and the wall. He said it would therefore be nice if it was situated between the anchor and the wall, otherwise part of the inflation could be wasted with it blowing up on the other side.

So, it is certainly not the case that one would not achieve any space-filling properties with a sac which was both inside and outside, but certainly it makes sense for it to be outside in accordance with the ordinary English.

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JUDGE HACON: Okay.

MR. ACLAND: So that is "disposed about the exterior".

Now, as far as the Bunched-up Patent is concerned, so if you can take claim 1 of that patent, but before we look at the claim, let us just remind ourselves of the figures that depict bunching-up. So it is figures 22-24 on page 47. What clearly emerges from what is described there or depicted there are three points which are relevant for what I am going to say in relation to construction.

First of all the valve, 20 is right at the distal end of the stent, as indeed are all the valves which are depicted in the specification. Secondly, upon deployment, so we have two deployed configurations which are 23 and then 24 when it is within the native annulus, we see circumferential folds being introduced. And thirdly, and this is described in the specification, one can see it, that is achieved by foreshortening of the stent.

So if we then go to the claims, and that is obviously only the context, but, as I said yesterday, there is a precious little to teach the skilled person what is meant by bunching-up or indeed sacs in this specification. Anyway, that is what is shown. Claim 1, so the first point is bunched up. What would "bunched up" be understood to mean? It is not a term of art and therefore we submit that the

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ordinary meaning is certainly a reasonable starting point for what "bunched up" would be understood to mean. That is where we turn to the dictionary. We see the dictionary, gathered together into close folds.

The ordinary English is a starting point. One has to then turn to purpose. The purpose of the claimed inventioning in the Bunched-up Patent is to seal against an irregular interface, an interface whose precise topography not only varies from patient to patient, but even within a patient the number, the location and size of what I call seep gaps is unknown. Therefore, there is a technical reason that supports my construction, which is more than just gathered together, but gathered together into close folds, because with close folds one improves the prospects of sealing against an unpredictable topography. That is the technical reason. That supports -- it is entirely consistent with -- the natural ordinary English language. That is the first point.

JUDGE HACON: Are you emphasising close folds or what?

MR. ACLAND: Yes, I am.

JUDGE HACON: Close?

MR. ACLAND: Yes, two things: one is folds and the other is close, because of the inherent unpredictability of what you are seeping into. If your little seep gaps are very close together -- close folds -- you have a better chance of your

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folds getting into them.

JUDGE HACON: Yes, I just want to be clear where it is going. You are saying if the folds are not close, that would fall outside the claim.

MR. ACLAND: Yes. If you only had two folds, one right at the top and one at the bottom ----

JUDGE HACON: That is what I am seeking to clarify. Are you talking about the number of folds? What do you mean by "close folds"?

MR. ACLAND: What I mean by close folds is essentially what one sees in figure 24. Now, obviously that is only schematic, but ----

JUDGE HACON: Just help me out a bit. Explain in regular language what you mean by close folds.

MR. ACLAND: I mean like the sort of thing one sees in figure 23.

JUDGE HACON: If it is not like that, it is outside the claim; is that what you mean?

MR. ACLAND: No, it obviously admits of variation, and plainly that is only schematic, but if your Lordship puts it to me, I am not suggesting it has to look exactly like that to infringe.

JUDGE HACON: I am not trying to be difficult, Mr. Acland, but you are placing emphasis on the words "close folds", so I am asking you what quite do you mean? You say, figure 23, but it

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could vary, obviously that is schematic, so there could be variations. Just explain a little bit more. What do you mean by close folds? Do you mean by a minimum number or enough folds that there are folds adjacent to each other without gaps? What do you mean?

MR. ACLAND: What I mean is whether one look at the device, look at the outer skirt, first of all, and identify folds. Those folds do not have to be directly adjacent like little spikes in cross-section.

JUDGE HACON: Okay, but they have to be close, so what does that mean?

MR. ACLAND: The folds, rather than having a fold and then a length of fabric, then another fold, they run together. Essentially, as one sees figure 23: they are a series of continual folds.

JUDGE HACON: Right, so you mean between each fold there must be an acute angle I think is what you mean, so there is no space, there is no ----

MR. ACLAND: Yes, they are not displaced from one another.

JUDGE HACON: There is an acute angle between folds, so in that sense one is closely located to the next.

MR. ACLAND: In that sense they are close, yes.

JUDGE HACON: I see. That is what you mean by close.

MR. ACLAND: It is what I mean.

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JUDGE HACON: I think I understand, and if they are not close, they are outside the claim.

MR. ACLAND: Yes, my Lord -- circumferential folds, okay? So we are now talking about the orientation of the folds.

JUDGE HACON: Yes. Is that in the claim?

MR. ACLAND: It is not in the claim, but I am going to submit to you why it would be necessarily understood to be imported into the claim. We see in figures 23 and 24 those horizontal folds -- I will call them. They are the natural consequence of foreshortening. What your Lordship is being asked to do is to adopt one or two constructions, my construction and Boston's construction. Boston's construction allows for vertical folds because, on Boston's construction, it is silent, it is blind to how those folds are configured. In other words, my Lord, their construction embraces folds that actually create leak paths.

JUDGE HACON: You mean their construction embraces exclusively vertical folds.

MR. ACLAND: No, not at all, includes vertical folds.

JUDGE HACON: That is why I said embraces.

MR. ACLAND: Yes, I see -- embraces, absolutely right.

JUDGE HACON: "Includes", if you prefer. You say if their construction includes vertical folds that would be non-functional.

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MR. ACLAND: Correct.

JUDGE HACON: So it cannot be right.

MR. ACLAND: That is a reason to reject their construction. It creates a leak path. If it creates a leak path, it cannot be sealed.

JUDGE HACON: You say on any view these folds must create a seal, so they must take a form which allows for that function to be performed.

MR. ACLAND: Correct. The next issue arises, going back to claim 1, from the language -- do you see -- a fabric seal extending from the distal end of the valve, proximally over the anchor. Would you just read that to yourself again, my Lord, just as a matter of ordinary English as a starting point? The valve has a distal end. The fabric must extend from that distal end in the proximal direction. That is how ----

JUDGE HACON: I am just making doubly sure I have it right. On figures 22, 23 and 24, the distal end is ----

MR. ACLAND: It is the bottom end.

JUDGE HACON: The top is the proximal end.

MR. ACLAND: That is right. You can see in figure 22 the outer fabric is extending from the distal end of the valve in the proximal direction.

JUDGE HACON: Yes.

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MR. ACLAND: In other words, the fabric that forms the seal must be found proximal to that distal end. That is how we read that claim, not as Boston reads that claim, because Boston's construction says this integer provides for the fabric seal to extend from the distal end of the valve in the distal direction and then in the proximal direction. In other words, if you look at figure 22, what they say is what is allowed is you can have a valve which is anywhere up inside the stent, so if the valve is higher up in the stent than is shown in figure 22, or indeed anywhere else in the specification, what this language contemplates is that the fabric that forms the outer skirt can run distally round the bottom and then proximally ----

JUDGE HACON: Presumably they say as long as it extends from the distal end proximally over the anchor, whatever else it does does not matter; is that what they say?

MR. ACLAND: That just is not ----

JUDGE HACON: Is that what they say? Mr. Meade will explain. I could conceive that as one possible construction.

MR. ACLAND: In effect, the reason my learned friend is construing the claim in the way that he does, in other words, allowing the fabric to extend distally first, is because he is trying to catch the inner skirt in the S3 device. That is why he is doing that. Does that make sense?

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JUDGE HACON: He is trying to catch the inner skirt.

MR. ACLAND: That is what he is trying to do.

JUDGE HACON: Why does he need to do that, because it has an outer skirt?

MR. ACLAND: That is what he does, my Lord.

JUDGE HACON: All right. If the claim covers a valve with the outer skirt, S3, that is enough.

MR. ACLAND: No, because it has to extend ----

JUDGE HACON: Why does he need to worry about the inner skirt?

MR. ACLAND: Plainly, it has to extend from the distal end of the valve.

JUDGE HACON: Understood.

MR. ACLAND: That is why he relies on the inner skirt, because he says the outer fabric has to extend to the valve.

JUDGE HACON: I see. Are you saying because it has to extend you have to follow it from its origin to where it goes and that includes going initially in the distal direction before it goes in the proximal direction?

MR. ACLAND: Exactly. That is the fly in the ointment as far as my learned friend's construction is concerned. That is why he has to write in not just extending from the distal end in the proximal direction, but extend distally and then proximally.

JUDGE HACON: The extension must be traced from origin to finish. Part of that extension, you say, is extending distally;

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therefore, it falls outside the claim when we get to infringement.

MR. ACLAND: Yes.

JUDGE HACON: I see.

MR. ACLAND: That is a way of looking at it. There is actually an easier way of looking at it, which is one looks at the position, the distal end of the valve.

JUDGE HACON: I should not have put it in terms of infringement. You say the extension must only go in one direction.

MR. ACLAND: Correct.

JUDGE HACON: When you trace the extension from source to finish, if it does not only go in the proximal direction ----

MR. ACLAND: You are out.

JUDGE HACON: You are out, I understand.

MR. ACLAND: Because you are only looking at what is on the outside of the stent. You look at what is outside the stent, and you say where does that start, where does that finish and you have to have that material extending proximally from the distal end of the valve.

JUDGE HACON: Throughout the extension, if I can put it that way.

MR. ACLAND: Throughout the exterior extension.

JUDGE HACON: You cannot have a beginning bit that goes in the distal direction; is that right?

MR. ACLAND: Correct. We not only submit that my learned friend

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is wrong on the natural meaning of the English, but also wrong on purpose because the purpose of this bunching is to provide an external seal, a seal against the irregular annulus, outside the stent. Therefore, on his construction, in so far as it allows material that comes up inside, what is that material doing for the purposes of sealing that exterior surface? It serves no sealing function.

JUDGE HACON: Do you mean the initial part of the extension?

MR. ACLAND: Correct.

JUDGE HACON: The distal direction part of the extension serves no sealing function.

MR. ACLAND: Correct.

JUDGE HACON: It is only the proximal part, as it goes up the outside, which can do that.

MR. ACLAND: As far as the language of the claim is concerned ----

JUDGE HACON: I understand, yes.

MR. ACLAND: To summarise, the issues that we think you have to decide on construction are five-fold.

JUDGE HACON: Are they listed here?

MR. ACLAND: They are in our skeleton, but I just wanted to make it clear.

JUDGE HACON: By all means.

MR. ACLAND: First of all, twin-walled or double-walled; secondly, disposed about the exterior. On the Bunched-up Patent, what

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is bunched-up? Secondly, does the claim support circumferential folds? Then, lastly, extending from the distal end of the valve proximally.

JUDGE HACON: "Does the claim support circumferential folds"?

MR. ACLAND: Yes, I am sorry, I am talking about fabric folds of the seal.

JUDGE HACON: Is that what you mean -- really? I thought you meant does the claim support ----

MR. ACLAND: No, is it confined to circumferential folds.

JUDGE HACON: Okay. When you said does the claim support, what do you mean? Is the claim limited to circumferential folds?

MR. ACLAND: Yes.

JUDGE HACON: All right. What is five?

MR. ACLAND: That was 5. 4 was is it limited to circumferential folds. 5 was extending from the distal end of the valve proximally. In so far as the Sapien 3 device is concerned, we have summarised in paragraph 194 how those issues of construction give rise to non-infringement. I have just one additional point to make in relation to the Sapien 3. My clients have provided a PPD. They had proffered a witness, Mr. Joseph, to be cross-examined on that PPD and in the end he was not required for cross-examination. Nevertheless, what you will see in Boston's closing submissions is that they continue to rely upon the photographs of Dr Lutter's sample to

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establish infringement. The issue is whether the S3 -- Sapien 3 -- as supplied by my clients infringes. We do not accept the provenance of Dr Lutter's device. We think it has been partly crimped, and certainly when Dr. Buller inspected it, it had a reduced diameter of something more like 20 mm. We have written to Boston's solicitors on the matter, but we have had no reply. What I would be inviting your Lordship to do is to -- and certainly as far as your judgment is concerned -- to consider the device as it is described and depicted in the PPD.

JUDGE HACON: Okay.

MR. ACLAND: Can I now do Cribier, first of all, and can you take two bundles: bundles A3 and C1. What I am going to do -- and this applies to both Cribier and also Bessler and Thornton, and I can tell you that the detail and the evidence references of what I am going to be suggesting to you are to be found in our closing submissions -- is articulate the simplicity of the case that arises as far as we are concerned on the three bits of prior art, the essential points. In so far as Cribier is concerned, if you turn to internal page 11, at the top of the page, the first three lines, "The invention will now be explained and another advantage and features will appear with reference to the accompanying schematical drawings." Do you see that?

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JUDGE HACON: Yes.

MR. ACLAND: We then turn to figure 6. I am sure your Lordship is now familiar with figure 6d: we have a valve leaflet, or rather a valve structure. We have a stent, the black line, and we have an outer cover together with an inner cover. Now, in bundle C1, if you "turn to Professor Fisher's first report, which is behind tab 4 and turn to paragraph 58, you will see what he is explaining, and let us just read it together:

"After my initial review of the Cribier Patent" -- so this is the first document he saw in the case -- "before I had seen or reviewed the Patents, Powell Gilbert asked me to comment on the sealing means described in the Cribier Patent. It was not surprised that the Cribier Patent proposed the abovementioned covers as a way of sealing to reduce leakage after implementation."

Then can you read the whole of paragraph 59 to yourself? So you have taken 59 on board. You will recall Professor Fisher was cross-examined on this and it was suggested to him that Powell Gilbert had specifically asked him to look at figure 6d. He said absolutely not. The professor himself had drawn attention to figure 6d and the reason was because it had an external cover that he felt was important in the context of sealing. Can I give you that evidence reference? It is T5, page 821. Are you not writing

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it down, my Lord.

JUDGE HACON: It is on the transcript.

MR. ACLAND: It is 821, line 16 to 822, line 24. Furthermore, the attractiveness of figure 6d had been apparent to the professor from the outset from his initial review of Cribier. That is T5, 827, lines 22 to 828, line 4. So he, like the skilled person, had focused on figure 6d because it offered attractive sealing solutions or an attractive sealing function. In his report then, if you turn on to paragraph 71 -- I am looking at 71 and 72 -- this follows. As far as the valvular tissue is concerned, he considers that the engineer would use pericardium, and as far as the external cover is concerned he would use PET (Dacron). The reason for using Dacron is the reason he uses there and if you go back to paragraph 44 it is because of the common-general-knowledge use of PET for other applications in this field and he refers to vascular grafts. Do you see 44?

JUDGE HACON: Yes.

MR. ACLAND: And he said in cross-examination that he would have come to that view or rather the skilled person would have formed the same view as he did because the same combination of pericardium plus Dacron had been used in surgical heart valves. That is T5, 834, line 14 to 835, line 7.

In order to get round Cribier, Boston has to convince

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your Lordship that the engineer when looking at figure 6d would implement the device so as to deliberately arrive at a taut external cover when the device was implanted.

Not only does Cribier nowhere state that the external cover must be taut, but Boston's approach requires the skilled engineer to treat figure 6d as a design blueprint which it is plainly not. It is to use the language of the Cribier patent, one of a number of schematic drawings. So that is the first two points. There is much more to it than that because a taut external cover would also defeat the purpose which Professor Fisher identified, namely to enhance the space-filling provided by an excess of material. So it defeats the purpose. Yet further, my Lord, with a material such as Dacron, the engineer will have to find a way of overcoming the inevitable consequences of the changing geometry of the stent between its fully expanded and its deployed configuration. I think you heard that.

Cribier, the patent, Cribier the man, used a balloon-expandable stent. When the balloon is deflated, the stent will recoil to some degree. In Cribier 2002, the circulation paper, the reduction in diameter was about 8.5%. We have given the reference in our skeleton. With the recoil obviously the circumference gets smaller. They will inevitably introduce some excess, but it is not just recoil

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because the stent disclosed in the Cribier patent foreshortens, as would the stent described in Cribier 2002, although to a lesser extent. As the stent expands against the lumen, it shortens in height.

Implications of foreshortening in relation to excess material can be seen in Professor Fisher's first report, paragraphs 67 and 68, so that is page 17. These diagrams are just illustrating a principle.

JUDGE HACON: Yes, this is not in dispute, is it, that if you foreshorten you will get some excess fabric?

MR. ACLAND: If you take any of those cells in the top figure and imagine the fabric that is taut across that, when the device is crimped, the sides come together, the top goes out. And if you read on to paragraph 80 of the professor's evidence: "... as can be seen by comparing the structures of figures 4 and 5 above the intersection points of struts either move towards each other (in the horizontal direction) or away from each other ... It would therefore be logical to incorporate excess material in the expanded configuration to accommodate the increase in height ..." And then 81: "Incorporating such excess material would form circumferentially oriented folds of material in the expanded configuration."

As I say, in order for Boston to get round that evidence, they have to establish that what the professor

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