Claim No HC-2015-004574

IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

BETWEEN:

EDWARDS LIFESCIENCES LLC

Claimant

and

BOSTON SCIENTIFIC SCIMED INC

Defendant

and

(1) EDWARDS LIFESCIENCES CORPORATION

Third Party

(2) EDWARDS LIFESCIENCES SA
(also known as EDWARDS LIFESCIENCES AG)

Fourth Party

(3) EDWARDS LIFESCIENCES LIMITED

Seventh Party

DEFENDANT'S CLOSING ARGUMENTS

Boston has incorporated closing submissions into its Skeleton Argument for Trial. Whilst there may be minor changes that have not been marked up, substantial additions to the text are indicated by the double sideline. References to "Edwards' Skeleton" are to Edwards' Skeleton Argument for Trial of 13/1/16.

Overview

Infringement

1. On infringement, Edwards now advances only a couple of very weak and insubstantial construction points, the functional basis for which was not even put to Boston's witnesses. It is entirely clear that the S3 uses the inventions of both of the patents.

The inventions and the Edwards' history

2. It is also clear that the use of the inventions has provided a major advance. Addition of the outer sealing skirt cut down moderate/severe leakage to zero in the Edwards S3 (as compared with the XT), and Boston's Lotus device (also with an outer sealing skirt) has the lowest leakage of all the many devices on the market. It is now known that even mild PVL is associated with higher mortality, but that knowledge came in 2013.

3. At the priority date in 2003, there was a very different understanding, that modest PVL was quite acceptable and not incompatible with a good clinical result.

4. Edwards and its predecessor in title PVT worked continuously in this field from pre-2003 right up until the present day, with the intimate assistance of Dr Cribier. So it knew all about the Cribier prior art (including figure 6d), but did not come up with the outer sealing skirt until the fifth generation of its product.

5. Nor did any other company (except the patentee, of course): the various other companies have come up with the variety of quite different solutions seen at GL-23 figure 5, none of which is as good as the Lotus (or S3) in meeting PVL.

6. In the period prior to Edwards coming up with the outer skirt, PVL had to be addressed in the Sapien products by the twin approaches of oversizing and redilation, but these were both appreciated to be unsatisfactory because they could lead to catastrophic annulus rupture among other complications (Schymik, GL-14).

7. Edwards could have sought to explain properly why it did not come up with the outer sealing skirt idea: as the Court saw in the discussion in relation to the evidence of Mr Joseph, Boston clearly flagged well in advance that it was going to take the point (by Mr Burdon's witness statement in July 2016, and in Lutter 1 and 2).

8. An obvious person to explain why Edwards failed to come up with it would have been Dr Cribier, who is still active and apparently still involved with Edwards, and could speak to the whole time period. Instead Edwards prepared no evidence and made the extremely late application to bring evidence from Mr Joseph, without even putting forward a statement of what he would say. During the oral evidence it made various unfounded theoretical suggestions of why the skirt might not have been added; they were worthless and desperate.

9. The fact that Edwards was in the field, working on the problem, well resourced, making other changes to its products to deal with PVL, aware of the cited prior art, and had the involvement of Dr Cribier, makes this a particularly powerful case of secondary evidence.

The prior art

10. That being said, Boston does not really need secondary evidence because the prior art is so weak.

11. By this stage in a patent action, a party attacking validity, if it has a clear and focused case, is able to come down to one or at most two citations. But Edwards has failed to do this. It is still running four very different citations with very different approaches and is just unable to identify its best case.

12. Thus Cribier is a complicated document with many ideas in it, but it would at least be seen by the skilled team to have some relation to reality. However, the skilled team would know that it was not taken in remotely the direction that Edwards say is obvious, and Edwards' attack is a classic hindsight *Technograph* one (in which the individual steps are also hopeless in a number of instances).

13. Bessler, by contrast, is not a real proposal and depends heavily on something (ablation of the native valve) which Edwards positively says was regarded as being unrealistic. It is also of a significantly different construction from Cribier, and is a self-expanding device and so contradictory to the Cribier approach, which depended on high radial forces. It is hard to see how Bessler can succeed if Cribier fails, and in Edwards' evidence and opening skeleton it was very much an afterthought with just a couple of pages, referring back to Cribier. The attempt to breathe fresh life into it during the oral evidence is a result of Edwards losing confidence in Cribier.

14. Thornton is from a completely different field altogether. It is an unclear exposition of a bad idea, and the attack involves taking one feature from it, inverting it, and using it in a completely different context. We remain unclear how Edwards will justify the combination of the Thornton flange with a TAVI device, but it is clearly abstract, artificial and ill-founded.

15. Seguin comes from yet another direction and contains very numerous ideas, many of which are plainly lacking in sense. It is a matter of comment that it is maintained despite Dr Buller accepting straight way in XX (in striking contrast to his written evidence) that the embodiments he relied on are just not feasible.

The patents

16. It must not be overlooked that there are two patents and two inventions. Edwards seems to take the approach that as long as it can make a case that some excess material outside the stent was obvious, then it wins on both patents. This is simply not the case as the bunched up patent ('254) requires that that material provide a seal and the sac ('766) patent requires an outer sac, which fills with blood in response to backflow pressure, to provide a seal.

17. Edwards' XX simply did not even attempt to reach the sac patent, from any of the pieces of prior art.

The witnesses

18. We make some specific points about details of the witnesses and their demeanours and approaches below. The very clear high level distinction, however, is simply that Boston's witnesses had relevant contemporary experience and Edwards' did not. Prof Lutter was directly involved in TAVI in 2003 (and continually thereafter), whereas Dr Buller was not until 2007, when he embarked on 7+ years' of work as an expert witness, never having any practical experience with patients or TAVI design. Prof Moore was closely involved with stent grafts; Prof Fisher did not have relevant experience.

19. Edwards sought to set up evidence that its experts got to the inventions from the prior art before, and without knowing of, the Patents. This failed because Dr Buller knew all about the commercial embodiments and their features and

inferred that the case was about the S3, and for Prof Fisher it is unknown what products he was aware of prior to this case, he appears to have been directed to the issue of sealing figure 6d in Cribier by Powell Gilbert (or at least that cannot be excluded), and he explicitly says in his evidence that the later 5 or 6 steps in his *Technograph* analysis from Cribier came after he saw the Patents (Fisher 1, paragraph 61).

The skilled team and the way the case was put by Edwards in XX

20. There was a discrete issue about whether stent grafts were the province of interventional cardiologists; Edwards' case on that has rather collapsed with it becoming clear that Dr Buller himself never worked with those devices, at all.

21. However, given the way that Edwards XX'd, a broader point has become important.

22. It was and remains common ground that this is a case where the skilled person is a skilled team of a clinician and an engineer, and further that the clinician would take the lead in most respects, drawing on the engineer where necessary. See e.g. Buller 1 paragraph 32.

23. Further, it was not Edwards' case in its evidence or opening skeleton that either Patent was invalid as being obvious to just one member of the team (i.e. not a *Schlumberger* case).

24. This all makes it quite extraordinary that Prof Lutter was not XX'd on the cited prior art on obviousness, at all. With the exception of a very cursory putting of anticipation by Seguin in the dying moments of his XX, he was not asked about the cited art at all. (Prof Moore was not asked about Seguin, but was asked about the other citations).

25. Parties often argue that some point was not put in XX and this can be, and often is, overdone, e.g. where the point is a minor one or where it has been challenged in substance but not in the precise words used by the witness.

26. That is not this case, however. Prof Lutter was just not challenged in his evidence on the prior art citations. His evidence on that must be accepted and Edwards is not now allowed to advance a case that was not put to him. Edwards' approach is particularly surprising since its opening skeleton identified a large number of points of Prof Lutter's evidence which it said were in dispute, and in some instances specifically said would be explored in XX (see e.g. paragraph 242 on Bessler).

27. We await Edwards' explanation of this approach. There are two excuses which clearly will not do: it is no answer that Prof Moore was asked, since he gives only the engineer's perspective, and it is no answer that time for XX ran short with Prof Lutter.

Introduction

28. This action concerns repositionable heart valves for transcathether heart valve (or "THV") replacement procedures that have been designed to prevent the problem of paravalvular leakage or "PVL".

29. Edwards commenced these proceedings originally seeking revocation of one, then two, of Boston's patents: European Patent (UK) 2,749,254 (the '254 Patent) and European Patent (UK) 2,926,766 (the '766 Patent). Both Patents derive from PCT/US2004/043607 (the "Application"). They are both entitled "*Repositionable heart valve*" and the earliest priority date of both is 23rd December 2003 (the "Priority Date"). They are 2 of 15 European patents or applications within the same family.

30. Both Patents are currently subjects of opposition proceedings at the EPO[1]. Edwards is one of the opponents against both.

31. Boston has counterclaimed that Edwards' product – the S3 valve – falls within the claims of both of the Patents. A Part 20 claim has also been brought against other members of the Edwards group. To the extent that there remain outstanding issues as to which Edwards' company is responsible for which acts, the parties have agreed to stay those matters until resolution of the technical issues[2].

32. Thus although Edwards started the proceedings, in substance they are now a claim for infringement with invalidity as a defence, and accordingly the issues that this Court has to decide are:

    (1) Does the S3 valve infringe?

    (2) Is the '254 Patent valid in light of Edwards' attacks based on:
        (i) Bessler (novelty and obviousness);
        (ii) Cribier (novelty and obviousness);
        (iii) Thornton (obviousness only);
        (iv) Insufficiency: this is advanced by way of squeeze with obviousness case;
        (v) Added matter;

    (3) Is the '766 Patent valid in light of Edwards' attacks based on:
        (i) Bessler (novelty and obviousness);
        (ii) Cribier (novelty and obviousness);
        (iii) Sequin (novelty of certain claims and obviousness);
        (iv) Thornton (obviousness only);
        (v) Insufficiency: again, advanced by way of squeeze;
        (vi) Added matter.

[1] The '254 Opposition commenced in September 2015, the '766 Opposition commenced in June 2016
[2] Consent Order dated 6/10/06 at § 1 B/26

Technical Background

33. The Patents are concerned with heart valves for use in THV replacement procedures. Replacement of the aortic valve of the heart by a THV is commonly known as "TAVI" – "transcatheter aortic valve implantation". At the Priority Date, TAVI was a largely experimental procedure at an early stage of its development. Dr Cribier, one of the leaders in the TAVI field, had carried out his first TAVI procedure[3] on a human patient only just over 18 months before the Priority Date. As at the Priority Date, only a handful more such procedures had been carried out, all by Dr Cribier. The technique was considered to be one of 'last resort', used only on the most poorly patients, in compassionate circumstances, who would be unable to survive the trauma of open-heart surgery. TAVI devices were not approved for use until 2007, some four years after the Priority Date. Until very recently, TAVI devices were only approved in most countries (including Europe) as an exceptional measure where the patient was thought to be at high risk in relation to open-heart surgery.

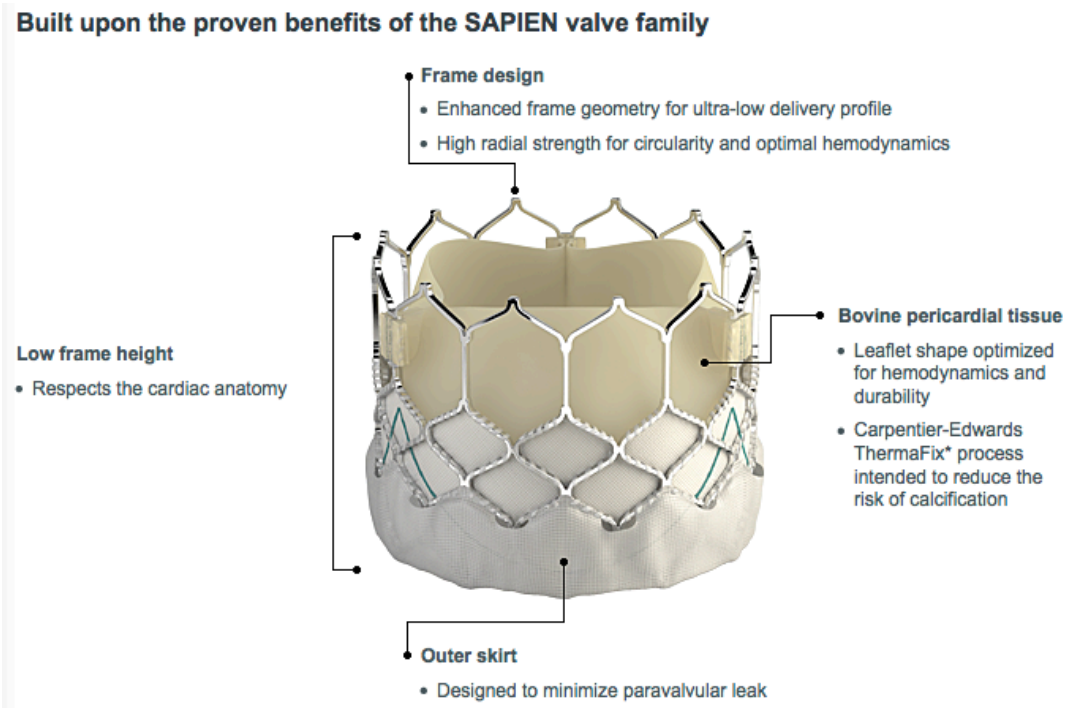
34. Against this background, the inventions disclosed in the Patents are forward thinking. The Patents recognise that a potential problem of TAVI devices is PVL, namely leakage which can occur both *through* the frame of the device as well as *around* its edges i.e. in the gaps between the sides of the TAVI device and the irregular, calcified native leaflets against which it was positioned when deployed.

35. The Patents then teach two broad types of seal which serve to prevent PVL. The '254 Patent is concerned with a seal formed of bunched up fabric that is designed to fill in the gaps between the exterior of the TAVI device and the irregular calcified leaflets against which it is positioned in use. The '766 Patent is concerned with a seal that comprises at least one fabric sac disposed externally around the TAVI device which is designed to fill with blood and which provides a seal between the exterior of the TAVI device and the

[3] A cardiologist, Dr Philip Bonhoeffer, had previously implanted a small number of transcatheter pulmonary valves (in 7 children and 1 adult) – Luttter 1 at §49

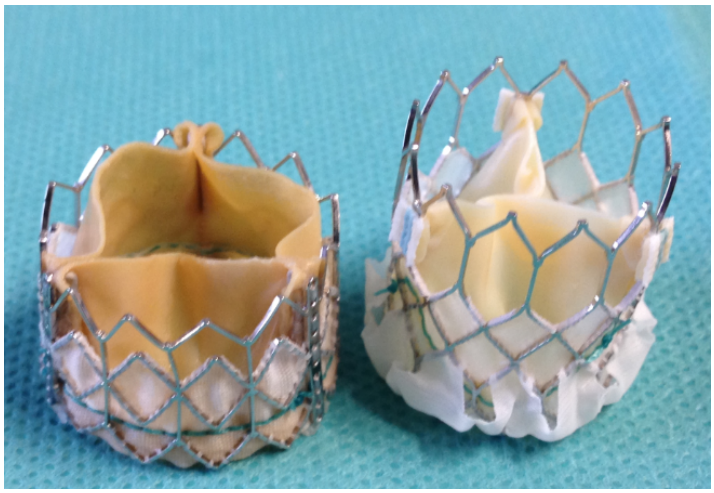
irregular calcified leaflets. Both of these seals were originally disclosed in the Application.

36. The teaching of the Patents was truly innovative. No such seal was present on early embodiments of TAVI devices. Indeed, Edwards' own TAVI product has gone through a number of development stages. Its first incarnation was as the device that Cribier himself used, a device that was manufactured by Percutaneous Valve Technologies ("PVT")[4]. That original technology was developed via the "Sapien"[5] and the "Sapien XT"[6]. However, it was not until 2014[7] that Edwards launched the S3 which, for the first time, incorporated an outer skirt which was specifically designed *"to minimize paravalvular leak"*[8] in a way which uses the inventions of the patents in suit:



[4] Edwards purchased PVT shortly after the Priority Date
[5] Available between 2005 and 2009
[6] Introduced in 2009: the Sapien XT had a new nitinol strut frame design, increased radial force, a larger inner skirt and a change to the leaflet design (Lutter 1, §155)
[7] Lutter 1, §§155-157
[8] e.g. Annex 6 Particulars of Infringement B/12

37. The following photograph[9] illustrates the difference between the Sapien (left) and the S3 (right) and, in particular, shows the outer skirt of the S3 which comprises excess fabric that is only attached at certain points, so as to form a number of sacs on the outside of the frame:



38. Thus Edwards has stated that its devices accomplish that which the patents in suit teach (minimising PVL by bunching and sacs), and it is clearly to be inferred that it regarded the benefit as worth making a significant change to its products. It is also plainly inconsistent with Edwards' obviousness case that it did not introduce this feature until so long after the priority date. Edwards has led no evidence to address these matters.

The Skilled Team

39. The parties are agreed that the Patents are addressed to a skilled team comprising an engineer and a clinician. There is, however, disagreement as to whether the clinician would be an interventional cardiologist, a radiologist or a cardiac surgeon with an interest in TAVI[10] or would simply be an interventional cardiologist[11]. Boston contends that the Skilled Clinician could be any of the three, provided he/she had an interest in TAVI. Edwards

[9] Fig. 6 Lutter 1 at §158
[10] Lutter 1, §88 & Moore 1, §§32 & 36
[11] Buller 2, §§6-7

contends that only the interventional cardiologist would be interested in the teaching of the Patent.

40. Following XX this dispute is of marginal, if any, relevance. It was clear from the XX of Prof Lutter that cardiologists and cardiac surgeons work closely together in treating patient with heart problems[12]. Furthermore, whereas an interventional cardiologist specialises in using percutaneous catheter-based treatments for the hart, he does not usually have experience of the great vessels (e.g. treatment of AAAs or TAAs): despite his written evidence to the contrary, Dr Buller did not have such experience[13]. In XX, his evidence was that this work would be done by interventional radiologists[14] and ascribed his interest in endografts to his surgical colleagues[15]. Prof Lutter's evidence was that interventional cardiologists, interventional radiologists and cardiac surgeons all practiced with catheters and wires. It is clear that there is an overlap between these specialities; TAVI was an alternative to surgery which both cardiologists and surgeons were interested in[16]. There is therefore no reason to exclude the Skilled Cardiac Surgeon from the Skilled Team.

The Witnesses

Expert witnesses

41. Reflecting the fact that these are Patents directed at a Skilled Team, both parties are relying upon the expert evidence of a clinician and an engineer.

42. Boston's clinical expert witness is Prof Lutter, a cardiac surgeon. Prof Lutter has been the Professor of Cardiac Surgery and Head of Department of the Experimental Cardiac Surgery and Heart Valve Replacement Department at

[12] T3/p363/24 – p365/14
[13] T4/p646/16-24
[14] T4/p647/22-23
[15] T4/p648/4-13
[16] See e.g. the debate over whether ablation techniques were generally preferred by surgeons - T4/p582/4 – p586/24

the University of Kiel, Germany, since 2008/09[17]. Prof Lutter's expert reports are at D1/1, D1/9 and D1/11. Prof Lutter has had a general interest in transcatheter and minimally invasive, cardiac surgical and cardiological procedures throughout his career. He implanted and conducted tests on one of the first transcathether aortic devices in animals back in 1997 and, more recently, has been interested in the development of transcatheter devices for use in replacing or repairing the mitral valve[18]. He routinely carries out transcatheter aortic valve implantation ("TAVI") procedures at the University of Kiel and regularly implants the S3: he estimates that he has carried out around 250 implantations of the S3 in the last two years (2015 & 2016)[19]. He has taught physicians to implant both the S3 and its predecessor, the Sapien XT[20].

43. Prof Lutter was a very fair witness who did his best to assist the court. Given his experience of working on TAVI devices at the Priority Date, he was excellently placed to assist the Court as to the thinking of the Skilled Clinician at the Priority date. His first-hand experience of implanting TAVI devices[21], including the S3, also put him in a very good position to advise on the various infringement issues. Large parts of Prof Lutter's evidence were not challenged at all (e.g. apart from a cursory challenge on Seguin, he was not challenged on any of the prior art). An attempt to sideline him on the basis that his experimental TAVI work on pigs involved placement just below or above the annulus[22], was entirely unconvincing. Similarly, the attempt to sideline him on the basis of his interest in ablation of native leaflets fell flat: not least because two of the pieces of prior art relied upon by Edwards teach ablation of the native leaflets[23].

44. Boston's engineering expert witness is Prof Moore. Prof Moore is the Professor of Biomedical Engineering at Imperial College, London. His expert

[17] Lutter 1, §§1-4
[18] Lutter 1, §§5-6
[19] Lutter 1, §8
[20] Lutter 1, §9
[21] T3/p406/4-p408/11
[22] T3/p433/7-21
[23] T3/p414/24-p436/11 & T4/p475/24-25

reports are at D1/4, D1/10 and D1/12. Prof Moore is a mechanical engineer by background, but has had a general interest in transcatheter and minimally invasive cardiovascular procedures throughout his career. Between 2001 and 2003, he held the position of Director of the Cardiovascular Engineering Centre at the Florida International University. He has worked extensively in the field of stents, advised numerous biomedical device companies and regularly presents conferences around the world as well as teaching cardiovascular biomechanics and the effects of stenting to Masters Engineering students[24].

45. Prof Moore was a very fair witness who patiently gave his evidence over two days. He gave careful answers to the questions he was asked and did his best to assist the court on the matters of biomedical engineering that arose. He was in an excellent position to assist the court given his breadth of experience in designing and developing stents: in particular, he was very knowledgeable and experienced in the area of endografts, one of the areas on which Edwards placed particular focus. During XX on one piece of prior art (Thornton), he dealt with assumption upon assumption, but gave sensible responses which reflected the views of the Skilled Engineer who, at the Priority Date (as at any other time) was simply interested in whether the teaching would work: if it did not, no number of assumptions would make it worthwhile trying[25].

46. Edwards' clinical expert witness is Dr Buller, a retired consultant cardiologist who was previously Head of Interventional Cardiology at the Queen Elizabeth Hospital, Birmingham[26]. His research interests included the prevention, diagnosis and treatment of heart disease and the development and clinical application of stents, especially coronary artery stents[27]. Dr Buller does not have first-hand experience of undertaking transcatheter heart valve replacements in patients: the first UK procedure was undertaken in 2007, after

[24] Moore 1, §§1-9
[25] T2/p250/19-24
[26] Buller 1, §16
[27] Buller 1, §23

Dr Buller had stopped performing invasive procedures[28]. Dr Buller's reports are at C1/1 and C1/5.

47. Dr Buller is a long-time expert witness who, after his retirement from clinical practice in 2008, has given evidence in very numerous litigations and in multiple jurisdictions, most frequently for Edwards (since 2007). Details of some are given in his first report. Those disputes have in some instances related to TAVI but to a variety of other technologies too. In relation to TAVI he has had far more litigation than clinical experience (the latter being: zero). None of this helped his approach and he was argumentative and not good at answering questions. To make matters more difficult, he came to TAVI litigation after the priority date, but then left it until 2013 to get even any training. By that time, the field had moved on massively and materially, the current designs were all in the literature, and the perception based on then-recent research was that even modest PVL had to be avoided. All this made it really impossible for Dr Buller to put himself in the shoes of the ordinary clinician in 2003 and he failed to do so. His written evidence also turned out to be materially unreliable and incorrect: the impression he gave in paragraph 28 of his first report was that he was experienced with TAA and AAA endografts (an important topic) but it turned out that he had no such experience. And in relation to Seguin, he accepted immediately in the witness box that the key embodiments were "not feasible" which was obviously a key point and was not disclosed in his written evidence at all. Caution is needed with his evidence for all these reasons.

48. Edwards' engineering expert witness is Prof Fisher, who has been Professor of Mechanical Engineering at the University of Leeds since 1993. In 1997 Prof Fisher became Dean of Research for the Faculty of Engineering at the University of Leeds, before becoming Pro-Vice-Chancellor for Research in 2001. In 2006 he was appointed Deputy Vice-Chancellor of the University of Leeds, a position he held until 2016. He is now director of four externally funded research centres with executive responsibility for leading those

[28] Buller 1, §29

centres[29]. Early in his career, whilst engaged in research, Prof Fisher's research interests included surgical bioprosthetic heart valves[30], although more recently his focus has been on orthopaedic devices[31]. Prof Fisher's reports are at C1/4 and C1/6.

49. Prof Fisher's evidence added very little to Dr Buller's. He had very limited experience in the field of TAVI: he only followed the literature at a distance, did not discuss TAVI work with colleagues and appeared only to have acquainted himself with TAVI devices and the details of the literature in the last 12 months, since he was instructed in this case[32]. Although the timeline of events was somewhat confusing, it appears that his attention was specifically drawn to the question of sealing when he was asked to consider the Cribier patent[33].

Witness to Edwards' Confidential Amended Product and Process Description

50. In light of the answers given by Dr Buller in XX, it was not necessary to XX Mr Russ Joseph, who signed Edwards' Confidential Amended Product and Process Description (the "PPD")[34]. Instead of giving disclosure about the S3, Edwards chose to serve the PPD, as permitted by paragraph 6.1(1) PD to CPR Part 63.

51. The purpose of a PPD is to enable all issues of infringement to be resolved: as the PPD is given as an alternative to providing disclosure, it must provide full particulars of the product said to infringe. The importance of providing full particulars has been emphasised by this Court on a number of occasions, most recently by Carr J in *Stretchline v H&M* [2016] RPC 14 at §§77-80 (see also Birss J in *Vringo v ZTE* [2015] EWHC 818 (Pat) at §§19-24). Paragraph 6.2

[29] Fisher 1, §§12-13
[30] Fisher 1, §§15-17
[31] Fisher 1, §18
[32] T5/p809/16-p814/25
[33] T5/p821/12-15
[34] Re-served on 22/12/16 at PPD/1

PD to CPR Part 63 requires that a PPD must be accompanied by a signed written statement which must state that the person making the statement:

(1) is personally acquainted with the facts to which the particulars relate;

(2) verifies that the particulars are a true and complete description of the product or process alleged to infringe; and

(3) understands that he or she may be required to attend court in order to be cross-examined on the contents of the particulars.

52. Edwards' PPD was signed by Russ Joseph, the Senior Director of Valve Development and Testing for Edwards Lifescience Corporation (the Third Party). In light of the evidence of Dr Buller in his second report, in which he expressed some uncertainty as to the way in which the S3 works[35], Boston wrote to Edwards requiring them to put up for cross-examination somebody with sufficient knowledge of the S3 and its intended design who could speak to the PPD[36]. As it transpired, it was unnecessary for Mr Joseph to give evidence. An example of the S3 available for inspection in Court.

Edwards' Civil Evidence Act Notice

53. Edwards have served a hearsay notice[37] purporting to rely on 11 documents disclosed by Boston, spanning a few hundred pages, which are contained in a separate trial bundle on account of their volume[38]. Boston wrote to Edwards asking them to particularise the statements in these documents that they were intending to rely on and the facts they were alleged to prove. To date, Edwards have refused to do so, merely identifying some pages[39]. If Edwards in fact wishes to rely upon any of the statements in the Bundle H documents, then Boston reserves its rights to make submissions on the weight (if any) to be afforded to such evidence if and when it is identified.

[35] Buller 2, §87
[36] ISC/p218
[37] B/22
[38] H
[39] ISC/pp 181, 189, 195, 210 and 212

Common General Knowledge ("CGK")

CGK – the law

54. The task of the Court is to read the Patents, the Application and the prior art through the eyes of the Skilled Team and with that Skilled Team's "common general knowledge" or "CGK" i.e. the information which, at the priority date, was common knowledge in the art or science to which the invention relates so as to be known to duly qualified persons engaged in that art or science[40]. The Court of Appeal has recently set out the basic principles pertaining to CGK in *Idenix Pharmaceuticals v Gilead* [2016] EWCA Civ 1089 at §§70-72. In particular, at §72, Kitchin LJ provided the following summary:

"*It follows that the common general knowledge is all that knowledge which is generally regarded as a good basis for further action by the bulk of those who are engaged in a particular field. It is that knowledge which those working in that field will bring to bear when they are reading or learn of a piece of prior art. It is not necessary that those persons have that knowledge in their minds, however. The common general knowledge includes material that they know exists and which they would refer to as a matter of course if they cannot remember it and which they understand is generally regarded as sufficiently reliable to use as a foundation for further work.*"

55. CGK is normally proved by reference to textbooks or widely read review articles. It is rare that something which has not been published or not published widely is CGK. This is important to bear in mind in the present case where Edwards (for the purpose of its obviousness case) asserts that various things were CGK with little or no documentary support, and all the more so when its experts were not directly involved with the specific field of the patents at the priority date.

[40] See §8-56 Terrell on the Law of Patents, 18th Ed.

CGK – the Primer

56. The parties have agreed a Primer that sets out a basic technical background to the Patents (A3/5). It is generally agreed that the information in the Primer would have been CGK of the Skilled Team at the Priority Date[41].

57. The following areas were CGK at the Priority Date:

58. The cardiovascular system: §§1-2 Primer set out a basic description of the heart, its four chambers and four valves: the tricuspid; pulmonary; mitral and aortic [§§1-2 Primer]. Further details are provided by Prof Lutter at §§19-24 Lutter 1 and by Prof Moore at §§20-21 Moore 1. In particular, focus is given to the aortic valve[42], which ensures that blood being pumped out of the left ventricle and into the aorta does not leak back into the left ventricle. The aortic valve is a tricuspid leaflet valve that is required to withstand high pressure of 120 mm Hg. Prof Moore describes the leaflets of the aortic valve as "*exquisite, paper thin structures, that have to function under highly dynamic physiological pressures"* [43]. For reasons unknown, the aortic valve is particularly prone to calcification[44].

59. Heart valve disease: §3 Primer introduces the two types of heart valve disease: congenital and acquired. The two most common defects caused by heart disease are:

    a. Stenosis: a narrowing of the valve that prevents it from opening fully. A common cause is degenerative calcification. Prof Lutter describes the process and consequences of calcification at §§29-31 Lutter 1;

[41] Lutter 1, §18; Buller 1, §36; Moore 1, §18 (where Prof Moore clarifies some points of terminology)
[42] The S3 is an aortic valve replacement and the primary application of the devices described in the '254 and '766 Patents is replacement of the aortic valve - §23 Lutter 1; §20 Moore 1
[43] Moore 1, §21.1
[44] See also §31 Lutter 1

b. Regurgitation / Insufficiency: where the valve fails to close tightly, permitting blood to leak backwards (in the case of the aortic valve into the left ventricle)[45].

60. Surgical replacement of diseased heart valves: The use of prosthetic heart valves to surgically replace diseased heart valves is discussed at §4 Primer. Prof Lutter provides further details at §§32-41 Lutter 1 and Prof Moore provides some clarification at §18.1 Moore 1. Various mechanical and bioprosthetic valves have been used over the years including the caged-ball device, tilting disc and bi-leaflet disc devices (all mechanical)[46] and the Medtronic Hancock and Medtronic Freestyle devices (both bioprosthetic devices)[47]. As Prof Lutter explains, surgical valve replacement is major open-heart surgery that requires use of a heart-lung machine. It is traumatic and not suitable for elderly or infirm patients[48].

61. Interventional cardiology: §5 Primer describes the branch of medicine known as "interventional cardiology", which emerged from the 1960s onwards. Interventional cardiologists use catheters to treat problems with the heart and associated vessels percutaneously. Examples of techniques used by interventional cardiologists are balloon angioplasty, which is used to open up stenotic heart valves, and atherectomy, which is used to remove plaque from inside arteries.

62. Stents: As set out at §5 Primer, stents are tubular structures used as scaffolding to hold an artery open, thereby permitting blood flow. Both balloon expandable and self-expanding stents were known at the Priority Date. Self-expanding stents were made of a spring or memory metal, such as nitinol and required a sheath to maintain them in their compressed form during delivery.

[45] See also §§25-28 Lutter 1
[46] See photographs at §34 Lutter 1
[47] See photographs at §36 Lutter 1; another bioprosthetic device - the Carpentier-Edwards device is at §4.6 Primer
[48] Lutter 1, §§32-33

63. Transcatheter heart valves ("THVs") & Transcatheter Aortic Valve Implantation ("TAVI"): §7 Primer sets out a basic introduction to TAVI, which is supplemented by §§43-75 Lutter 1[49]. In very brief outline, work on THVs began in the late 1980s with the first THV being implanted in pigs using a catheterisation procedure in 1989. It was not until just over 18 months before the Priority Date of the Patents, in April 2002, that Dr Cribier performed the first-in-man implantation of a THV in the aortic valve position.

64. Dr Cribier's first implantation was in a 57-year old man who was too ill to withstand surgical intervention: indeed, whilst the procedure was successful the patient died shortly afterwards for unrelated reasons[50]. Between April 2002 and August 2003, Dr Cribier carried out a further 5 or 6 implantations in patients. One of those patients died due to early migration of the device[51].

65. In a paper presented by Dr Cribier to the TCT Conference in Washington in September 2002, the procedure was described as a "*last resort option"*[52]and Dr Cribier concluded that the technique *"may become an important therapeutic alternative for non-operable or high surgical risk patients with aortic stenosis*"[53].

66. The device used by Dr Criber was described in a review that appeared in the Journal of the American College of Cardiology in February 2004[54]. The device was developed by a company called Percutaneous Valve Technologies Inc[55] and comprised three bovine pericardial leaflets mounted within a stainless steel balloon expandable stent[56].

[49] With which Prof Moore agrees: Moore 1, §29
[50] Lutter 1, §51
[51] Lutter 1, §53
[52] Exhibit GL11 at D2/11, p7
[53] Exhibit GL11 at D2/11, p28
[54] Exhibit GL12 at D2/12
[55] Later purchased by Edwards in Dec 2003 / Jan 2004 – Lutter 1, §54
[56] Exhibit GL12 at p699 / top of left hand column: see Fig. 1 which is a photograph of the device

67. A review, co-authored by Prof Lutter, of the state of the art of TAVI in or shortly after the Priority Date, is exhibited to Prof Lutter's report at Exhibit GL2. Whilst that review identifies various drawbacks with TAVI, as Prof Lutter explains most of those were not regarded as primary obstacles: it was recognised that many were acceptable given that TAVI procedures were a procedure of last resort for patients would almost certainly die without intervention[57]. TAVI devices were not approved in Europe until 2007[58] and, until very recently, they were only approved in most countries (including Europe) as an exceptional measure where the patient was thought to be at high risk in relation to open-heart surgery[59].

68. Transcatheter Access Routes: these are described at §8 Primer. The most common approach is called the "retrograde" approach, in which the device is delivered through a catheter to the heart against the blood flow. In the "antegrade" approach, the device is delivered though a catheter in the same direction as the blood flow.

Issues arising as to the CGK

69. Following exchange of reply evidence, it is apparent that the following points arise as to the CGK of the Skilled Team at the Priority Date:
    c. The extent to which paravalvular leakage ("PVL"), in particular "Type 3" PVL, was known to be a problem for TAVI;
    d. The extent to which surgical replacement valves constituted the CGK of the Skilled Team.
    e. The extent to which stents or endografts constituted the CGK of the Skilled Team.

[57] Lutter 1, §§62-63
[58] Lutter 1, §67
[59] Lutter 1, §97

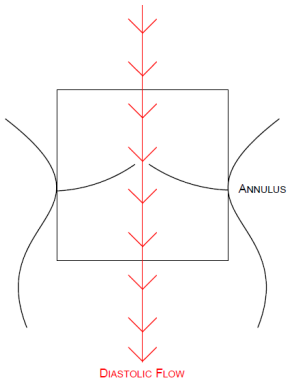
PVL as a problem for TAVI

70. TAVI was an experimental procedure at the Priority Date. Only a small handful of procedures had been carried out in patients[60] and even then as a 'last resort'[61]. As a consequence, whilst the Skilled Team would have had a basic knowledge of the procedure and might have performed or observed a procedure in animals or humans[62], knowledge about the procedure was still at an early and experimental stage.

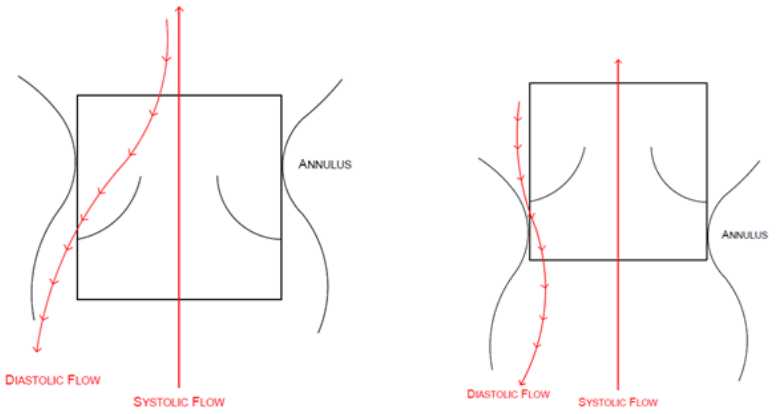
71. In the Review paper co-authored by Prof Lutter in 2004, various difficulties with TAVI were identified, one of which was the need to avoid "*paravalvular regurgitation*"[63]. As Prof Lutter explains at §§77.6-77.8, there are now known to be various ways in which leakage may occur through a THV: however only the first two of these were known to be problems at the Priority Date:

    (a) Type 1 leakage: this occurs where the leaflets of the valve, which are intended to meet one another when closed, do not in fact come together to create a closed seal. As a consequence, there is leakage of blood back into the left ventricle through the gap(s) between the leaflets during diastole. In the diagram set out at §§77.6 Lutter 1 (copied at sub-paragraph (b) below), Type 1 leakage would occur through the gap between the leaflets along the straight bold red arrow (as shown below). Good leaflet design and selection of materials can prevent Type 1 leakage.

[60] Lutter 1, §97
[61] Lutter 1, §90
[62] Lutter 1, §§99-100
[63] Exhibit GL2 at p2203, top of right hand column

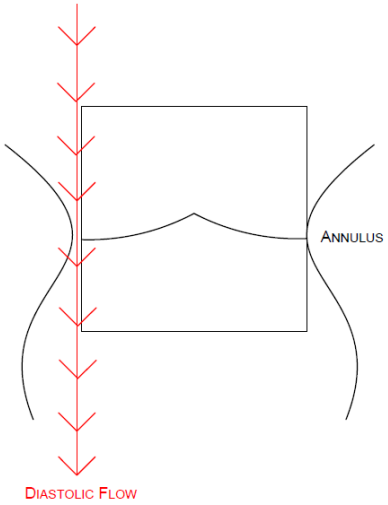


(b) Type 2 leakage: this type of leakage was generally known as "PVL" at the Priority Date and had been acknowledged as an issue, albeit in the context of TAVI was not considered to be a major problem. Type 2 leakage occurs between the replacement device and the annulus through the bars of the stent frame. As illustrated in the diagrams at §77.6 Lutter 1 (copied below), it occurs where the base (or hinge points) of the THV leaflets are not properly aligned with the annulus, such that there is a gap either below or above the annulus through which blood can pass through the bars of the stent frame (as shown below). Fabric covers over the stent frame were added to help to avoid this type of leakage.



(c) Type 3 leakage: this type of leakage occurs between the stent (or anchor) and the anatomy of the placement site. The presence of the calcified native leaflets, which are pushed out of the way by the THV, means that the anchor site is not uniform and therefore, there may be gaps between the sides of the THV and the lumen through which blood can flow. This type

of leakage is illustrated at Fig. 11 '254 Patent and Fig. 13 '766 Patent and the diagram below:



It is Prof Lutter's view that this type of leakage was not CGK at the Priority Date. To the extent that people were aware of Type 3 leakage, the solution was thought to lie in ablating the native leaflets, so as to provide a uniform surface against which to place the THV, or in using a stent with strong radial forces and/or oversizing the stent so as to ensure that it pushed the native leaflets out of the way and embedded itself directly in the lumen.

72. In his reply report, Dr Buller takes issue with Prof Lutter and sets out his opinion that Type 3 leakage was part of the CGK at the Priority Date. The extent to which this was the case will be a matter for exploration at trial. In any event, as Prof Lutter explains, in the context of TAVI at the time (an experimental, option of 'last resort'), PVL (whether Type 2 or Type 3) was not considered to be a big problem. That is clear, for example, from the Dalby article cited by Dr Buller where despite the presence of some leakage, the first implantation by Dr Cribier was considered a success: *"Positioning was satisfactory and aortography and echocardiography indicated excellent valve function with only a small paravalvular leak"*[64]. Dr Buller further states that the potential for Type 3 leakage to occur would have been readily apparent to

[64] Exhibit NPB-8, C2/8

the Skilled Cardiologist because calcification was known to cause stenosis of the aortic valves[65]. Whilst calcification was known to cause stenosis of the aortic valves, when it came to reports of PVL in the case of TAVI, Prof Lutter's evidence is that the Skilled Cardiologist would have understood the leakage to be Type 2 leakage[66].

73. Dr Buller relies upon Chapter 75 of "*The Textbook of Interventional Cardiology"* as being CGK of the Skilled Cardiologist. Prof Lutter's view is that the detailed exposition of the development of percutaneous devices in that chapter would not constitute the Skilled Cardiologist's CGK[67]: instead, the Skilled Cardiologist would have a more basic understanding of the field. Prof Lutter's view is also that the reference to "*perivalvular leak"* in Chapter 75 is a reference to Type 2 leakage i.e. between the valve and the frame[68].

74. In light of the evidence, the following can be said about the CGK concerning PVL at the Priority Date:

75. Firstly, it was known that mild / moderate PVL had been observed in the first in-human TAVI procedure: Cribier '02 paper [C2/7] & Dalby [C2/8]. However, the observation of PVL did not detract from the conclusion that the first in-human TAVI procedure had been a success[69]. It was also noted in Cribier '02 that the degree of PVL remained stable during follow-up monitoring[70].

76. It is important to remember that it was not until nearly a decade after the Priority Date (May 2012) that Kodali reported in his seminal paper that PVL after TAVI was associated with increased long-term mortality[71]: this was the first report that even mild PVL was associated with an increased rate of late

[65] Buller 2, §§33-36
[66] See e.g. Lutter 2, §22
[67] Lutter 2, §21
[68] Lutter 2, §22
[69] A "fantastic" result – XX Lutter – T3/p448/14
[70] C2/7/3 (first column – *"PHV Echocardiographic Assessment")*
[71] D2/22/p7 (first column)

deaths[72] and was a "*disturbing finding"* that was not *"anticipated or expected"*[73]. Buller's evidence was that this was an important paper[74] which was discussed by those interested in the field[75]. A follow-up literature review which focussed on Kodali's findings was published in 2013 by Généreux[76] in the Journal of the American College of Cardiology[77]: that review described PVL after TAVI as "*the new 'in vogue' Achilles' heel of TAVR"*. Dr Buller's evidence was that the Kodali result was *"a topic to discuss"* in 2012/2013 and remains controversial today[78].

77. Given the impact of Kodali's findings on those interested in TAVI in 2012, great care must be taken when reading references to PVL in the contemporaneous literature. At the Priority Date, it was simply not appreciated that PVL was a serious problem which had an impact on clinical outcome.

78. Secondly, there was no understanding that PVL could occur by different mechanisms i.e. there was no differentiation between Type 2 and Type 3 PVL. PVL was simply considered to be leakage that occurred around the valve as opposed to through the valve (the latter being caused by non-apposition of the replacement valve leaflets)[79]. In XX, Buller's evidence was as follows:

"Type 2 and type 3 were not distinguished between. What this patient had was paravalvular leakage. That is reported clearly. That means that blood was flowing round the outside of the valve. There was no differentiation back in the time of this paper, 2002, between so-called type 2 and type 3 which I think has been invented by Professor Lutter for this litigation. There was leakage reported that was paravalvular, i.e. not through the valve itself and they say the cause of it, Cribier says the cause of it was non-apposition. That means the

[72] T4/p552/20 – p553/14
[73] T4/p555/22-p556/4
[74] published in the New England Journal of Medicine: in Buller's view, the leading medical journal in the world and one that only contained papers of significance to the wider medical community – T4/p548/4-13
[75] T4/p553/15-21
[76] D2/23
[77] a "*very reputable and very important journal"* in Dr Buller's opinion – T4/p554/5-20
[78] T4/p555/25-p556/2
[79] T3/p455/13-14

stent had not come into contact, it was not opposed to the surrounding tissue…

…

What mattered was that the valve was leaking around the outside, not through the valve and therefore there was blood flowing around the area that in an idea situation would have been sealed.

…

You can tell that there was leakage around the outside of the stent because the stent is not opposed. The device is not opposed to the tissue and therefore there is flow between the annulus and the stent. In Professor Lutter's breakdown, if it flows through the struts of the stent it is called type 2, but it makes no difference whether it comes down the outside, all outside, or whether some comes through and in a real world some would come from both. Blood is mixing together. If there is a mesh work like chicken wire, it does not matter whether it weaves in and out of the chicken wire or whether it is coming down the outside of the chicken wire. It is blood flow.

…

He tells you it is not type 1, because otherwise it would not be paravalvular, so Cribier definitely tells you it is not through the valve, it is paravalvular, so it is coming round the outside. He goes on with the description because it is non-opposed, means that there is flow around the outside of the stent between the stent and the tissues"

[T4/p602/7 – p604/7]

79. This is important as it indicates that the precise mechanism of PVL was not known at the Priority Date: the Skilled Team only had a rudimentary understanding of what was happening from Cribier '02[80]. This is entirely consistent with Prof Lutter's evidence[81].

80. Thirdly, it was generally understood that an inner cover or inner skirt could help to minimise PVL [see Buller's XX at T4/p615/8-18].

[80] Autopsy could not be obtained so it was not possible to determine the cause of the PVL – C2/7/p3 (first column – "*Clinical Evolution"*) & T3/p465/5-p469/7
[81] T3/p453/24-p454/3

81. Fourthly, to the extent that PVL was recognised by the Skilled Clinician as something to be avoided, it was appreciated that other methods were available to deal with the problem[82]. Two methods, in particular, (oversizing and post-dilation) were used immediately in the post-Priority Date period and a third method, (ablation) remained the subject of research:

    (1) **Oversizing**: this involved oversizing the stent to ensure that it pushed into and embedded into the lumen[83]. This was foreshadowed in Andersen (C2/6);
    (2) **Re-dilation / Balloon post-dilation:** a method used during the implantation procedure: if the clinician observed PVL he would re-dilate the device to further expand it and ensure it embedded in the annulus[84];
    (3) **Ablation:** removal of the native leaflets[85]. Dr Buller's evidence in XX was that this was an approach favoured by surgeons – one of the 'two camps' interested in TAVI at the Priority date[86].

82. The methods of oversizing and re-dilation became standard practice in the post-Priority Date years (as TAVI became a practiced method of treatment) notwithstanding the potential risks. In particular, both techniques increased the risk of aortic rupture with potentially catastrophic consequences for the patient[87]. It is notable that Schymik welcomes the S3 in 2014 because it reduced the need for oversizing and re-dilation as compared to the Sapien XT[88].

[82] Lutter 1, §77.7 [D1/1] and see Buller XX at T4/p618/3-p631/11
[83] A recommendation made by Cribier – e.g. in his 2005 paper referred to by Lutter at D1/11/§14
[84] Lutter 3, D1/11/§16
[85] An approach that is discussed in both the Bessler and Seguin prior art
[86] T4/p582/4 – p586/24
[87] in addition there was an increased risk of cerebrovascular events (strokes and mini-strokes) with re-dilation – see Buller XXT4/p628/20-p629/19
[88] D2/14/pp3-5 & see Buller XX at T4/619/21 – p631/11

Knowledge of surgical replacement valves

83. In his first report, Dr Buller refers to two chapters in textbooks that he states would have formed part of the Skilled Cardiologist's CGK. The first is Chapter 15 of "*Overview of Cardiac Surgery for the Cardiologist"*, 1994. Dr Buller relies upon that chapter as providing the basis for the Skilled Cardiologist's knowledge of mechanical and prosthetic surgical replacement heart valves. Prof Lutter does not agree that the details in that chapter would have formed part of the CGK of the Skilled Cardiologist. In his view, the Skilled Cardiologist would only have had a basic knowledge of the key features of surgical replacement valves, including the different types and key differences between mechanical and biological valves[89]. In particular, Prof Lutter disagrees with Dr Buller that the Skilled Cardiologist would have understood the sewing rings of surgical replacement valves to have been designed to prevent leakage around the outside of the device. To the contrary, the purpose of a sewing ring was to attach the valve in position. When replacing a heart valve during surgery, the native annulus is cleaned before sewing the replacement valve in place. As a consequence, the valve is sutured into a clean site. The sewing rings are quite stiff and are designed to sit in the supra-annular position (on top of the annulus). The surgeon tightly sutures the device in place in such a way as to avoid leakage between the native tissue and the sewing ring [90].

84. During XX of Prof Lutter, the following points emerged about surgical heart valve replacement:

    (1) Surgical heart valves such as the Carpentier-Edwards Perimount could be implanted either intra-annularly or supra-annularly: but Prof Lutter's view was that supra-annularly was preferable and that was the position most surgeons would have adopted[91];

[89] Lutter 2, §§17-20
[90] Lutter 2, §§24-32; see also Moore 2, §§9-15
[91] T3/p379/21-23 & T3/p382/9-p386/20 and CX-GL/24

(2) Where the tissue was calcified or too friable, one method was to use pledgets (pieces of Teflon or Dacron underneath the stitches), but the preferred method was to use a pericardial strip to enhance the annulus[92];

(3) It was desirable to remove calcium during surgery to avoid leakage around the replacement heart valve[93]. At best, Prof Lutter's XX established that some surgeons would be content to leave some calcium behind if it was too difficult to remove, despite the risk of leakage[94];

(4) Sewing rings were quite stiff: Edwards handed up a Starr-Edwards device during XX of Prof Lutter which he confirmed was stiff[95]. During his XX, the only specific example of a surgical / cardiological component that Prof Fisher gave as analogous to a gasket or O-ring was the sewing ring of a surgical heart valve[96]. Given the stiffness of such a sewing ring, it would clearly not be suitable for sealing Type 3 leakages around a TAVI. Edwards did not adduce evidence, nor XX either of Boston's witnesses, on whether such a device could be adapted for use in TAVI: such a case would be hopeless given the requirement of a TAVI to crimp in its delivery configuration.

85. It was put to Prof Lutter that the sewing ring provided a sealing surface for the device[97]. It's not clear where this point gets Edwards. Obviously, the replacement heart valve had to be sewn into place. Equally obviously, in so doing, a seal will be formed between the replacement valve and the native anatomy.

Knowledge of Stents / Endografts

86. Dr Buller's evidence is that the Skilled Cardiologist would have extensive knowledge of various stents / endografts for the treatment of abdominal aortic

[92] T3/p379/24-p380/15
[93] Lutter's evidence was that calcium accumulated both on the valve itself as well as spreading into, above and below the annulus – T3/p375/14-p376/11: this was entirely consistent with his written evidence – D1/1/§30
[94] T3/p389/16-p402/24
[95] T3/p402/25-p405/20
[96] T5/p816/13-p818/19
[97] T3/p387/9 – p389/12

aneurysms ("AAAs"). Prof Lutter disagrees for the reasons he sets out at §§33-37 of his second report. Prof Moore also disagrees with many of the points made by Dr Buller. In particular, it is Prof Moore's evidence that the endografts commercially available as at the Priority Date were designed to eliminate any folds or wrinkles in the graft material. Such material was not designed to act as a seal and, to the extent that there were any folds or wrinkles in the material, they would have been minimal and not sufficient to create a seal between the graft and the native anatomy[98].

87. This point is likely to be of importance when considering Thornton, which is a prior art patent for a stent / endograft for treating AAAs.

88. One surprising point to come out of Dr Buller's XX given Edwards' position on the composition of the skilled team and Dr Buller's own evidence as to his experience and professional interests, was Dr Buller's admission that he had not in fact implanted any AAA or TAA device: he therefore had no first hand knowledge of using the Gore Excluder[99].

89. Edwards have focussed extensively on endografts in their evidence and in their XX of Boston's expert witnesses. In summary, the issues of CGK that arise and the conclusions on them are as follows:

(1) Was it CGK that wrinkling of outer covers was a problem?

90. There is no dispute between the parties that, to the extent the Skilled Team were aware of endografts at all, it was CGK that endografts should be oversized to ensure a good seal between the graft and the vessel wall. Given the catastrophic consequences that would result if an aneurysm burst, this was key.

91. Edwards' contention is that the covers of endografts were made of a substantially inelastic material such that, upon implantation, there was

[98] Moore 2, §§16-31
[99] T4/p646/16-24 (despite his earlier confirmation of §28 at T4/p538/10-12)

necessarily wrinkling in the cover: when fully expanded, there would be no wrinkling, however because they were oversized, when deployed, there would be an excess of fabric which would wrinkle and cause leak paths.

92. Edwards' case on this was based upon Dr Buller's evidence. He, in turn, relied upon the Schurink paper[100] which reported on a 1999 experiment performed using home-made stent-grafts[101]: the experimenters covered two commercially available stents – the Gianturco (which was a self-expandable stent) and the Palmaz (which was a balloon-expandable stent) – with fabric and implanted them in cadaveric aortas. The authors reported that the outer cover of the Gianturco stent wrinkled but the outer cover of the Palmaz stent did not[102].

93. On any view the Schurink paper is a poor basis to support an assertion that endografts wrinkled on deployment. It would be surprising if commercially produced endografts, whose whole purpose is to prevent blood reaching the aneurysm sac[103], were constructed in such a way that their covers wrinkled in use and thereby opened up leakage paths into the aneurysm sac. Indeed, it was Prof Moore's evidence that this was not the case as it was undesirable for such wrinkles to be present[104]. Prof Moore had extensive experience of endografts[105] and was in a much better position than Dr Buller to assist the court on this point. In any event, the Schurink paper shows that even in the home made devices, the balloon-expanded device did not have any longitudinal wrinkles (see above). Dr Buller's rather extraordinary evidence that it had very small wrinkles, practically significant but too small to see, should be rejected.

[100] C2/4 & see Buller 1, §73
[101] T4/p655/22-p656/23
[102] T4/p658/14-p659/3
[103] Moore 1, §§92-93
[104] Moore 1, §106: *"a bad and undesirable feature"*; Moore 2, §§20-21
[105] Designing and testing – see Moore 1, §87. He also lectured on them – Moore 2, §21

(2) If it was CGK that wrinkling of outer covers was a problem, was it CGK to use a seal to address the issue?

94. This is the Gore Excluder point. Edwards' position is that the Gore Excluder was a CGK product and it was CGK that the "sealing cuff" of the Gore Excluder was designed to prevent Type 1 endoleaks caused by wrinkles in the outer cover and further was known to flare upon deployment in the aorta (so as to form a flange).

95. Care has to be taken on this point as two Gore Excluders[106] were introduced into evidence by Dr Buller:

- the AAA device (Buller 1, §74): the Instructions for Use at C2/5 [2002] related to this device;
- the TAA device (Buller 2, §15): this was a second generation device that was subject to an investigational device exception[107].

96. The only reference to the "sealing cuff" is in the Instructions for Use for the AAA device: those instructions simply identify the sealing cuff as being a piece of ePTFE/FEP near the aortic end of the trunk[108]. There were no documents in evidence providing details as to what the sealing cuff was intended / designed to do; how the sealing cuff was constructed; and/or how the sealing cuff worked[109]. Even Prof Moore, who had used the Gore Excluder as a teaching aid for 9 years, was not familiar enough with how it was constructed to know how the sealing cuff was in fact attached[110]. There is also no evidence of longitudinal wrinkles.

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[106] T4/p643/7-10
[107] C2/10 & T5/p666/12-18
[108] C2/5/p1 – they provide no explanation as to the construction of the cuff or as to how it is intended to work – T2/p195/1-13
[109] In XX, Dr Buller was unable to identify any specific documents that supported his belief as to these matters (T5/p669-671/9). Prof Fisher had no recollection of being aware of the Gore Excluder prior to his involvement in this case – T5/p816/20-25
[110] T2/p192/6 – p193/17

97. Dr Buller had never actually used the Gore Excluder himself[111]. He based his analysis of how the sealing cuff was supposed to work simply on his assertion that longitudinal wrinkles were well-known (Boston disputes this for the reasons given above) and the fact that the Instructions for Use called it a "sealing cuff"[112].

98. There was therefore no evidence before the Court as to the purpose, construction or operation of the sealing cuff on either of the Gore Excluder devices. Boston submit that nothing useful can be taken from the Gore Excluder.

99. Of the 13 or so commercially available endografts at the Priority Date[113], the only one that Edwards identified as having had a sealing cuff was the Gore Excluder[114]. Boston's position is that this is instructive: it suggests that the 'wrinkling' problem identified by Edwards was not in fact a problem at all. Designers of AAA / TAA devices were well aware of the need to ensure against endoleaks and did so by proper design of their devices (selection of appropriate materials etc.) and oversizing[115] as opposed to using some form of sealing cuff.

(3) In what type of tissue were endografts to be placed?

100. This is a subsidiary point which goes to the degree to which the Skilled Team working on TAVI might expect to derive assistance with PVL by looking across to the field of endografts. Edwards' position is that endografts were known to be placed in calcified, irregular vessels which had similar characteristics to the calcified, irregular annulus that TAVIs were to be placed in. Accordingly, Edwards' argument is that sealing means used in endografts would be of interest to the Skilled Team.

[111] T4/p644/20-23 & p646/15-19
[112] T4/p662/4-8 & p662/22-p663/2
[113] See Rutherford paper – DXX/17/p2 – Chart: "Devices for the endovascular repair of AAAs" – put to Dr Buller at T4/p640/16 – p642
[114] T4/p644/13-19
[115] Moore 1, §95

101. Following XX, it is clear that endografts are designed to be placed in healthy tissue. It may be that in particular desperate cases, a clinician feels comfortable using an endograft 'off-label' but the instructions for use and recommended practice is to implant in healthy tissue:

(1) The papers relied upon by Dr Buller and/or put to Prof Lutter in XX to support the contention that endografts were placed in calcified tissue (Buller 2, §22) do not support the contention for which they are cited:
   a. Chuter [C2/11] is simply an early investigation into the feasibility of AAA endografts[116];
   b. Allen [C2/3] warns against implantation in heavily calcified vessel walls;
   c. Chaikof [CX-JM/10] simply proposes a scoring system for assessing treatment protocols for AAAs: one relevant factor suggested for inclusion is the degree of calcification[117];
   d. Boston Patent [CX-JM/9], filed in May 2003, speculated that calcification played a role in endoleaks, but Prof Moore's evidence was that he was not aware of any data to that effect at the Priority Date[118].

(2) The ideal placement is healthy tissue and instructions for use of commercial endografts state that if there are calcifications, the device should not be implanted[119] - see e.g. Gore Excluder Instructions for Use[120];

(3) Presence of normal aorta of 1.5-2cm long, a criteria for placement: Parodi article[121].

[116] Dated 2003 – *"visionary and revolutionary work"* – p11
[117] T2/p172/3-5 & p173/17-20
[118] T2/p175/10-17
[119] T2/p163/3-15
[120] *"minimal thrombus and/or calcification"* – T4/p647/14-25
[121] DXX/1/p10 & T4/p651/5-p654/5

Foreshortening

102. Foreshortening is the decrease in length of a stent when it expands from its crimped configuration to its deployed configuration. It was not necessary at the Priority Date to have foreshortening: whether or not there was foreshortening depended critically upon the geometry of the stent[122]. By the Priority Date, it was known that coronary stents only foreshortened by a couple of % points[123].

103. Foreshortening was generally considered a bad thing both for coronary and aortic stents: it was problematic because if the stent foreshortens too much, it is difficult to get into the right position[124].

Desirable characteristics for a THV

104. It was established with Dr Buller during XX that it was CGK at the Priority Date that the following were desirable characteristics for the design of a THV, namely that the THV:

(1) Had to work as a valve – T4/p572/6-p572/19;
(2) Had to be firmly anchored – T4/p572/20 - 25
(3) Had to last a long time – T4/p576/16 – p577/2;
(4) Had to be deliverable - T4/p573/9-20;
(5) Had to have a low delivery profile: i.e. small diameter when crimped up – T4/p573/21 – p575/3;
(6) Had to have a delivery system i.e. guidewire, catheter etc. – T4/p575/18-21
(7) Had to be capable of being positioned accurately – T4/p573/2-8;
(8) Had to be visible on imaging – T4/p575/9-17;

[122] T4/p587/11-15: Palmaz-Schatz foreshortened by 10%, Wallstent by 30-50% (T4/p587/16-p588/19)
[123] Table 1 at CX-JM/8/p4 & XX Buller T4/p592/18-p593/22
[124] T4/p590/4-6

(9) Had to have the right size and shape so that it did not interfere with other anatomy: too high and it occludes the coronary arteries; too low and interferes with other parts of heart, in particular the mitral valve – T4/p576/11-15;

(10) Had to seal and resist leakage – T4/p575/22-23;

(11) Had to consider the geometry of stent – radial forces & foreshortening – T4/p575/24 – p576/6;

(12) Had to consider whether to use a balloon expander or self expander – T4/p576/7-10;

(13) Had to consider simplicity of design for manufacturing costs etc. – T4/p577/3-8;

(14) Had to take into account various medical considerations e.g. anti-coagulant regime – T4/p577/9-22.

105. In summary, the design of a TAVR device was an extremely multi-factorial and challenging one in 2003. The scope of the challenge facing the Skilled Team is well described by Cribier himself, in a paper presented in 2014[125].

The Application

106. We deal with the Application here because it contains the same teaching as the Patents and, given Edwards' attacks on the basis of added matter, it is convenient to start by considering the teaching of the Application.

107. The Application[126] is called "*Repositionable Heart Valve*" and it describes the invention as relating to: *"methods and apparatus for endovascularly replacing a heart valve. More particularly, the present invention relates to methods and apparatus for percutaneously replacing a*

[125] DXX/4, put to Buller during XX at T4/p580/7-13
[126] A2

heart valve with a replacement valve using an expandable and retrievable anchor"[127].

108. Under the heading "Background of the Invention", the Application describes valve replacement surgery and sets out its risks (e.g. bleeding, infection and stroke) and disadvantages (e.g. use of general anaesthesia and heart-lung machine; 1-2 week hospital stay; recovery time of weeks to months)[128]. It then goes on to describe the various steps that have been taken to replace heart valves using interventional cardiology. In particular, the THV developed by Percutaneous Valve Technologies ("PVT"), which was first implanted in a patient in April 2002[129], is described. However, various disadvantages of that device are noted. Critically, the PVT device is not reversible and the stent is not retrievable[130]: this is a serious drawback as misplacement of the stent can either block the patient's coronary ostia, which open into the coronary arteries[131], or, over time, wear away the leaflets of the mitral valve[132]. In addition, the PVT device has a large cross-sectional delivery profile, which means that a more complex method of delivery may be required[133]. Other prior art devices are also considered and their disadvantages (such as poor accuracy in deployment and lack of radial strength) noted.

109. The Application is a large document which contains numerous inventions relating to TAVI devices. For the purposes of this case, the important sections are as follows.

Risk of PVL

110. The risk of paravalvular leakage or regurgitation is described at p32/lines 23-28, by reference to Fig. 13 (p28/140):

[127] p1/3-6
[128] p1/6-26
[129] This is the Cribier device
[130] p2/5-10
[131] §2.2 Primer
[132] See diagram at §1.1 Primer for relative positioning of aortic and mitral valves
[133] p2/11-17 and see §8 Primer for description of retrograde and antegrade delivery

*"a risk of paravalvular leakage or regurgitation around apparatus of the present invention is described. In Figure 13, apparatus 10 has been implanted at the site of diseased aortic valve **AV**, for example, using techniques described hereinabove. The surface of native valve leaflets **L** is irregular, and interface **I** between leaflets **L** and anchor 30 may comprise gaps where blood **B** may seep through. Such leakage poses a risk of blood clot formation or insufficient blood flow".*

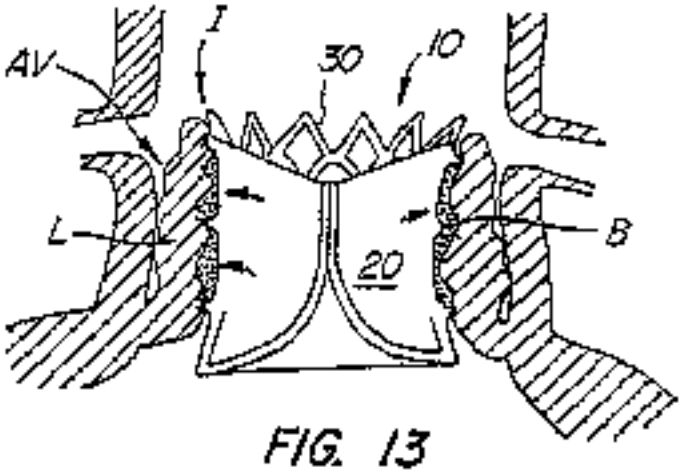


FIG. 13

111. It is clear from this description that the Application is primarily concerned with Type 3 leakage: i.e. leakage between the device and the native leaflets. However, the proposed solutions to this problem deal with the problem of Type 2 leakage (i.e. leakage through the bars of the device) as well.

First method of sealing replacement valve against leakage

112. Having set out the problem of PVL, the Application then teaches the two methods for sealing the replacement valve against leakage claimed in the Patents. The first of these methods is described by reference to Figs. 14-16[134] and teaches the use of sacs, externally disposed around the anchor. This is the

[134] pp28-29/140

method of sealing with which the '766 Patent is concerned. The relevant passages are as follows:

a. p32/29-33: *"Referring to Figure 14, optional elements for reducing regurgitation or leakage are described. Compliant sacs 200 may be disposed about the exterior of anchor 30 to provide a more efficient seal along irregular interface I. Sacs 200 may be filled with an appropriate material, for example, water, blood, foam or a hydrogel. Alternative fill materials will be apparent"*;

b. p33/1-7: *"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 discrete, 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"*;

c. p33/8-13: *"With reference to Figures 16, exemplary techniques for fabricating sacs 200 are provided. In Figure 16A, sacs 20 comprise 'fish-scale' slots 202 that may be back-filled, for example, with ambient blood passing through replacement valve 20. In Figure 16B, the sacs comprise 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."*

Second method of sealing replacement valve against leakage

113. The second method, with which the '254 Patent is concerned, is described by reference to Figures 32-34[135] and also in relation to the specific embodiment illustrated at Figures107A-C[136]. The key teaching is at p34/26-31 and is as follows:

[135] Figures 32-34 at p40/140
[136] pp134-136/140 and see description of this specific embodiment at p84/30 – 86/2 & 22-32

"Figures 32-34 show another way to seal the replacement valve against leakage. A fabric seal 380 extends from the distal end of valve 20 and back proximally over anchor 30 during delivery. When deployed, as shown in Figures 33 and 34, fabric seal 380 bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets 382, particularly when the pockets are filled with blood in response to backflow blood pressure. This arrangement creates a seal around the replacement valve"[137]

114. Figs. 32-34 are as follows:

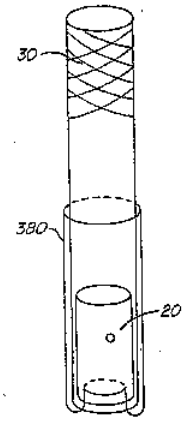


FIG. 32

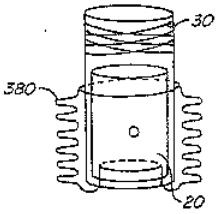


FIG. 33

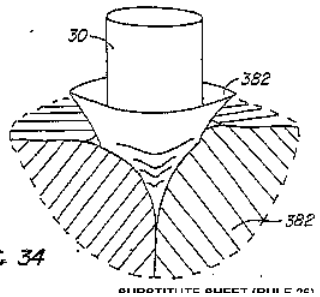


FIG. 34

[137] At p34/26-31

The '254 Patent

115. The '254 Patent repeats the general teaching of the Application in the "Background of the Invention" section. The "Summary of the Invention" is at [0017] and refers to the fabric seal which is bunched up in the deployed configuration:

"The fabric seal can bunch up to create fabric flaps and pockets. The seal can bunch up and creates pleats. The seal can comprise a pleated seal. The pleating can create a seal around the replacement valve. The seal can bunch up in response to backflow blood pressure. The bunched up fabric or pleats can occur in particular when the pockets are filled with blood in response to backflow blood pressure…At least a portion of the seal can be adapted to be captured between the native valve leaflets and a wall of the patient's heart when the anchor and replacement valve are fully deployed. The seal can be adapted to prevent blood flow around the replacement valve and the anchor when the anchor and the replacement valve are fully deployed".

116. Fig. 11 is described as a demonstration of PVL around the replacement heart valve and anchor[138]: it is the same figure as Fig. 13 of the Application. Similarly, the description of Fig. 11 at [0056] is the same as that at p32/lines 23-28 Application.

117. At [0057] – [0059], the Patent teaches the methods for reducing regurgitation or leakage that form the basis of the '766 Patent. The teaching at [0062] and further teaching at [0103], in relation to Figs. 22-24, is relevant in the context of the claims of the '254 Patent. Those figures and teaching replicate Figs. 32-34 of the Application and the associated teaching at p34/26-31 and p86/22-32 Application. Similarly, Figs. 107A-C are replicated in the '254 Patent (as Figs. 29A-C) and the teaching relating to them is replicated at [0097] – [0099].

[138] p3 / col 4 / lines 52-53

118. Prof Lutter's reaction to the '254 Patent is informative. In particular his view was that "*the '254 Patent shows clear consideration of the problem of PVL and suggests a number of elegant and feasible solutions*"[139].

119. Boston asserts the following claims of the '254 Patent as being independently valid: claims 1, 2, 3, 4, 5, 6, 9 and 13[140]. Claim 1 is for:

(a) Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:
(b) An expandable anchor (30)
(c) Supporting a replacement valve (20)
(d) The anchor having a delivery configuration and a deployed configuration **characterised by:**
(e) A fabric seal (380)
(f) Extending from the distal end of the valve (20)
(g) Proximally over the anchor in the delivery configuration
(h) Wherein the seal is bunched up in the deployed configuration.

120. Claims 2 to 3 are for the apparatus in which the bunching of the seal creates fabric flaps and pockets (claim 2) and pleats (claim 3). The monopoly is therefore not (as Edwards' seek to argue) confined to any particular form of bunching. Claim 4 is for an apparatus in accordance with any of claims 1, 2 and 3 in which the seal comprises a pleated seal. Claim 5 is for the apparatus of claims 3 or 4 where the pleating creates a seal around the replacement valve. Claim 6 is for the apparatus of any of claims 1-5 in which the seal bunches up in response to backflow blood pressure. The monopoly therefore covers devices where the bunching of the fabric seal occurs in response to blood pushing on the fabric seal once the device is *in situ*. Claim 9 is for the apparatus of any of the preceding claims in which the anchor foreshortens during deployment. This claim is potentially important in light of one of Edwards' added matter attacks (which we deal with below). Finally, Claim 13

[139] Lutter 1, §81
[140] Re-Amended Notice of Independent Validity of Claims B/21: infringement of claim 13 is no longer pursued [ISC/p245]

is for the apparatus of any of the preceding claims in which at least a portion of the seal is adapted to be captured between native valve leaflets and a wall of the patient's heart when the anchor and replacement valve are fully deployed[141].

The '766 Patent

121. Again, the '766 Patent repeats the general teaching of the Application. At [0020] the invention of the '766 Patent is summarised as:

"...an apparatus for endovascularly replacing a patient's heart valve as set forth in the appended claims. The apparatus comprises an expandable cylindrical anchor supporting a replacement valve. The anchor has a delivery configuration and a deployed configuration. The apparatus has at least one sac disposed about the exterior of the anchor to provide a seal".

122. The risks of PVL are illustrated by reference to Fig. 13 (which is the same as Fig. 13 of the Application) at [0064][142].

123. At [0065] – [0067], the use of sacs as a seal is described by reference to Figures 14 – 16. The wording is the same as set out in the Application.

124. Prof Lutter's reaction to the '766 Patent was similar to his reaction to the '254 Patent. In particular, he was "*surprised and impressed by the invention"* and wished that he had thought of it back in the early 2000s when he was involved in designing TAVI devices[143].

[141] Infringement of this claim is no longer pursued, though it is maintained as independently valid – ISC/p245
[142] at p53
[143] Lutter 1, §85

125. Boston asserts the following claims of the '766 Patent as being independently valid: claims 1, 2, 3, 4, 6, 7 and 17[144]. Claim 1 is for:

(a) Apparatus for endovascularly replacing a patient's heart valve,
The apparatus comprising:
(b) An expandable cylindrical anchor (30);
(c) Supporting a replacement valve (20);
(d) The anchor (30) having a delivery configuration and a deployed configuration,
(e) And at least one sac (200) disposed about the exterior of the anchor (30) to provide a seal.

126. Claims 2 to 4 are concerned with the way in which at least one sac of the apparatus of claim 1 may be filled with blood: Claim 2 is to the apparatus of Claim 1 wherein at least one sac is adapted to be filled with blood; Claim 3 is to the apparatus of Claims 1 and 2, wherein at least one sac is adapted to be filled by blood washing past the at least one sac; and Claim 4 is for the apparatus of any of the preceding claims in which the at least one sac comprises one or more slots that can be used to back-fill the at least one sac with ambient blood passing through the replacement valve. The monopoly of the '766 Patent therefore covers apparatus in which the sac is filled with blood *in situ* and there are dependent claims limited to such an arrangement (which is potentially relevant to Edwards' attack based on Seguin).

127. Claim 6 is for the apparatus of Claims 1-5 in which at least one sac is adapted to provide a seal along an irregular interface between the native valve leaflets and the anchor. The monopoly therefore covers apparatus where the seal adapts to the native anatomy. Claim 7 provides that the at least one sac of the preceding claims may be provided as a continuous cylinder. Therefore, there is no requirement for a number of discrete sacs. Finally, Claim 17 is for the apparatus of any preceding claim wherein it is configured to be implanted at the site of a diseased aortic valve.

[144] Re-Amended Notice of Independent Validity of Claims B/21

Construction

Construction: the law

128. The principles of construction are well known. The Court must apply Article 69 of the EPC and its Protocol and determine what the person skilled in the art would have understood the patentee to be using the language of the claim to mean (*Kirin Amgen Inc v Hoechst Marion Roussel Ltd* [2004] UKHL 46; [2005] RPC 9 at [30]-[35]). Further guidance on the application of this test was summarised by the Court of Appeal in *Virgin Atlantic Airways v Premium Aircraft Interiors UK Ltd* [2010] RPC 8 at [5]).

"The task for the court is to determine what the person skilled in the art would have understood the patentee to have been using the language of the claim to mean. The principles were summarised by Jacob LJ in Mayne Pharma v Pharmacia Italia [2005] EWCA Civ 137 and refined by Pumfrey J in Halliburton v Smith International [2005] EWHC 1623 (Pat) following their general approval by the House of Lords in Kirin-Amgen v Hoechst Marion Roussel [2005] RPC 9. An abbreviated version of them is as follows:

> *(i) The first overarching principle is that contained in Article 69 of the European Patent Convention;*
>
> *(ii) Article 69 says that the extent of protection is determined by the claims. It goes on to say that the description and drawings shall be used to interpret the claims. In short the claims are to be construed in context.*
>
> *(iii) It follows that the claims are to be construed purposively—the inventor's purpose being ascertained from the description and drawings.*

(iv) It further follows that the claims must not be construed as if they stood alone—the drawings and description only being used to resolve any ambiguity. Purpose is vital to the construction of claims.

(v) When ascertaining the inventor's purpose, it must be remembered that he may have several purposes depending on the level of generality of his invention. Typically, for instance, an inventor may have one, generally more than one, specific embodiment as well as a generalised concept. But there is no presumption that the patentee necessarily intended the widest possible meaning consistent with his purpose be given to the words that he used: purpose and meaning are different.

(vi) Thus purpose is not the be-all and end-all. One is still at the end of the day concerned with the meaning of the language used. Hence the other extreme of the Protocol—a mere guideline—is also ruled out by Article 69 itself. It is the terms of the claims which delineate the patentee's territory.

(vii) It follows that if the patentee has included what is obviously a deliberate limitation in his claims, it must have a meaning. One cannot disregard obviously intentional elements.

(viii) It also follows that where a patentee has used a word or phrase which, acontextually, might have a particular meaning (narrow or wide) it does not necessarily have that meaning in context.

(ix) It further follows that there is no general "doctrine of equivalents."

(x) On the other hand purposive construction can lead to the conclusion that a technically trivial or minor difference between an element of a claim and the corresponding element of the alleged infringement nonetheless falls within the meaning of the element when read purposively. This is not because there is a doctrine of equivalents: it is because that is the fair way to read the claim in context.

(xi) Finally purposive construction leads one to eschew the kind of meticulous verbal analysis which lawyers are too often tempted by their training to indulge."

129. At §104 of Edwards' Skeleton it refers to the proposition, expounded by the Court of Appeal in *Virgin v Premium* at §§10-16, that the skilled reader is taken to know about the practice of divisional applications and, accordingly, knows that where a patent is a divisional there are, or may be, aspects of what is described in the specification which are claimed in some other patent or patents divided out from the original application.

130. Edwards goes on to rely upon this point at §§140 & 161 in support of its point that the claims of the two Patents are mutually exclusive: Edwards' contention is that the Skilled Team would understand the claims of the '254 Patent to exclude seals comprising a sac and the claims of the '766 Patent to exclude seals comprising a bunched up seal.

131. Edwards' reliance upon the *Virgin v Premium* divisional point is misplaced and based on a misunderstanding of the CA's judgment in that case[145] [JA-1/5].

132. In *Virgin*, the parent application described a number of inventions including the following two for business class airline seating:

[145] See explanation in Opening at T1/p63/12-65/16

a. the first was a space-packing invention (a herringbone arrangement of seat/beds intended to optimise space);
b. the second was a flip-over invention (the contoured seat was flipped over when converted to bed mode to give a flat, and supposedly more comfortable, bed surface).

133. A number of divisionals were spun out of the parent application and Virgin sued Premium, an aircraft seating manufacturer, in respect of one of these divisionals. Premium's product was designed to be arranged in a herringbone on an aircraft but did not utilise a flip-over seat. It argued that there was no infringement as, properly construed, the claims were limited to flip-over seats (which were described in the specific embodiments of the invention).

134. At first instance Lewison J held that the claims of the Patent were limited to flip-overs. However, the CA disagreed. They found that the skilled reader would be taken to know about the practice of divisional applications and that would affect his/her understanding of the claim: in particular, he/she would recognise that aspects of what were described in the patent might actually be claimed in some other patent or patents divided out from the original application [§§10-15].

135. On the particular facts of the case before it, the CA held that the space-packing idea was wholly unrelated to the flip-over idea: as such the skilled reader would have no reason to believed that the patentee intended to limit its claim to flip-overs [§48]. At §49, Jacob LJ explained the relevance of the skilled person's knowledge of divisionals as follows:

"Now it is of course true that the only specific embodiment is a flip-over bed/seat. And, because that would strike the notional skilled reader as a good idea he would expect it to be patented somewhere. But because he knows…that the patentee has divided out what is in this patent from a parent application he would not necessarily expect that to be done in this patent."

And at §54 concluded:

"So we think the notional skilled reader would go by the claim and not look for or expect any hidden limitations in it"

136. So the proposition in *Virgin* is that where there are a number of divisionals and the parent application identifies numerous inventions, it is **not** the case that the skilled reader will understand the claims of one divisional as being limited to a device that **only** incorporates one of the inventions to the exclusion of the other inventions. However, that is exactly the proposition that Edwards seek, erroneously, to draw from *Virgin*.

Construction: the *Virgin* point

137. Here, the Skilled Team would recognise that two of the inventions of the Application relating to sealing – bunching and sacs – could be present in the same embodiment. Contrary to the suggestion of Edwards at §§140 & 161, the Skilled Team would not read the claims of either the '254 or the '766 Patent in a limited or exclusionary way. There is simply no technical reason to do so:

(a) Both patents are concerned with solving the problem of Type 3 leakage – both have the same teaching on this point: [0064] & Fig. 13 '766 Patent cf. [0056] Fig. 11 '254 Patent;
(b) Both patents teach that the behaviour of the seal can respond to backflow blood pressure: e.g. [0065] & [0067]'766 Patent and see claims 2, 3 & 4 all of which concern sacs filling with blood; [0062] '254 Patent and see claim 6 in which the seal bunches in response to backflow blood pressure;
(c) Figs. 27-29 '766 Patent (which are the same as Figs. 22-24 '254 Patent) illustrate the bunching up of the external seal but could easily be converted into sacs of the type shown in Fig. 16 '766 Patent (Fig. 14 '254 Patent) by introducing openings into the fabric of the external seal;

(d) Although the inventions are taught separately in the Patents, they are not inconsistent: there is no incompatibility of the teaching and, indeed, the teaching of both is included in both Patents (see [0071] '766 Patent which is the teaching of bunching; and [0057]-[0059] '254 Patent which is the teaching of sacs);

(e) The description of the "bunched-up" invention refers to the creation of *"fabric flaps and pockets"* upon bunching: it is difficult to draw any clear-water between a "pocket" and a "sac". Indeed, save for his point on construction of the term 'sac', Dr Buller did not see there to be any material difference[146].

138. The acid test when it comes to construction is purpose: unless there is a deliberate limitation in the claims (which is not the case here), the Court ought not to read them restrictively unless there is some positive reason to suppose the patentee wanted to limit his monopoly. There is no such positive reason here. To the contrary, in the context of inventions that can clearly be used in combination and are taught side-by-side, with obvious parallels between them, it would be absurd to consider the patentee intended that products incorporating both of his inventions ought to be excluded from the monopoly of his claims.

Construction: the '254 Patent

139. Three points arose from Edwards' Skeleton:

(1) The meaning of "bunched up";

(2) The meaning of "proximal" and "distal";

(3) "Flaps", "pockets" and "pleats" of claims 2-5.

[146] See his XX on the various pieces of prior art: T5/p731/21-p733/10 (Cribier); p474/2-5 (Bessler); p776/19-24 (Thornton)

The meaning of "bunched up"[147]

140. Boston's position is that the term "bunched up" is simply an ordinary, English expression[148], which refers to the fact that, in its deployed configuration, the fabric of the seal is gathered in some way. There is no requirement that the bunching be done in any particular way or that it results in a neat and organised arrangement. Depending on the precise shape of the irregular annulus in which the seal finds itself, the bunching will lead to the formation of flaps, pockets and / or pleats. The patentee is not teaching that the bunching has to take place in any particular way or lead to a particular orientation or arrangement[149].

141. Whilst the parties are agreed that the term "bunched up" is not a term of art, Edwards suggests at §146 of its Skeleton that the Shorter OED dictionary of "to bunch" is of assistance: *"Make into a bunch or bunches; gather (material) into close folds"*. In particular, Edwards seizes on the second part of that definition to suggest that there is a requirement that the seal is gathered into close folds in its deployed configuration [§149 Edwards' Skeleton].

142. However, the Patent does not teach that the bunched up seal is one in which the material is gathered into close folds. Furthermore, there is no technical requirement for that to be the case. Adopting a purposive approach, there is no reason for limiting the term in the way suggested by Edwards. This is especially so given the purpose of the seal which, as Edwards accepts at §149 of its Skeleton is to: "*block gaps in the irregular interface between the native leaflets and the anchor, through which blood may seep"*. If the seal is intended to block gaps in an irregular interface, it is clearly not in keeping with that purpose to require that the seal be arranged in close folds.

[147] Dealt with in opening at T1/p70-p71/12
[148] Indeed, Dr Buller confirms that the terms "bunched up", "pleats", "flaps" or "pockets" are not terms of art to the Skilled Cardiologist – Buller 1, §123
[149] See Moore 1, §§39-40

143. As set out above, depending on the precise shape of the irregular annulus in which the fabric of the seal finds itself, the bunching will lead to the formation of flaps, pockets and/or pleats. These are the various possibilities taught at [0062] & [0103] and claimed by subsidiary claims 2-5 and those terms, which cover a variety of different configurations of fabric, give further guidance to the Skilled Team as to what the term "bunched up" means.

144. The '254 Patent contains no teaching that the bunching has to take place in any particular way or lead to a particular orientation or arrangement [see unchallenged evidence of Moore at §§39-40 of his first report – D1/4].

145. Edwards also argues that the folds must be bunched up in a vertical as opposed to horizontal manner [§154 Edwards' Skeleton]. Its position, based on the evidence of Dr Buller[150], is that Figs. 22, 23 and 24 Patent indicate that the flaps / pockets / pleats are intended to be circumferentially oriented i.e. horizontal. According to Dr Buller, this would make sense to the Skilled Cardiologist because, if such structures were vertical, they would create leak paths allowing the flow of blood between the seal and the surrounding tissue.

146. Edwards' position is flawed for the following reasons:

147. Firstly, it places undue reliance upon the schematic figures of the Patent[151]. Whilst the drawings can be used as an aid in interpreting the wording of the claims, they are simply an aid. Furthermore, the description is also important and it would be wrong to place undue emphasis on the schematic diagrams whilst ignoring the wording of the claims and the wording in the description. Fig. 23 schematically shows what might happen to the fabric seal when the anchor foreshortens. However, it illustrates what happens when the device is surrounded by empty space. Therefore it is not surprising that in this idealised situation the fabric seal is shown in neat folds. If that process occurs within a restricted, irregular area, then clearly the resulting

[150] Buller 1, §126; Buller 2, §§96-98
[151] In stark contrast to the position adopted with respect to the prior art see e.g. Buller 1, §149

cross-sectional appearance will be very different. It is clear from that description that a neat, orderly bunching is not contemplated: see e.g. [0103] where the patentee teaches that *"the fabric seal 380 bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets 382"*. The Skilled Team knows that the spaces formed by the native valve leaflets will vary from patient to patient and therefore would not understand Fig. 23 to require an orderly, regular arrangement. Further support can be derived from Fig. 29C where the seal 60 is shown to conform to the shape of the native valve leaflets.

148. Secondly, it proceeds on the false assumption that the patentee is teaching that the bunching, pleating etc. must always be in one orientation: either horizontally or vertically. From that false assumption, Dr Buller reasons that as vertical folds would lead to gaps through which blood could flow, horizontal folding must have been intended. But, the patentee is not teaching that the bunching, pleating etc. must always be in one orientation. To the contrary, it teaches at [0062] that: *"When deployed…fabric seal 380 bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets 382…"* In order for the fabric flaps and pockets to extend into spaces formed by the calcified valve leaflets, which are an irregular shape[152], the resulting bunching, folding etc. must itself be irregular. Furthermore, this is illustrated by Fig. 24, where it is clear that there is a mixture of horizontal and vertical folding in the seal.

Proximal / Distal[153]

149. Claim 1 requires that in its **delivery configuration** the seal must extend from the distal end of the valve proximally over the anchor. Edwards says that this means that the seal must extend on the outside of the device proximally of the upper position of the valve. Reliance is placed upon [0062]

[152] Moore 2, §32
[153] Dealt with in opening – T1/p71/13 – p73/14

and Figures 22-24. However, neither [0062] nor Figs. 22-24 support this point of construction.

150. All this element of the claim is stating is that the seal starts at the distal end of the valve i.e. the inflow end, and then proceeds down and around the distal/inflow end of the device and over the outside of the anchor/device proximally (i.e. towards the outflow end/operator). This is clear from the teaching at [0062] and Figs. 22-24 '253 Patent[154]. In those figures the "proximal" end is at the top of the figure and the "distal" end is at the bottom. This arrangement ensures that the fabric forms a continuous seal (barrier) between the edge of the valve and the surrounding anatomy once expanded. Edwards' construction has no functional meaning.

"Flaps", "pockets" and "pleats" of claims 2-5

151. This is dealt with at §143 above.

Construction: the '766 Patent[155]

152. The points of construction that arise on the '766 Patent are closely related and concern the meaning of the word "sac" and the meaning of the words "sac disposed about the exterior of the anchor". Boston's position is that the purposive construction of these terms presents no difficulty to the Skilled Team: all that is required is that there is a cavity – a volume - outside the device which acts as a seal to block the flow of blood between the outside of the device and the native anatomy. The subsidiary claims 2-4 require that the cavity can be filled with (circulating) blood. The teaching of the Patent is clear: the precise form or arrangement of the sacs is immaterial.

[154] In opening, references was made to [0071] and Figs 27-29 '766 Patent which are identical to the equivalent passages in the '254 Patent
[155] See Opening – T1/p73/19 – p76/18

153. Edwards takes a rather convoluted point concerning the precise construction of a 'sac': they say that it must comprise at least two layers of material, both of which must be situated on the exterior of the anchor.

154. It is common ground that the word "sac" is not a term of art and is not intended to have any special meaning[156]. Again, Edwards turn to the Shorter OED definition for assistance[157]. However, the only assistance that can be derived from that definition is that a sac is a "cavity" i.e. a space which can be filled.

155. Edwards puts forward a strained construction of the term 'sac' in an attempt to get a non-infringement argument up and running. The cavity disposed around the outside of the frame of the S3 is formed on one side by the outer skirt and, on the other, by the inner skirt, which is sutured to the frame (as explained at §10 PPD). The diagram at X1, which was referred to during opening, illustrates Edwards' construction point. On their construction, only a device in which the inner and outer skirt are configured as set out in Diagram D infringes (the configuration shown in Diagram B would also infringe, subject to the distal/proximal point discussed above).

156. However, there is no technical difference between configuration D and configuration C and no reason why the skilled person would understand the patentee to be limiting himself to configuration D. That is particularly so when one considers Figs. 27 & 28 of the '766 Patent. Whilst primarily illustrating the concept of bunching, those figures would also be understood as illustrating a cavity disposed about the exterior of the anchor which could be filled with blood to form a seal between the exterior of the anchor and the native anatomy. The cavity in those figures is bounded by the outer skirt (outside the anchor) and the inner skirt (within the anchor). The skilled person would recognise that Fig. 28 could be made into a 'sac' simply by introducing openings of the type illustrated in e.g. Figs. 16A and 16B, in which case the Fig. 28 embodiment would fill up with ambient blood to form a seal. There is

[156] Buller 1, §107;
[157] §165 Edwards' Skeleton

no reason why the skilled person would think that if such openings were introduced into Fig. 28, there would nevertheless not be a 'sac' within the meaning of the '766 claims simply because one part of that cavity was defined by an inner skirt.

157. Edwards rely upon the evidence of Dr Buller that the description of the sacs set out in the '766 Patent is limiting. In particular, with respect to Fig. 16, he states that the Skilled Cardiologist would understand that the '766 Patent teaches sacs with both an 'inner' and an 'outer' layer both of which are situated on the outside of the anchor [158].

158. This proposed construction is based on a misreading of the '766 Patent. The teaching of the '766 Patent is general and does not require the sacs to have two discrete layers nor does it require that both layers be situated on the outside of the anchor. Any arrangement that results in a sac disposed about the exterior of the anchor will do. It is the purpose of the sac that is important: it should be capable of being filled with material e.g. ambient blood and thereby create a seal around the outside of the device. Although not strictly a matter for expert evidence, in XX it was clear that Dr Buller understood the purpose of the sac:

"...if your purpose with these things is for them to essentially inflate and fill gaps between the anchor and the wall, it would 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. This is a structure that is designed to potentially fill gaps between anchor and walls, so you put it between the anchor and the wall"

[T5/p792/9-16]

159. Adopting a purposive construction, it is clear that it doesn't matter where the inner membrane of the sac is located, provided that the construction

[158] Buller 1, §§118-119; §211

of the sac is such that the cavity that fills with blood fills with blood on the outside of the stent so as to provide a seal on the outside of the stent.

160. Dr Buller also relied on the fact that column 4 lines 44 to 45 of the '766 patent says that figure 16 "shows alternative seal designs for use with replacement heart valves and anchors", and he said that this indicated that the sacs of figure 16 have to be put on the outside of anchors. This is not a purposive point but an extremely literalistic lawyers' point. Anyway it makes no sense even in its own terms since one can perfectly well take a sac of figure 16 and install it on an anchor with one layer inside and one layer outside.

161. Finally, Dr Buller had a point in his evidence (not pursued in XX or in Edwards' opening) that for a woven anchor in combination with a fully enclosed sac (such as would be used if gel-filled) it would be necessary to have one layer inside the anchor and one outside. Since woven anchors and enclosed sacs are merely options, this goes nowhere.

162. No case was put to Prof Moore or Prof Lutter that Edwards' position makes any purposive sense.

163. One further point taken by Edwards on construction is the "Pavcnik" point [§172 Edwards' Skeleton]. It is said by Edwards that Pavcnik, which is cited at [0019] '766 Patent[159], discloses a heart valve with a sac whose walls traverse the anchor. Edwards relies upon the proposition that the skilled reader would not assume that the patentee intended to cover something old[160] to support its argument that the term "sac" has a very specific meaning in the '766 Patent. Even assuming that the Pavcnik disclosure is as Edwards' suggest, that argument can only get off the ground if the **only** difference between Pavcnik and the '766 Patent is the construction of the sac. That is plainly not the case: if it was, then undoubtedly Pavcnik (which was published over two years before the Priority Date) would have been cited as prior art

[159] C2/9
[160] See *Virgin v Premium* at §21 – JA-1/5

against the '766 Patent. Prof Lutter clearly explains a number of differences at Lutter 2 paragraphs 38 and 39[161].

The Key Claims

164. We have set out above the claims that Boston relies upon as being independently valid in the sections on the '254 and '766 Patents. Boston's position is that the S3 infringes all of the claims of the Patents. However, given the PPD and the expert evidence to date, it is anticipated that the Court can focus on the independently valid claims. Of those, and based on Edwards' case as developed in its evidence, it appears that claims 1-3, 6 and 9 of the '254 Patent and claims 1-4 and 7 of the '766 Patent are the most likely to be of importance.

Infringement

165. The S3 was launched in January 2014. Whilst its design builds upon previous Edwards' TAVI devices[162], the S3 was advertised as having a new feature: namely an *"outer skirt – a cuff of fabric surrounding the valve frame – providing a seal to address paravalvular leak"*[163]. This new feature is heavily promoted by Edwards: see e.g. Edwards' website[164]; and the Edwards' S3 brochure[165].

[161] See also Moore 2, §33
[162] Including the PVT device used by Cribier. A side-by-side photograph of the S3 and one of Edwards' previous generation of PVT devices (the Sapien) is at Lutter 1, §159, Fig. 6 (A4 version at Exhibit GL-13)
[163] See Press Release at Annex 1 to Particulars of Infringement
[164] Annex 2 to Particulars of Infringement
[165] Annex 6 to Particulars of Infringement

166. Edwards have provided a Confidential Amended PPD[166] for the S3. Extracts from Edwards' S3 training manual are at Annex 3 to the PPD and describe the positioning of the S3 *in situ*.

167. In addition, the Court has available to it:

a. the promotional materials referred to above, all of which are annexed to the Particulars of Infringement;
b. an animation on Edwards' website showing the deployment of the S3 device[167];
c. a copy of the Instructions for Use for the Edwards S3 Kit - Transfemoral[168];
d. photographs of the S3 exhibited to Prof Lutter's report[169];
e. videos of Cadaver Studies and Gasket Tests showing the behaviour of the S3 to simulated fluid flow[170];
f. a paper by Schymik et al., entitled "*How to adapt the implantation technique for the New S3 Transcatheter Heart Valve Design"*[171] which was published in the Journal of Interventional Cardiology in 2014 and which describes the S3 in use.

168. A sample of the S3 product will also be available for inspection in Court.

Infringement of the '254 Patent

169. There is no dispute between the parties that the S3 comprises all the elements that make up the pre-characterising portion of Claim 1 of the '254

[166] Confidential PPD Bundle
[167] Moore 1, §§132-133: shown during Opening at T1/pp5-11
[168] Annex 8 to Particulars of Infringement
[169] Exhibit GL-13; Lutter 1, §158
[170] Confidential Disclosure Documents on USB stick – PPD/6
[171] Exhibit GL-14

Patent[172]. The dispute relates to whether it comprises the elements that make up the characterising portions of the claims.

170. Both Prof Lutter and Prof Moore have prepared claim charts for the '254 Patent[173]. In respect of those features that Edwards have not admitted are present in the S3 device, both experts set out their reasons for concluding that the S3 device does fall within the claims. The experts' analysis in their claim charts was not challenged in XX.

171. The key dispute between the parties relates to the outer skirt of the S3 device. Boston's position is that the outer skirt fulfils the characterising features of the claims. It comprises a fabric seal which extends from the distal end of the valve proximally over the anchor in the delivery configuration. The excess of material in the skirt, permits it to bunch up in the deployed configuration so as to create fabric flaps, pockets and pleats which form a seal around the replacement valve.

172. Edwards' own materials state that the outer skirt was designed to reduce PVL[174]. The way in which the outer skirt works is described by Schymik:

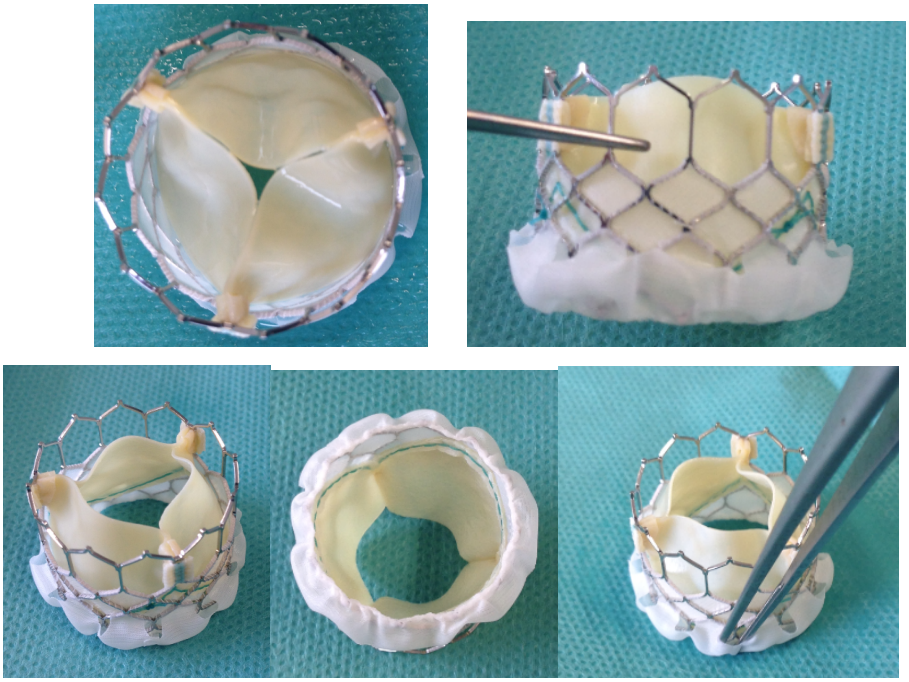
"The S3 outer skirt is another important design feature intended to fill the gaps between the prosthesis and the native anatomy, thus minimizing the risk of PVL."[175]

"Once the [S3] is properly positioned within the initial orientation of the middle balloon marker at the level of the native leaflet hinge points, the outer skirt will be located under the annulus in all valve sizes, despite the foreshortening of the lower inflow portion of the valve (Fig. 4). If there is an

[172] Edwards' Response to Notice to Admit Facts dated 28/4/16: NB since service of that document, Boston has asserted the validity of additional claims
[173] Annex A Lutter 1; Confidential Annex A Moore 1
[174] See the publicity materials and also §25 Confidential Amended PPD, which states that the outer skirt is designed to bulge radially outwards upon deployment
[175] p2, right hand column

incomplete apposition, the outer skirt can conform to the native anatomy, close the gaps, and reduce the risk of PVL"[176]

173. Prof Lutter's photographs[177] of the S3 show the excess of fabric in the outer skirt:



Looking at these pictures it is easy to see how the outer skirt provides a seal when the device is placed *in situ* in accordance with Edwards' instructions (with part of the outer skirt sitting in the annulus and part sitting just below[178]). Depending on the anatomy of the native site, the outer skirt will bunch to form fabric flaps, pockets and pleats and thereby conform to the anatomy of the native site.

174. Dr Buller's evidence is that the S3 implements a "*fundamentally different approach*"[179] to the issue of sealing than that set out in the '254 Patent (although he has conceded in his reply report that he is "*not aware to what extent the Outer Skirt functions to reduce PVL and how it precisely*

[176] p4 / right hand column
[177] Figs. 1 – 5 Lutter 1
[178] See Annex 3 PPD and Moore 1, §§141-143
[179] Buller 1, §215

behaves"[180]). It is not accepted that the S3 implements a fundamentally different approach to that set out in the '254 Patent; to the contrary. In any event, this evidence indicates that Dr Buller has adopted the wrong analysis when considering infringement. The question is not whether the alleged infringement adopts "the same approach" as any particular embodiment described in the Patent: it is whether the alleged infringement falls within the claims of the Patent and this is to be determined by comparing the alleged infringement against the features of the claims.

175. Dr Buller refers to the fact that the outer skirt is designed to bulge radially outwards and states that in its deployed condition the pleats of the S3 outer skirt are substantially in the vertical direction. This is not correct: even the photographs above indicate that the fabric forms flaps, pockets and pleats in a variety of orientations and that is where the skirt is not constrained by the native anatomy of a patient. In any event, for the reasons set out in the construction section above, the '254 Patent is not limited to horizontal pleats: any type of bunching is covered. In particular, whereas Claim 2 covers apparatus wherein the fabric seal bunches up to create fabric flaps and pockets, Claim 3 covers an apparatus wherein the fabric seal bunches up to create fabric flaps, pockets and pleats.

176. In any event, Dr Buller's analysis fails to consider the S3's behaviour *in situ*. When deployed according to Edwards' instructions, the outer skirt will conform with the native anatomy of the patient and close any gaps between that anatomy and the device and hence reduce the risk of PVL[181]. Prof Moore sets out in his report calculations as to how much of the outer skirt would be sitting at or above the annulus when positioned in accordance with Edwards' instructions. His conclusion is that most of the outer skirt will, when correctly positioned, be in contact with the native leaflets[182].

[180] Buller 2, §87
[181] See Schymik article. See also Prof Lutter's evidence at Lutter 1, §§173-174 and Prof Moore's evidence at Moore 1, §137
[182] Moore 1, §§142-143

177. All the available evidence indicates that the outer skirt of the S3 acts in the same way as the fabric seal of the '254 Patent. Whilst the precise configuration that it will adopt *in situ* will vary from patient-to-patient, it is clear that the excess of fabric enables bunching around the device *in situ* thereby creating a seal that reduces the risk of PVL (both Type 2 and Type 3).

Non-infringement points taken in Edwards' Skeleton

178. At §§198-203 of its Skeleton, Edwards takes the following points on non-infringement:

179. **No close folds:** as set out in the construction section above, the term "bunched up" does not require the fabric to be gathered into close folds. However, in any event, if, contrary to Boston's primary contention on construction, the Court were to find that the term "bunched up" did require some regularity to the fabric seal, the S3 fulfils this criterion. As shown in Fig. 11 PPD (Tab 1/p8) it has 12 crenellations, which are evenly spaced around its circumference, and which impart a degree of regularity to its 3-d shape in its expanded condition (see e.g. Fig. 16 PPD – Tab 1/p11). The skilled person would not expect that regularity to be preserved once the S3 is deployed as, the whole teaching of the Patent is, that the annulus into which it is squashed is irregular.

180. **Proximal / distal**: Edwards take two non-infringement points on this at §§199-200 Edwards' Skeleton:

181. Firstly, Edwards argue that as the top of the Outer Skirt stops short of the suture line of the leaflets, it does not extend proximally from the distal end of the valve. Boston illustrated Edwards' argument in opening[183] by reference to the schematic diagrams at X1: Boston understands Edwards' position to be that only the configurations shown in Diagrams C & D [X1/p2] meet the proximal / distal requirement of the claim.

[183] T1/p76/22-p78/14

182. Edwards' point is a bad one:

(1) Firstly, there is no requirement that the outer skirt must come up to the height of the leaflets: the wording of the claim does not require it nor is there any purposive reason for such a requirement (see construction section above);

(2) Secondly, and in any event, the construction of the S3 is such that at various points the outer skirt does in fact extend over the suture line of the leaflets. The suture line is shown in green in Figs. 7-10 [PPD/1]: as is clearest from Fig. 10 the suture line undulates up and down – as a consequence, and as can be seen on Fig. 16 [PPD/1/p11], sometimes the outer skirt is above the suture line and sometimes it is below. Unless there is to be read into the claim a requirement that the suture line must sit below the outer skirt at all points, the S3 does therefore infringe even on Edwards' construction. Alternatively, this illustrates the absurdity of Edwards' argument on construction: what purposive basis is there for saying that only devices in which the outer skirt is always above the suture line (as opposed to only sometimes) infringe?

183. Secondly, Edwards argue at §200 that "bunched up" does not simply mean "gathered in some way" or there being an "excess of fabric" because, if that were the case, there would be bunching up in the delivery configuration as well as in the deployed configuration. This argument proceeds on the assumption that "bunched up" is the opposite of "extending" i.e. Edwards read "extending" as meaning "not bunched up". However, there is no basis in the Patent for reading "extending" in this way. As we have explained, all that is meant by the phrase "extending…" is that the seal extends distally and then up and back-over (proximally) the device. It is not intended and there is no purposive reason as reading "extending" as having the opposite meaning to "bunched up".

184. In any event, it is not clear from the PPD exactly what the outer skirt looks like in the delivery configuration (Fig. 18 is the only image illustrating this – that is a CAD image and is entirely unclear). The dimensions set out in

Table 1 indicate that the frame foreshortens during deployment and footnote 10 to the table indicates that the diameter of the frame also changes. No information is given about the outer skirt height in the crimped configuration: that information would be necessary to determine the non-infringement point made by Edwards. Boston's position is that the outer skirt should bunch up on deployment: it is the stated intention that the S3 outer skirt bunches up upon deployment (§25 PPD). There is no purposive reason for assuming that the bunching up should start from a fully extended fabric.

185. **No circumferential / perpendicular folds / gathering of material**: Boston's primary contention is that there is no requirement for the bunching to occur circumferentially or perpendicular to the vertical axis of the device. However, if there were such a requirement, the S3 would meet that requirement in any event. In its expanded condition, there is a degree of bunching in the horizontal direction as shown e.g. at Figs. 15 & 16 PPD: the top surface of the bulge is equivalent to the top surface of Fig. 23 '254 Patent.

186. **Claims 2-5**: At §202 of its Skeleton Edwards refers to a photograph prepared by Boston in the German proceedings and suggests at §203 that Boston's construction loses sight of the language of the claims: it is argued that the excess material of the S3's outer skirt bulges out but does not form flaps and pockets or pleats. As set out in the construction section above, the reference to flaps, pockets and/or pleats by the 'bunching up' of the fabric simply informs the skilled person that there are a wide variety of ways in which the fabric seal can bunch up. In other words, there are a wide variety of ways of configuring the fabric to fall within claims 1-5.

187. However, if Edwards presses for a specific definition of 'flaps' 'pockets' and 'pleats' then we say that the German figure shows the way in which the S3 has these various features quite well. The upper surface of the individual bulges are flaps; the bulges themselves are pockets and the vertical segments between the bulges are pleats. Obviously, in the deployed state, the configuration of the skirt will vary depending on the pattern of calcification.

188. **Claim 13**: this claim is no longer asserted for the purposes of infringement[184].

Infringement of the '766 Patent

189. Edwards admits that the S3 comprises the first four features of claim 1 of the '766 Patent. However, it is not admitted that feature (v) i.e. "*at least one sac (200) disposed about the exterior of the anchor (30) to provide a seal"* is present. Nor is it admitted that the specific features of the other claims said to be independently valid are present in the S3[185].

190. Again, both Profs Lutter and Moore have prepared claim charts setting out their analysis of the infringement position as regards the '766 Patent[186].

191. The Orange Gasket video graphically shows just how the S3 uses the "sac" feature of the '766 patent, bulging into the gap shown, and Dr Buller accepted that it inflates "*like a parachute*" XX T5/784, 786.

192. The position on infringement of the '766 Patent can be taken relatively briefly. The key issue is whether the outer skirt forms at least one sac disposed about the exterior of the anchor to provide a seal: it is Edwards' position that the S3 does not fall within any of the claims of the '766 Patent because it does not have a "sac" as the cavity that fills with blood to form a seal between the exterior of its device and the native anatomy is bounded, on one side, by the inner cover [§206 Edwards' Skeleton].

193. It is Boston's case that the outer skirt does form at least one sac: this is apparent from a photograph of the device[187]. It does not matter for Boston's purpose whether the manner in which the outer skirt is attached to the frame

[184] Though Boston maintains its claim to independently validity: ISC/p245 & T1/p73/15-18
[185] Edwards' Response to Notice to Admit Facts dated 28/4/16: NB since service of that document, Boston has asserted the validity of additional claims
[186] Confidential Annex B to Lutter 1 and Confidential Annex B to Moore 1
[187] See e.g. photographs at GL-13

results in one continuous sac around the anchor (with a number of openings) or in a number of discrete sacs around the anchor[188].

194. The evidence of Prof Lutter is that when deployed *in situ* those parts of the outer skirt that are not compressed between the frame and the native leaflets / annulus, will inflate like a parachute and fill with blood, which will coagulate within the skirt[189], thereby forming a seal between the device and the native anatomy of the patient. Prof Moore is of a similar view[190].

195. Dr Buller's evidence is that the S3 implements *"completely different approaches to the issue of sealing"*[191]. His reasoning at §§211-214 is based upon his construction of the term "*sac disposed about the exterior of the anchor"*, which we have dealt with above. The limitations that he reads into the claims of the '766 Patent, and upon which he concludes that there is no infringement, are not supportable.

196. The construction of the S3 is such that there is a cavity that is capable of filling with blood to form a seal between the exterior of the device and the native anatomy. It therefore comprises a "*sac disposed about the exterior of the anchor"* and falls within the claims of the '766 Patent.

Validity

Bessler

197. Bessler is a US Patent that was filed in June 1996 and published on 5th January 1999. It is entitled "*Artificial Heart Valve and Method and Device for Implanting the Same"*. It teaches a replacement heart valve device for percutaneous and transluminal implantation.

[188] See e.g. claims 7 and 9
[189] Lutter 1, §173.2 & §174
[190] Moore 1, §138
[191] Buller 1, §210

198. The Bessler heart valve is illustrated in Fig. 4. The accompanying teaching is at column 5 / 28-43. As set out there, the Bessler heart valve comprises:

a. a stent member (made of wire formed in a closed zig-zag configuration);
b. a valve member (which is flexible and includes a plurality of leaflets); and
c. a cuff portion, which extends from the periphery of the leaflet portion and is sutured to the stent. The cuff is described as being "*upstanding*" (column 3 / 57). Prof Lutter reads this as indicating that the cuff is stiff and straight[192]. Claim 1 of Bessler refers to the cuff portion as being *"configured to position the valve snugly and sealingly at a valve site"*[193].

199. In addition to teaching the Bessler heart valve, Bessler also teaches *"methods and devices for the percutaneous and transluminal removal of the diseased or defective heart valve*"[194]. For example, Figs. 8-11 illustrate a device for the percutaneous and transluminal removal of a diseased or defective heart valve and the description teaches that the device will be used for *"cutting or grinding away the defective heart valve*"[195]. Bessler clearly contemplates that the Bessler heart valve will only be implanted once the diseased or defective heart valve has been removed[196]. Surprisingly, and incoherently, Dr Buller and Prof Fisher took the line that the removal of the native valve would make no material difference to the sealing task for the prosthesis. This makes no sense and is the opposite of the way that the case was put to Prof Moore.

200. The evidence of Prof Lutter is that the cuff would serve two purposes: firstly, provide something to which to attach the replacement leaflets and

[192] Lutter 1, §106
[193] column 9 / 27-28
[194] column 4 / 26-30
[195] column 6 / 37-38 & 53-54; and see also column 7 / 21-25
[196] column 8 / 33-50

secondly, to prevent leakage through the frame (i.e. Type 2 leakage)[197]. Both Profs Lutter and Moore agree that the cuff on Bessler would not prevent Type 3 leakage, only Type 2[198].

201. It was only in Edwards' experts' reply evidence that it was suggested that Bessler teaches a cuff with an excess of material so as to trap blood[199]. Boston does not agree that Bessler does teach such a cuff: there is no explicit teaching to this effect (indeed the teaching that there is points the other way), and nor is it apparent from the diagrams. We say, it is telling that this point was only raised in reply evidence. Given the teaching of the '254 Patent, if Bessler did indeed teach a cuff that was capable of forming a seal with the native anatomy due to an excess of material, it is surprising that neither of Edwards' experts pointed this out in their first report.

Cribier

202. Cribier is an International Patent Application that was filed on 31st December 1997 and published in July 1998. It is entitled "*Valve Prosthesis for Implantation in Body Channels*". One of its inventors is Dr Alain Cribier, the same Dr Cribier that performed the first TAVI procedure on a human patient in April 2002.

203. Cribier is a substantial document, comprising 40 pages of text and 18 diagrams. It has numerous aims and objective and, as Dr Buller agreed in XX, there were various teachings within it with which the Skilled Team would be interested e.g. helical valve, two-balloon catheter etc. Dr Buller described Cribier as having a: *"wealth of teaching in it and there are many, many ideas"*[200].

[197] Lutter 1, §107
[198] Moore 1, §84; Lutter 1, §§107-108
[199] Buller 2, §§63-64; Fisher 2, §21
[200] T5/p677/24 – p678/20

204. As described in the Abstract, the focus in Cribier is on providing a valve prosthesis for use in aortic stenosis with a structure that is capable of resisting the powerful recoil force and to withstand the forceful balloon inflation performed to deploy the valve and embed it in the aortic annulus. Cribier describes a prosthesis in which a supple valvular structure is supported by a strong frame[201].

205. At p20/26, Cribier teaches that: "*the valvular structure of the invention…includes advantageously a third part, i.e. the internal cover 19 to be fixed on the internal wall of the frame 10. This internal cover prevents any passage of blood through the spaces between the bars 11 of the frame in case the implantable valve would be positioned with the fastening line of the valvular structure on the frame not exactly on the remains of the dilated aortic valve i.e. either above or below".*

206. Figs. 6(a)-(c) illustrate the internal cover. Cribier describes the purpose of the internal cover as follows:

"The internal cover makes a sort of "sleeve" below the fastening of the valvular structure on the internal surface of the frame, covering the spaces between the frame bars of the frame at this level, thus preventing any regurgitation of blood through these spaces" [202]

207. Cribier then goes on to state that:

"The internal cover can also have another function, i.e, it can be used to fasten the valvular structure inside the frame, as described below.
At Figure 6d, the internal cover 19 is extended at its lower end 19' to an external cover 19" which is rolled up to be applied on the external wall of the stent 10. The internal and external cover are molded, glued or soldered to the bars of the stent 10.

[201] p13 / 5
[202] p22/17-20

The coupling process of the valvular structure on the frame is of importance since it has to be very strong without any risk of detachment of the valvular structure from the frame during millions of heart beats with pulsatile blood flow alternatively opening and closing the valvular structure"[203]

208. Prof Lutter's view is that Cribier was concerned with minimising Type 2 leakage by use of the cover shown in Figs. 6(a)-(d)[204]. Prof Moore is of a similar view and sets out in some detail his understanding of Cribier's teaching and objectives[205]. In particular, he explains that, from a bioengineering perspective, the Fig. 6(d) embodiment would be preferable as it would provide the necessary cover to guard against Type 2 leakage whilst also ensuring that the valvular structure was firmly attached[206].

Thornton

209. Thornton is a US Patent filed on 23rd December 1996 and published on 18th January 2000. It is entitled "*Endolumenal stent-graft with leak-resistant seal"*. Thornton is not concerned with heart valves. Instead it teaches an abdominal aortic aneurysm (or "AAA") device.

210. Prof Moore explains the purpose and general design of AAAs at §§89-96 of his first report[207]:

a. An AAA is an enlargement of the aorta in the abdominal section of the body. As the diameter of the aorta increases, the wall of the aorta becomes thinner, increasing the stress applied to it. Eventually, the aorta wall may burst, typically leading to the death of the patient within a few minutes.

[203] p22/21-30
[204] Lutter 1, §116
[205] Moore 1, §§50-67
[206] Moore 1, §§68-76
[207] See also Lutter 1, §§124-132

b. From 1991 onwards, self-expanding stents were used to create endografts that replaced the function of the aorta in the region of the AAA. Endografts were essentially stents covered with graft material (either on the internal or external surface of the stent). Endografts were designed to provide a route through which blood could pass without exerting pressure on the thinned wall of the aneurysm. In addition, in the event that the aneurysm did burst, the graft material was designed to clot the blood and prevent the patient from bleeding out.

c. The secure anchoring and sealing of an endograft is important. A secure anchor is necessary to ensure that the endograft does not migrate. A good seal is needed to ensure that blood flows through the stent, as opposed to around it (in which case pressure will continue to be exerted against the aneurysm sac).

211. Thornton is concerned with teaching an implantable medical device which provides an *"artificial conduit for flow through the endolumenal body space"*[208]. It teaches a seal member which *"is secured to the outer surface and is adapted to occlude leakage flow externally around the tubular wall between the outer surface and the endolumenal wall when the tubular member is deployed within the endolumenal body space"*[209]. Its teaching is primarily directed towards treatment of AAAs[210]. As explored with Dr Buller in XX[211], there are numerous differences between endografts and TAVI devices:

(a) They treat different conditions: aortic stenosis (narrowing) v aneurysm (expansion);

(b) They are implanted in different parts of the anatomy;

(c) They are very different sizes and shape;

(d) There is no valve in an endograft;

(e) The pressure gradients experienced are different[212];

[208] Summary of Invention – column 3 / 57-58
[209] column 4 / 6-10
[210] although the standard boilerplate wording that it could be used for other applications is included
[211] T4/p633/12 - p640/15
[212] see Moore D1/12/p3

(f) The importance of sealing is different: whereas leakage into an aneurysm sac is potentially catastrophic, in TAVI a good clinical result was still obtained even where there was PVL;

(g) In AAA treatment, an endograft implantation is an alternative to surgery: at the priority date, TAVI was for patients who were not suitable candidates for surgery.

212. Two possible sealing methods are disclosed: the first is described as an "*occlusive cuff that forms a flange as a one-way valve over the conduit tubing member's outer surface"*; the second is a seal member that is "*over the outside surface of the stent graft"*[213]. These methods are further described by reference to Figs. 1 and 2 at column 7 / 20 – column 8 / 7 and at column 8 / 8-31. The document is clear that wrinkles are bad and may lead to leakage, but that the occlusive cuff solution addresses this problem. See figure 3 and the narrative at columns 9 and 10. This requires an occlusive cuff *without wrinkles*.

213. Prof Moore's opinion is that both solutions are problematic[214]. He explains his reasoning further, by reference to the forces in play, at §§7-17 of his third report.

Seguin

214. The last piece of prior art relied upon by Edwards is Seguin. Seguin is an International Patent Application filed in October 2001 and published in May 2002. It is entitled "*Tubular support for setting, by percutaneous route, a substitution cusp"*. It contains a number of different ideas[215] and is directed at providing a support (or stent) for positioning a replacement valve by a percutaneous route. That support is not cylindrical but has distinct sections, each of which has a different shape and size[216].

[213] column 4 / 33-34
[214] Moore 1; §§100-104: see also Lutter 1 at §§136-140
[215] Lutter 1, §146
[216] See e.g. Figs 1 and 2; Moore 1, §118

215. One of the objects of the Seguin invention is to: *"provide a support allowing complete sealing of the replacement valve, even in case of a remaining cardiac annulus having a more or less irregular and/or a more or less calcified surface"*[217]. At p6 / final two paragraphs, Seguin sets out his teaching as regards sealing means. Further teaching is given by reference to Figs. 17-21 at p11/ 5th paragraph – p12 / 2nd paragraph[218]. The various methods are as follows:

(a) use of a compressible band of material affixed to a peripheral strip[219]: Prof Lutter's view is that this is not a practical suggestion given the width of compressible band which would be required around the diameter of the device to form a reasonable seal[220]. Prof Moore also has concerns about the delivery size of such a device[221];

(b) use of loose fluid or semi solid: this requires a material to be applied using a cannula between the annulus and the strip, most probably once the device is in position (although the teaching on this is not clear). The material congeals after injection. Prof Lutter's view is that this is a far-fetched and probably impossible suggestion[222]. Prof Moore similarly has major concerns regarding this embodiment[223];

(c) use of an attached chamber: a peripheral strip 8 is attached to the peripheral strip 6 and defines a chamber which, in cross-section in the inflated state, has two widened ends protruding on either side of the strip 6. The teaching of the embodiment is unclear for various reasons explained by Prof Lutter[224] and Prof Moore[225];

(d) use of an unattached chamber: the strip 6 receives an inflatable insert 8 with a diabolo-shaped cross-section in the inflated state, insert 8 can be

[217] p2, 5th paragraph
[218] see also p10 / 2nd paragraph
[219] the peripheral strip is itself included in the median portion of the device – p8 / final paragraph
[220] Lutter 1, §152.1
[221] Moore 1, §124.1
[222] Lutter 1, §152.2
[223] Moore 1, §124.2
[224] Lutter 1, §§152.3-152.4
[225] Moore 1, §§124.3-124.4

inflated using a catheter. Again, there are various ambiguities about the teaching of this embodiment and potential impracticalities with the suggestion[226].

216. In all of the sealing means taught by Seguin, element '8' is attached to strip '6'. Strip '6' is a continuous ring that encircles the anchor: it is not part of the anchor itself. Figs. 3 & 4 of Seguin illustrate how elements '6' and '8' combine with the anchor (elements '3' and '4') in both the deployed and crimped configurations. Both Dr Buller and Prof Fisher were taken to Figs. 3 & 4 during XX. Dr Buller's evidence was that use of element '6' was "*a very bad idea"*: and "*not ... a feasible idea*"[227]:

"No, I think this ring is a very bad idea. This flower arrangement, this solid ring around and crimping it down, I do not take it as being either a realistic or a very clever teaching"[228]

"I still think it is bad. I would not implement the band. I think this band and collapsing it into a flower shape is a bad idea. You would not get a good profile. I personally do not think it is very realistic and I would not do it"[229]

217. Dr Buller also agreed that some of Seguin's proposed sealing arrangements would not work e.g. Fig 18 was a bad idea because the glue could go to the head and cause a stroke[230]. At best, Fig 20 was "*not an impossible idea"*[231]. The band '6' in Fig. 19 was *"a very bad idea"* consequently Dr Buller *"was not very interested in its lower shoulder"*, which is the element against which Seguin teaches housing the peripheral strip '8'[232]. In XX Dr Buller suggested that if the Skilled Team chose to pursue Fig. 19, it would drop feature '6' and use a blow-up chamber on the outside of a more

[226] Lutter 1, §§152.5-152.7; Moore 1, §124.5
[227] T5/751/15
[228] T5/p750/18-21
[229] T5/p751/4-8:
[230] T5/p753/25-p754/14
[231] T5/p754/15-24
[232] T5/p755/10-20

conventional stent[233]. None of these design changes were suggested in Dr Buller's written reports and there is no evidence as to how the Skilled Team would have implemented them.

218. Prof Fisher was of a similar view: he did not consider that Fig. 4 was feasibly demonstrated in Seguin and further work would have to be done[234]. His evidence was that the various sealing means shown in Figs. 17-21 were *"concepts and needed further engineering design work"*[235].

Novelty

Novelty: the law

219. The test for novelty was set out by Lord Hoffmann in *H Lundbeck A/S v Generics (UK) Ltd* [2008] RPC 19 at §9:

"In order to anticipate a patent, the prior art must disclose the claimed invention and (together with common general knowledge) enable the ordinary skilled person to perform it"

220. The Court of Appeal provided a helpful summary of the test in *Ferag v Muller Martini* [2007] EWCA Civ 15 at §§4-12. In particular, the Court of Appeal stressed that there are two parts to the test: to anticipate the prior art must both disclose the invention and enable it. Disclosure requires that the prior art "*contain clear and unmistakeable directions to do what the patentee claims to have invented*". To be an enabling disclosure, the prior art has to provide enough information to enable the skilled person to make or do that which is covered by the claim.

[233] T5/p758/7-25
[234] T5/p843/22-24
[235] T5/p845/18

Novelty of '254 over Bessler

221. In its Response to Edwards' Notice to Admit[236], Boston made various admissions as to the disclosure of Bessler. However, as is apparent, Bessler does not give clear and unmistakeable directions to produce a heart valve that falls within the claims of the '254 Patent. In particular, there is no teaching of a fabric seal that is designed to bunch and thereby prevent Type 3 PVL[237].

Novelty of '254 over Cribier

222. Again, in its Response to Edwards' Notice to Admit, Boston made various admissions as to the disclosure of Cribier. However, the teaching of Cribier does not materially differ from that of Bessler and Cribier does not give clear and unmistakeable directions to produce a heart valve that falls within the claims of the '254 Patent. Cribier teaches a tight or taut cover to prevent Type 2 leakage. It does not teach a fabric seal that is designed to bunch and thereby prevent Type 3 PVL[238].

223. There was a suggestion during XX of Prof Moore that if a relatively stiff membrane was used in implementing Fig. 6(d) then "seep gaps" between the stent and adjacent tissue (as illustrated in Fig. 13 '766 Patent (same as Fig. 11 '254 Patent) might lead on recoil and foreshortening to there being an excess of material. Prof Moore's response was that such an outcome was not certain[239]:

"A: It is going to be a fairly complex 3D structure and with two very different materials joined to each other and you are saying that the outcome is going to be this, as an absolute, and that is the only possible outcome and I just say

[236] B/19
[237] See Lutter 1, §§108-109; Moore 1,§§82-84
[238] Lutter 1,§118;Moore 1, §§76-77
[239] T3/p318/7-p320/17

that there is more to the design process. There might be multiple possible outcomes and you have proposed one, and you are asking me to say that that is the only possible outcome?
Q: I am asking you to agree with me that that is an outcome of the condition that I am just describing
A: One of the many possible outcomes"

And at T3/p321/9-13:

""Again, that is one, perhaps one possible outcome of this design process, which is not what is taught in the patent. So, it is the same issue. There are probably multiple ways of approaching that design problem and multiple outcomes and one of them might be what you say"

224. Even if there was excess material, in diastole the pressure gradient / resultant forces would not be such as to push that excess material into the seep gap – T3/p322/14 – p323/25 (in particular p323/20-25):

"It is a fairly complex biomechanical problem. If the seep gap has a clear passageway to the aortic site then its pressure is going to be close to that of the pressure in the aorta, which would be about the same as the pressure on the inside of the stent and the cover and there would be essentially no pressure difference across there to push the thing outward"

225. If there was a pressure difference, and excess material, it was possible that the cover could be pushed out "*but again that is not what is taught in this patent"* – T3/p325/2-6. If this is pursued as part of an anticipation attack it is hopeless.

226. Dr Buller agreed that there were many factors affecting whether there would be a significant bulging out of the outer skirt, even if figure 6d were used: XX 5/704-706, did not maintain that any bulging would necessarily be significant, and accepted that Cribier contained no teaching to use such bulging for achieving a seal. On this evidence, too, anticipation is hopeless.

Novelty of claims 1, 2, 6, 7 & 17 of '766 over Seguin

227. The evidence of Edwards' own experts is fatal to the anticipation case. Prof Moore's evidence of the technical difficulties the Skilled Engineer would face if he tried to put Seguin into effect were not even challenged[240]. Therefore, and as set out above, the teaching of Seguin is far from clear and unambiguous. Nor is it enabling. It is therefore not novelty destroying[241].

228. In addition, Seguin does not teach the use of sacs on the exterior of a cylindrical anchor that are adapted to be filled with ambient blood upon implantation. Therefore even if, which is denied, it teaches claim 1 of the '766 Patent, it certainly does not anticipate claims 2, 3 or 4 or their dependent claims[242].

Novelty of '766 over Cribier

229. Cribier does not disclose the use of sacs or sacs that fill with blood. It therefore does not anticipate the '766 Patent[243]. This is in addition to the points on '254 above, which mean that there is no anticipating disclosure of any sort of material bulging of any kind, let alone sacs.

[240] See D1/§§113-127, in particular §125: *"Given the lack of clarity in Seguin, I do not consider that the average skilled team would have been able to construct a practical, working prototype of a transcatheter aortic heart valve described in Seguin, without making significant modifications"*
[241] Moore 1, §126; Lutter 1, §153
[242] Lutter 1, §153; Moore 1, §127
[243] Moore 1, §78; Lutter 1, §118

Novelty of '766 over Bessler

230. Again, the teaching of Bessler does not depart from Cribier in any material respect. The same reasoning applies: Bessler does not anticipate the '766 Patent[244].

Obviousness

Obviousness: the law

231. The Court will be familiar with the *Windsurfing / Pozzoli* approach to obviousness:

(1)(a) identify the notional "person skilled in the art"
(1)(b) identify the relevant common general knowledge of that person;
(2) Identify the inventive concept of the claim in question or if that cannot readily be done construe it
(3) Identify what, if any, differences exist between the matter cited as forming part of the 'state of the art' and the inventive concept of the claim or the claim as construed
(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

232. When considering a piece of prior art, the skilled person must read and consider it as a whole: it is impermissible to focus on a particular passage out of context (*Novartis v Focus* [2016] EWCA Civ 1295 at §§89-92).

[244] The allegation of invalidity of the '766 Patent in light of Bessler was a late amendment made by Edwards: accordingly Profs Lutter and Moore did not deal with it in either of their reports.

233. Whilst the skilled person is taken to read the cited prior art with interest, it is legitimate to consider whether a particular piece of prior art would have come to the attention of the skilled person in the first place, as that might inform the Court as to whether it would be obvious to move from that piece of prior art to the patented invention. As Laddie J put it in *Inhale v Quadrant* [2002] RPC 21 at §47:

"A fiction in patent law is that the notional uninventive skilled man in the art is deemed to have read and assimilated any piece of prior art pleaded by the party attacking the patent claim. If the invention is obvious to that person in the light of a particular piece of prior art, the claim is invalid. It is no answer to say that in real life the prior art would never have come to the attention of a worker in the field, for example because it was tucked away on the top shelf of a public library or because it was in a language which nobody in the art knew. The notional skilled person is assumed to have read and understood the contents of the prior art. However that does not mean that all prior art will be considered equally interesting. The notional skilled person is assumed to be interested in the field of technology covered by the patent in suit, but he is not assumed to know or suspect in advance of reading it that any particular piece of prior art has the answer to a problem he faces or is relevant to it. He comes to the prior art without any preconceptions and, in particular, without any expectation that it offers him a solution to any problem he has in mind. Some pieces of prior art will be much more interesting than others. A document directed at solving the particular problem at issue will be seized upon by the skilled addressee. Its very contents may suggest that it is a worthwhile starting point for further development. But the same may not be the case where a document comes, say, from a distant and unrelated field. For example, in theory a notional skilled person engaged in trying to improve the operation of an internal combustion engine is assumed to know, have read and assimilated the contents of all published material including those, say, in the baking field. It may be that a document in the latter field discloses something which, if applied to the internal combustion art, would produce a marked improvement in performance. However, the person skilled in the art is not deemed to read the baking document in the knowledge, or even with a suspicion, that it is of

significance to the problems he has to deal with. It may be that it is written in such a way that, although he understands it, the skilled person will dismiss it as irrelevant to his work. The more distant a prior art document is from the field of technology covered by the patent, the greater the chance that an intelligent but uninventive person skilled in the art will fail to make the jump to the solution found by the patentee."

234. Similarly, whilst the skilled person will read a piece of prior art "with interest", the Court recognises that, having read the prior art, the skilled person will discard it on the basis that it is not of interest to the skilled person (*Vernacare v Environmental Pulp Products* [2012] EWPCC 41).

Obviousness of '254 over Bessler

235. The key difference between Bessler and the claims of the '254 Patent is that Bessler does not teach the use of a bunched up seal on the exterior of the valve device to prevent PVL. The question is whether, viewed without hindsight, it would have been obvious to the Skilled Team to move from the Bessler device to the inventive concept at the Priority Date. Boston's position is that the answer is clearly no:

(a) There was no motivation at the Priority Date to take the Bessler device as a starting point and seek to improve it. TAVI was at a very early stage of development and the few reported cases showed promising results. There was no indication that the Bessler device would not work equally well;

(b) The Skilled Team would recognise that one purpose of the cuff in Bessler was to prevent leakage through the bars of the device (i.e. PVL Type 2 leakage). As it was not CGK at the Priority Date that PVL Type 3 leakage was a problem, the Skilled Team would see no need to try and improve upon the seal already provided;

(c) In addition, the Skilled Team reading Bessler would see that Bessler teaches ablation of the native valve[245]. The Bessler device is not intended to interact with an irregular surface[246]. Therefore, even if the Skilled Team was aware of the problem of PVL Type 3 leakage, it would consider that problem to be solved in the light of Bessler by employing ablation techniques;

(d) The Skilled Team would be anxious to avoid adding material which would add to the diameter and delivery profile of the device when crimped[247].

236. Neither Prof Lutter nor Prof Moore considers the inventive concept of the '254 Patent to be obvious in the light of Bessler. Dr Buller's analysis is based upon Cribier, which we deal with next[248]. Prof Fisher assumes that the Skilled Team would want to enhance the space filling properties of the Bessler device[249]: it appears that he may have overlooked the fact that Bessler is designed to interact with a clean site.

Edwards' case on Bessler

237. It is difficult to see why Edwards persist with Bessler: the argument put to Moore depended upon ignoring the key teaching of Bessler and supplementing the basic teaching of a heart valve with knowledge about the Cribier device. On that basis, Bessler does not get Edwards any further than Cribier and is a worse starting point.

238. In XX, both Dr Buller and Prof Fisher were questioned about what they considered the key point of difference was between Bessler and Cribier: both indicated that they relied upon the specific teaching in Bessler that the

[245] Lutter 1, §108
[246] Moore 1, §82
[247] Lutter 1, §121: see also §77.3
[248] Buller 1, §162
[249] Fisher 1, §92

outer cover would act as a seal[250]. That teaching is found only in the language of claim 1: *"wherein the cuff portion is configured to position the valve snugly and sealingly at a valve site"*.

239. As set out above, Bessler teaches:

(i) a heart valve for percutaneous implantation – the Bessler valve differs from that in Cribier as it is mounted on a self-expanding stent and would therefore apply less radial force generally[251]; and

(ii) a method and device for the percutaneous and transluminal removal of the diseased or defective heart valve.

240. Although Bessler contemplates that the Bessler valve will only be implanted once the defective valve is removed, Edwards XX of Prof Moore sought to establish that the Skilled Engineer would dismiss the teaching concerning ablation of the native leaflets for two reasons:

a. no such device existed at the priority date[252]: although this is a factor that might be expected to make this part of Bessler's teaching more, not less, interesting to the Skilled Engineer;
b. the Skilled Engineer knew from his CGK that Cribier had carried out a TAVI without ablation[253]: in which case, why not just jump straight to Cribier?

241. If the Skilled Team were interested in solving PVL, an obvious drawback of Bessler is that it teaches a self-expander and that might not be strong enough to push the native leaflets out of the way[254]. It is no answer to say that the Skilled Team would use a balloon, as the design of the Bessler

[250] T5/p734/12-22 (Buller) and T5/p837/5-11 (Fisher)
[251] T5/p746/15-22
[252] T2/p235/3-p257/10
[253] T2/p257/23 – p258/13
[254] T2/p257/14 – p259/4 & T2/p261/14-15

stent might not be appropriate for use with a balloon: it was, after all, specifically designed for use with an SES[255].

242. Prof Moore's evidence was that the Skilled Engineer would appreciate that the purpose of the cuff was to prevent leakage through the wireframe (Type 2)[256]. There was discussion about whether or not the cuff was shown to be taut but (i) it clearly is, (ii) loose baggy material would be bad for the delivery profile, and (iii) Prof Moore's answers were convincing[257], see, in particular T2/p277/9-18:

"Okay, so as shown in figure 1 the cover is taut and it is being pulled on by other parts of the stent structure, so it is clearly not forming a straight line between the valleys of the stent, for example, at approximately the point shown by the number 22 in figure 1, that part of the cuff is displaced axially from actually the very bottom of the stent. Again, another indication that the cuff is taut around the stent. So, if you were to make an ink pad stamp, as you propose, I suspect that you would not see any sort of connection between the valleys at all"

243. Prof Moore's evidence was that if the cuff were attached to the frame in the fully-expanded state, this would not mean that cuff would be loose: endografts were made without covers of both pericardium and PTFE without being loose in the deployed configuration[258].

244. Prof Moore was questioned about the effect of blood pressure around the Bessler device during diastole. Prof Moore explained that the only pressure gradient is across the valve, creating a force in the axial direction. There is therefore no pressure gradient / radial force that would push the cover outwards[259]. Even if there was, it unlikely that it would be sufficiently great

[255] T2/p262/5 – p263/8 & T2/p265/15-p266/2 & p266/16-18; & T2/p267/7-8
[256] T2/p268/4-7
[257] T2/p272 / 12 – p277/18. See also T2/p279/10-20 for a possible technical reason for choosing a taut cuff
[258] T2/p285/4 – p288/9
[259] T2/p292/7 – p294/11

and/or that the elasticity of the material would be sufficient to allow the fabric to be pushed out to a significant degree[260].

245. The obviousness case on Bessler should fail. In light of the CGK about Cribier and assuming that the Skilled Team focussed on avoiding the problem of PVL, then Bessler's teaching to ablate the native leaflets would be of obvious interest. Rather than ignore the ablation teaching, the skilled team would focus upon it as an alternative way to avoid PVL. It is of note that the post Priority Date literature explored in XX did demonstrate that at least one school of thought for avoiding PVL: the other school of thought was oversizing / re-dilation which is akin to the suggestion in Cribier that you want a stent with a strong radial force.

Obviousness of '254 over Cribier

246. It is not obvious to move from Cribier to the '254 invention[261]. There would be no motivation to do so, and Edwards' case proceeds in numerous steps driven only by hindsight.

247. Edwards' experts suggested that it would be obvious to replace the taut cover of Cribier figure 6d with an excess of material[262]. However, it became apparent in XX that their reasoning had been infected with hindsight. Whilst both suggested in their reports that they provided their opinions on the prior art (save for Seguin which was introduced later) before seeing the Boston patents, neither came to Cribier in ignorance of the issues in this case.

248. This was most striking in the case of Dr Buller. He attended a training course on TAVI at the New York Presbyterian Hospital / Columbia Medical Centre in the Summer 2013. That course was sponsored by Edwards and overseen by the team of clinicians involved in the Partner trials. Just three months before that course, in March 2013, the Généreux paper was published

[260] T2/p294/12 – p295/22
[261] Lutter 1, §121; Moore 1, §77

which commented on the controversial results of the May 2012 Kodali paper. Authors of both of these papers were at New York Presbyterian Hospital / Columbia Medical Centre. Dr Buller's evidence was that various TAVI devices were looked at on the course, including those of competitor products. His evidence was also that the Kodali findings were discussed at that time. Given the table of devices shown in the Généreux paper, which included the Lotus and the S3, and given the teaching in the Généreux paper that new designs of TAVI device could overcome the problems of PVL, it would be astonishing if Dr Buller had not been taught on the course about the S3 and its advantages over the Sapien XT in terms of overcoming the problem of PVL.

249. Prof Fisher's evidence was that he had browsed the websites of TAVI device manufacturers after being instructed in this case in early 2016. He had also read literature in the TAVI field since being instructed[263]. It is very likely that he would have come across the S3, and probably the Lotus as well, and seen that one of the S3's advertised new features was an outer skirt designed to reduce PVL.

Edwards' Case on Cribier

250. Edwards' case on obviousness in light of Cribier depends upon[264]:

(1) The Skilled Team focussing on the teaching relating to sealing to the exclusion of all the other interesting ideas: this requires them to identify PVL as a particular problem, despite the CGK that Cribier had implanted a TAVI and obtained a good clinical outcome even with mild / moderate PVL;
(2) The Skilled Team focussing on Fig. 6(d) despite the fact that Fig. 6(b) gives the best solution from a delivery profile perspective;
(3) Ignoring the fact that Cribier did not, in fact, use an external cover in 2002/03;

[263] T5/pp814-815: Edwards' website entry for S3 is at B/8
[264] T5/p720/15-730/21

(4) Taking numerous steps from figure 6(d) to move to a baggy cover which would create circumferential folds on foreshortening. The steps include: realising the cover would be baggy, making it more baggy, appreciating that it could be used to seal, preserving the foreshortening taught despite the art moving away from it, deciding positively to exploit the foreshortening, using different materials for the inner and outer skirts, and attaching the outer skirt loosely and more loosely than the inner skirt.

251. The XX of Buller highlighted the insuperable difficulties with the obviousness attack based on Cribier:

(1) The Skilled Team would have had Cribier's actual work in mind when it read the Cribier patent at the Priority Date[265];
(2) The focus on sealing would therefore require the Skilled Team to identify PVL as a particular problem requiring solution, despite the reports at the time that good clinical outcomes were obtained[266];
(3) The Skilled Team would have persisted in pursuing different sealing means despite the teaching in Cribier that taught the concept of oversizing (in the sense that the better the valve is attached to the wall, the less leakage)[267];
(4) The Skilled Team would have selected the Fig. 6(d) cover in the hope that it would be an improvement over an internal cover alone, despite Cribier containing no teaching to the effect that an external cover provided an additional layer of protection against leakage[268].

252. Fatally, the obviousness attack based on Cribier entirely ignores what Dr Cribier, the inventor, did himself. He was aware of what his own patent said yet he did not choose to solve the PVL problem by adopting the external

[265] T5/p673/21-23
[266] T5/p678/24-p679/11
[267] T5/p684/17-25
[268] T5/p686/§10-25

cover. Despite his continued involvement with Edwards, it was not until the 5th iteration of the device that the outer skirt was introduced[269].

PVT	Cribier-Edwards	Sapien
		
Sapien XT	**Sapien 3**	
		

253. If Edwards / Cribier had the idea to use an outer skirt, there was no technical reason why they couldn't implement that idea. Buller's evidence in XX that profile size was a limiting factor was wholly unconvicing, especially given the reductions in size between the various iterations of the Cribier-Edwards / Sapien devices[270].

254. An obviousness case was put to Prof Moore on the basis that the skilled engineer is told that one of the design criteria presented is to design a device that minimises PVL: on that assumption, the engineer immediately appreciates that implementing Cribier with an external cover with an excess of

[269] Edwards acquired PVT in 2004 [DXX/4/p127 – *"The input of Edwards Lifesciences"; T4/p580/18-p581/13*] and Cribier remained associated with Edwards throughout this time [T4/p570/21-p571/18 & DXX/4 which identifies Cribier as a consultant for Edwards in 2014]

[270] T4/p631/16 & see CX-GL/14 where 23mm device reduced in diameter from 22F to 16F: Dr Buller's re-examination on this point was unconvincing given that even the largest device of the Sapien XT (29mm device, which was a new introduction in that generation) had a diameter of 4F less than the largest Edwards Sapien: on any view there was 4F of diameter to play with. There was no suggestion that an outer skirt could not be accommodated given that extra space.

relatively stiff membrane in the deployed configuration enhances its space-filling properties and prevents leakage [T3/330/22 – p332/13].

255. Prof Moore's response was that this would require changes to Cribier that were not taught and, even then, the design criteria may not be met:

"so that sounds like a different design problem…and process than what Cribier has described, and it actually would not be automatic or a determined outcome as you seem to think that there would be excess material that would fill gaps in the way that is needed. That would be then I would think a new idea and a new process to design something that would do that, because it would not be a given, a guaranteed outcome of some excess material"[271]

256. Essentially, it would require a new design process:

"…that will increase the delivery profile so we have to think about the trade-offs between the different design criteria, which is why it is not a simple process, so then the design challenge, which is very different from what Cribier says, would be to design something that ends up being that way in its deployed configuration. That is, as I said, complete different from what Cribier does"[272]

257. Prof Lutter was not challenged on Cribier.

258. Neither of Edwards' experts disputed that choosing figure 6d would increase the delivery profile, or that Cribier placed a lot of emphasis on that design characteristic. It will be recalled that it was a characteristic on which Dr Buller had placed particular emphasis in his first report, paragraph 91.

259. Their only response was that this was a "trade off". That will not do: Cribier emphasises, and the skilled person, would emphasise, delivery profile. They would not emphasise sealing particularly, since the real life device

[271] T3/p332/14-22
[272] T3/p333/4-11]

sealed well and since there is no teaching in Cribier that the sealing of, for example, figure 6b would be lacking. There is, further, no teaching that figure 6d has any particular sealing benefit, let alone one that could be increased by making it baggy so as to have an even worse delivery profile. So the "trade off" is between something that was taught as important and something that was not taught at all. That cannot be the approach of the ordinary skilled person.

260. The stepwise *Technograph* approach to get from figure 6d (even if that were a legitimate and obvious starting point) to the invention of the '254 patent was very obvious on the face of the report of Prof Fisher and of Dr Buller, but especially the former. He set the steps out over several pages starting from paragraph 61 of his first report, and the XX showed the many unsupported steps which it involved: XX 5/827-835.

Obviousness of '254 over Thornton

261. There are multiple differences between Thornton and the claims of the '254 Patent.

262. Firstly, Thornton describes an AAA device. Whilst the Skilled Clinician may have had a basic knowledge of AAAs and stent-grafts for treating them, Prof Lutter's evidence is that treatment of AAAs was generally reserved for vascular surgeons[273]. Thornton is therefore a piece of prior art that would have been, at best, on the periphery of the Skilled Team's technical field. As such, whilst the Skilled Team would have read Thornton with interest, they would not necessarily have appreciated that it had anything useful to teach them about percutaneous prosthetic heart valves[274]. It should be noted that whilst Prof Lutter had some knowledge of AAA devices, he did not consider any of them when designing his TAVI devices: he did not consider that there were any particular design features that would be of assistance in the

[273] Lutter 1, §124
[274] See also Moore 1, §97

design of TAVI devices[275]. Prof Moore's evidence is that the sealing solutions described in Thornton provide a quite different function to that of the seal in the '254 Patent: AAA devices also do not have to contend with leaflets or the adverse axial pressure gradient found across the aortic valve[276].

263. Secondly, Thornton describes two types of seal. The first is a flange, which appears to be made from a stiff material. It is not obvious that such a device would assist with sealing a heart valve and thereby preventing Type 3 leakage[277]. The second is a hydrophilic gel or polymer foam. Whilst that might be more likely to provide good apposition between the valve and the location site, it would be unlikely to prevent Type 3 leakage[278]. In any event, it would not be clear how to deliver such a device[279]. Prof Moore's evidence is that both types of seal would have taken up a lot of space and therefore compromised delivery profile: Thornton simply does not provide the Skilled Team with the motivation to explore this route with the obvious difficulties that they would then encounter[280].

264. Adaptation of the Thornton device to create a replacement heart valve would require significant modification. Even if the Skilled Team were interested in doing so (which is not accepted), it would not be obvious how to do so[281]. In particular, given that folds in the graft material of AAAs were considered to be disadvantageous, even if the Skilled Team did attempt to adapt Thornton, the introduction of folds and bunches would not come to mind: to the contrary, in light of the teaching in Thornton that wrinkles could provide leakage paths, it would be counterintuitive[282].

[275] Lutter 1, §133
[276] Moore 1, §105; Moore 3, §§7-17
[277] Lutter 1, §138; Moore 1, §§101-102
[278] Lutter 1, §140
[279] Lutter 1, §140; Moore 1, §104
[280] Moore 1, §100
[281] Lutter 1, §143; Moore 1,
[282] Moore 1, §§106-107

Edwards' case on Thornton

265. Edwards' case as put to Moore on Thornton requires the Skilled Team to do the following:

(a) Identify that the "tubular member-seal member" is of utility in the field of endografts: for the reasons given in the CGK section above, this would not be done – any issues concerned with wrinkling of the cover of an endograft would be addressed in the design / manufacturing process;

(b) Identify that the "tubular member-seal member" is of utility outside the field of endografts: Prof Lutter's evidence was that he did not consider any AAA devices when designing his own TAVI devices or consider them to include any helpful features[283]. This evidence was challenged in XX on two bases:

- first, that he was not seeking to design a device that implanted within the diseased leaflets – even if this was the case, which Prof Lutter did not accept, it was not shown to have any impact on the design criteria[284];
- second, that there were various references in the TAVI literature to endografts – this did not get Edwards anywhere. Boston does not dispute that people working in TAVI recognised that stents had potential application in TAVI[285]: obviously they did – an anchor was required on which to mount the valve – the question is whether the Skilled Team thought they could derive any further assistance from endografts. We say no. There was certainly no evidence that the Skilled Team would seek out pieces of prior art, such as Thornton, and seek to implement an aspect of its teaching;

(c) Recognise that one field of utility is a THV device: this requires two steps:

[283] D1/9/§33
[284] T4/p470/10-p475/15
[285] see e.g. D2/6/p4 – *"stents are used extensively in many cardiovascular applications…"*

- Firstly, drawing a parallel between Type 1 endoleaks and Type 3 PVL, despite the fact that there are numerous significant differences between AAA treatment and TAVI [see §211 above];
- Secondly, and despite the fact that Thornton teaches that Type 1 endoleaks are caused by wrinkling of the fabric outer cover of endografts when implanted using oversizing [column 10/ 13-24] and that those wrinkles are *bad*, nevertheless choosing to apply an outer fabric inspired (it is said) by Thornton, which wrinkles: the somersaults involved in this step of the reasoning alone indicate that the obviousness case from Thornton simply does not work;

(d) Choose to take the Fig. 1 embodiment (i.e. a flange / one-way valve) as opposed to the Fig. 2 embodiment (an expandable ring of hydrophilic polymer or gel-foam);

(e) Choose to adopt the option wherein the geometry is imparted by flow in the occluded direction (as opposed to relaxed geometry of the flange);

(f) Choose to adopt the Thornton teaching that a thin ePTFE tape can be used with one end bonded to the outer surface and the other end left free to form the unadhered flange [Figs. 19A & 20A embodiment];

(g) Recognise that Thornton had been implemented in the Gore Excluder [and was therefore a workable device – contrary to the evidence of Moore and Lutter];

(h) Take the seal, invert it, and add it to a THV.

266. Edwards' obviousness case is critically dependent on establishing that Thornton's seal member is of real interest to the Skilled Team. However, the fatal flaw in Edwards' argument is that the Thornton device would simply not work. Prof Moore was unshakeable on this in his XX.

267. As mentioned during opening, a similar obviousness case was attempted in *Abbott v Evysio* [2008] EWHC 800 (Ch): the Court cautioned against an approach that takes part of the CGK and mosaics them out of

context [§180 JA-2/20]. At §194, Kitchin J, as he then was, commented that an attack that proceeded on the basis of modifying a CGK stent in light of a prior publication of another stent design was "*rather unusual"* and, whilst in principle it could succeed, it had to be established on the evidence. Here, Edwards have simply failed to establish the case on the evidence. Note also that Kitchin J rejected the attack because the purportedly obvious mosaic had not happened in reality (and so in the present case).

268. The case was only put to Moore, despite Prof Lutter having dealt with Thornton at §§122-143 of his first report[286] and §§59-62 of his second report[287]. Prof Lutter's opinion was that even if, which he doubted, the Skilled Team would have been interested in Thornton or found anything useful in it, they would not have thought it obvious to modify the device so as to come up with the inventions of either the '254 or the '766 Patents. Prof Lutter specifically dealt with Dr Buller's suggestion as to how the Thornton flange could be incorporated onto a TAVI device at §61 of his second report where he stated that:

"I do not consider this a minor or obvious modification"

That evidence was not challenged.

269. Prof Moore was XX'd at length on Thornton but his opinion of what the Skilled Engineer would make of its teaching remained consistent throughout: in short, the Fig. 1 embodiment would not work: in particular, if the teaching to use thin walled ePTFE was adopted:

- The Skilled Engineer would not find the proposal to use thin-walled ePTFE tape useful: he would recognise that such a seal would be smashed between the endograft and vessel wall: it would not flare out[288];

[286] D1/1
[287] D1/10
[288] T2/p210/3-9 & p212/24-p213/3

- The only way the seal would form the shape of a flange when deployed in a vessel would be if it had sufficient structural rigidity to push the endograft away from the vessel wall: it would have to be stronger than the endograft plus the blood pressure applied to the inner wall of endograft[289];
- Proof Moore would have disregarded the teaching as something "*just not very realistic or functional*"[290];
- Even on the assumption, with which Prof Moore disagreed, that there is a lack of conformity between the endograft and vessel where there is calcification of the landing area[291], Prof Moore did not consider that ePTFE tape would flare:
    - Where conformity, tape flattened between wall and endograft;
    - Where non-conformity, tape would not fill with blood and flare out for multiple reasons:
        - Tape had fixed circumference at both attached and free ends: free end of tape would not stretch to a sufficient degree to fill the space between endograft and lumen[292];
        - Tape is pinned at two points because it is pinned to the wall at healthy lumen – this constrains its ability to stretch to fill gap[293].

270. Even on the assumption, which Prof Moore also disagreed with, that the Skilled Engineer would understand the sealing cuff to serve a useful purpose in sealing against flow of blood around the endograft his view was that *"it is just not going to work"*[294].

271. Even on the basis of a third assumption that was put to Prof Moore, namely that the Skilled Engineer is told by the Skilled Clinician that one of the design criteria is to minimise PVL between implanted device and calcified

[289] T2/p214/23 – p215/4
[290] T2/p215/24 – p216/9
[291] T2/p221/15 – p222/3
[292] T2/p224/2-12 and T2/p227/9-18
[293] T2/p224/13-23 and T2/p229/19 – p230/9
[294] T2/p231/7-p232/10

leaflets (i.e. Type 3 leakage), Prof Moore's evidence was that the Skilled Engineer would not think that the PTFE tape / cuff would be a good idea:

"*The skilled engineer would not have thought this to be useful at all*"[295]

"*Because it is not useful*"[296]

272. Even if the Skilled Engineer recognised that ePTFE would not increase the delivery profile of the device to an unacceptable degree, he would only include it if satisfied that it would serve a useful purpose:

"Anything you put on the device is going to increase the delivery profile, not just by its geometry but also the crimpability. Everything that you put on there has to serve a really good purpose or there is no reason to put it on"[297]

273. The final assumption put to Prof Moore was that the Skilled Engineer would assume that ePTFE did have a benefit because it would serve a useful purpose in reducing PVL around the device[298]. It's not clear how this line of questioning can possibly assist Edwards. In any event, Prof Moore's answers were consistent with his previous evidence:

"even if this one person that you have hypothesized thinks that it might be of benefit, the others are going to say, "No, that is not going to work""[299]

274. Edwards' counsel indicated in XX that Edwards would criticise Prof Moore for not taking on board the assumptions put to him[300]. Such criticism would be unfair. Prof Moore was assisting the Court with the thinking of the

[295] T2/p235/2-3
[296] T2/p236/10
[297] T2/p241/23 – p242/2; see also T2/p242/12-14; T2/p242/23-24; T2/p243/5
[298] T2/p243/6-14 & see also T2/p246/4-22
[299] T2/p243/18-21; see also: T2/p244/23 – p245/4 & T2/p247/10 – p248/9
[300] T2/p250/9-18]

Skilled Engineer at the time – even if the skilled clinician showed him Thornton and said that part of the design brief was to minimise PVL, the skilled engineer would nonetheless dismiss Thornton because it did not provide a practical solution:

"Well, I am a very practical person and in my engineering world I do not take on design propositions that have no physical basis and that I know are not going to work. That is what I am having trouble with: starting with that assumption and then continuing on to some other things that, to me, are not going to matter"[301]

275. Boston's position is that the obviousness case on Thornton fails. Prof Moore's evidence was convincing and Prof Lutter was not challenged at all. In contrast, Dr Buller's evidence was unconvincing. His understanding of Thornton's teaching was based on his assumption of the mechanism of operation of the Gore Excluder[302]: a product with which he had no first-hand experience and for which there was no evidence as to its construction or mechanism of action. The drawings that he created during XX to illustrate his understanding of how Thornton worked were not based on the teaching of Thornton itself[303]. Critically, he had no explanation for the direct inconsistency of using a wrinkly cuff to cure the problem of a wrinkly cover.

276. As for Prof Fisher, he agreed with Dr Buller's analysis of how Thornton would work: he had nothing significant to add[304].

Obviousness of '766 over Bessler

277. The difference between Bessler and the claims of the '766 Patent is the absence of sacs around the exterior of the device as a seal. For the same reasons that it is not obvious to go from Bessler to the invention of the '254

[301] T2/p250/19-24
[302] T5/p667/5-13
[303] See T5/p760-p767/19
[304] T5/p838/22-p842

Patent, it is equally unobvious to move to the invention of the '766 Patent, but in addition, neither Edwards witness explained or could explain where there was a sac in what they proposed to do with Bessler (since there would be only one layer of material), and nothing was put to Prof Moore to get to a sac. A sac intended to bulge out from backflow blood pressure so as to seal would be even harder to reach.

Obviousness of '766 over Cribier

278. Again, for the reasons it is not obvious to move from Cribier to the '254 invention, it is similarly not obvious to move from Cribier to the '766 invention[305].

Obviousness of '766 over Thornton

279. As with the '254 Patent, there are multiple differences between Thornton and the claims of the '766 Patent. As a consequence, it is simply not obvious to move from Thornton to the '766 Patent invention. Particular problems would include: (i) the impractical nature of the increase in delivery profile; (ii) the foam cuff would take up some of the cross-sectional area through which the blood would flow; (iii) it wouldn't be clear where to place the flange or occlusive cuff given the risk of obstructing the coronary ostia[306].

Obviousness of '766 over Seguin

280. Given the way that Seguin was put during XX: only Prof Lutter was questioned on it and only in the most cursory way[307]; and given also the way that Edwards' own witnesses responded to Seguin in XX, there is no credible

[305] Lutter 1, §121; Moore 1, §78
[306] Moore 1, §§109-112
[307] T4/p532/3-p534/23

case left on obviousness over Seguin. For completeness, Boston reiterates the points made in opening:

281. The Skilled Team would have real difficulty if it decided to try and put Seguin into effect and/or to modify it. That is because the teaching in Seguin is lacking in clarity and raises more questions than it answers[308]. We submit that this is one of those pieces of prior art whereby the Skilled Team, having read it with interest (as the law requires one to assume), would decide they were not interested in taking it further: rather than providing an obvious starting point, it simply poses a research project. However, even assuming the Skilled Team did try to put progress Seguin by putting one of the embodiments discussed in Seguin into effect, there is no reason why the Skilled Team would chose to focus on developing a seal in accordance with any of Figs. 17 – 21. Seguin's primary teaching is a particular design of stent which comprises distinct sections with different shapes and sizes and which is designed to anchor the device better against the ventricle wall. The Skilled Team might chose to focus their attention on developing one of these stents and see whether the new design did indeed improve performance over known stents. Indeed, given that Seguin teaches that the primary object of the invention is to provide a stent that is more likely to remain in position[309], this seems the most likely course of research that the Skilled Team would adopt assuming it decided to do anything with Seguin at all. Even if the Skilled Team did chose to focus on the teaching regarding seals, there is no reason why it would consider adapting the Seguin teaching so as to incorporate sacs that would fill with blood *in situ*[310].

[308] Lutter 1; §153; Moore 1, §126
[309] See page 2, 3rd paragraph; page 2, 8th paragraph – page 3, 1st paragraph
[310] Moore 1, §127

Insufficiency

Insufficiency: the law

282. By section 72(1)(c) Patents Act 1977 a patent may be revoked if *"the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art*". Kitchin J (as he then was) set out the general principles underlying the requirement of sufficiency in *Eli Lilly v Human Genome Sciences* [2009] RPC 29 at §239:

(i) the first step is to identify the invention and that is to be done by reading and construing the claims;
(ii) in the case of a product claim that means making or otherwise obtaining the product;
(iii) …
(iv) sufficiency of the disclosure must be assessed on the basis of the specification as a whole including the description and the claims;
(v) the disclosure is aimed at the skilled person who may use his common general knowledge to supplement the information contained in the specification;
(vi) the specification must be sufficient to allow the invention to be performed over the whole scope of the claim;
(vii) the specification must be sufficient to allow the invention to be so performed without undue burden.

Alleged insufficiency of '254 and '766 Patents

283. The insufficiency argument in this case has been introduced at a late stage: it first appeared in the Re-Re-Re-Re-Amended Grounds of Invalidity,

which were served on 13th December 2016[311]. It is quite clear that the insufficiency argument is raised by way of squeeze (see §§2A & 7 of the Re-Re-Re-Re-Amended Grounds of Invalidity). The wording of the insufficiency plea is based upon paragraph 121 of Prof Lutter's first report, in which he says in support of his view that it would not be obvious to move from Cribier to either of the Patents that: *"people working on these devices would be anxious to avoid any material which would add to the diameter and delivery profile of the device when crimped"*.

284. The attempted squeeze is hopeless for the following reasons:

(1) Firstly, the Patents specifically tell the Skilled Team to use a fabric seal and/or sacs exposed around the exterior of the device. The Skilled Team is given clear and unambiguous directions to do this: consequently, any anxiety that the Skilled Team may have, falls away;

(2) Secondly, the Patents specifically explain to the Skilled Team why the fabric seal and/or sacs are desirable, namely to reduce the risk of Type 3 leakage (see Fig. 11 & [0056] '254 Patent; Fig. 13 & [0064] '766 Patent). Therefore, even if the Skilled Team had some anxiety, said anxiety would be alleviated as they would know there was good reason for the patentee's teaching;

(3) Thirdly, at no point has it been suggested by Edwards or its experts that the teaching of either the '254 or '766 Patents is insufficient: once the idea to use the fabric seal or sacs has been given, the Skilled Team has no difficulty in putting that idea into effect.

[311] B/13

Added matter

Added matter: the law

285. Section 72(1)(d) permits the Court to revoke a patent on the ground that the matter disclosed in the specification of the patent extends beyond that disclosed in the application for the patent, as filed. To determine whether there has been added matter, the Court must:

(a) "*ascertain through the eyes of the skilled addressee what is disclosed, both explicitly and implicitly in the application;*
(b) do the same in respect of the patent as granted;
(c) compare the two disclosures and decide whether any subject matter relevant to the invention has been added whether by deletion or addition.

The comparison is strict in the sense that subject matter will be added unless such matter is clearly and unambiguously disclosed in the application either explicitly or implicitly"[312]

286. Further guidance was given by Kitchin J in *European Central Bank v Document Security Systems Inc* [2007] EWHC 600 (Pat) at §§97-101.

287. Edwards' pleading of the added matter attack[313] proceeds on the erroneous assumption that unless the claims reproduce all the elements of the specific embodiments taught in the description they will add matter. That is not the law. To the contrary, it is perfectly permissible to use more general wording in the claims and thereby capture embodiments that do not map precisely onto the specific embodiments taught within the scope of the monopoly provided that, in doing so, no new information about the invention

[312] per Aldous J, *Bonzel v Intervention Ltd*
[313] See in particular §§ 3(1)-(5) & 8(1)-(5)

is disclosed. This was made clear by Floyd LJ in *AP Racing v Alcon Components* [2014] EWCA Civ 40 at §§29-33[314]:

"29 Is the patent nevertheless bad for added matter because it claims a wider class of asymmetric PSBs than are disclosed in the application? The judge thought it did because it claimed all asymmetric PSBs and not just hockey stick shaped ones. Whether he was right depends on an analysis of the extent to which it is legitimate to add features to a claim which describe the invention in more general terms than a specific embodiment.

30 There is no doubt that the claims of the patent form part of the disclosure for the purposes of assessing whether there is added matter. However the claims perform a different function from the disclosure in the body of the specification. The primary function of the claims is to delimit the area of the patentee's monopoly. Thus in Texas Iron Works Inc's Patent [2000] R.P.C. 207 the patentee had disclosed "slips and cones" which acted as hanger units in an oil well hanger. In the granted patent the patentee coined the phrase "liner hanger unit" to define his monopoly, although the phrase was apt to cover units other than slips and cones. Aldous LJ. (with whom Simon Brown and Mantell LJJ. agreed) said this at p.245:

> *" ... the purpose of the claims in a patent is the identification of the ambit of the protection and disclosures are normally a matter for the specification. The application before the amendment clearly and ambiguously disclosed slips and cones which acted as hanger units. The amendment did not alter that disclosure. By using the phrase "liner hanger unit" in the claim the patentee did not disclose any other construction of liner hanger: the term was used to widen the ambit of the monopoly."*

31 In AC. Edwards Ltd v Acme Signs & Displays Ltd [1992] R.P.C. 131 it was argued that three features of a claim of the granted patent were stated in more general terms than the disclosure of the specific embodiment. Thus, for

[314] And see also Birss J at §173 *Hospira v Genentech* [2014] EWHC 3857 (Pat)

example, the application disclosed the use of a coil spring and cotter arrangement as a retaining means, but the relevant added feature simply specified a "spring means". Fox LJ. (with whom Staughton LJ. and Sir Michael Kerr agreed) concluded that this did not add matter. Fox LJ. said:

> *" ... claims, as a source of disclosure, have no greater force than the other admissible documents ... Mr Whittle is, I think, correct when he says that the claim* covers *those matters because the patentee chose to limit its claim by reference to features other than the three in question. In practical terms I do not think there is anything very surprising about that result since the purpose of the claims is the identification of the ambit of protection. Disclosures are normally a matter for the specification. One looks, no doubt, at the whole of the issued patent specification in determining what it discloses, but even so, I find no disclosure in claim 1."*

32 In Decision T 0653/03, Toyota Jidosha KK, 8 April 2005 (unreported) , the Technical Board of Appeal of the European Patent Office concluded that the replacement of the term "diesel engine" by the term "combustion engine" in a claim to a method of purifying exhaust gas constituted added matter. The Board concluded that the disclosure of the granted patent would be understood to mean that the method of the invention was suitable for any type of engine, not merely diesel engines, and that such a teaching could not be derived from the application as filed.

33 It is clear from these decisions that the law does not prohibit the addition of claim features which state in more general terms that which is described in the specification. What the law prohibits is the disclosure of new information about the invention. In the Toyota case there was such a disclosure of new information, namely the new information that the invention was suitable for engines other than diesel engines. However in Texas Iron Works and A. C. Edwards the specification and claims when read together did not disclose any new technical information, despite the generalisation involved in the added claim feature."

288. Therefore whilst intermediate generalisation is not permissible, it is permissible to generalise out from the specific embodiments described and thereby produce a monopoly that is wider than the specific embodiments provided that such generalisation does not add matter. Kitchin LJ explained the point in *Nokia Corporation v IPCom* [2012] EWCA Civ 567:

"56 Turning to intermediate generalisation, this occurs when a feature is taken from a specific embodiment, stripped of its context and then introduced into the claim in circumstances where it would not be apparent to the skilled person that it has any general applicability to the invention.

57 Particular care must be taken when a claim is restricted to some but not all of the features of a preferred embodiment, as the TBA explained in decision T 0025/03 at point 3.3:

> *"According to the established case law of the boards of appeal, if a claim is restricted to a preferred embodiment, it is normally not admissible under Art.123(2) EPC to extract isolated features from a set of features which have originally been disclosed in combination for that embodiment. Such kind of amendment would only be justified in the absence of any clearly recognisable functional or structural relationship among said features (see e.g. T 1067/97, point 2.1.3)."*

58 So also, in decision T 0284/94, Neopost/Thermal Printing Mechanism [2000] E.P.O.R. 24, the TBA explained at points 2.1.3–2.1.5 that a careful examination is necessary to establish whether the incorporation into a claim of isolated technical features, having a literal basis of disclosure but in a specific technical context, results in a combination of technical features which is clearly derivable from the application as filed, and the technical function of which contributes to the solution of a recognisable problem. Moreover, it must be clear beyond doubt that the subject matter of the amended claim provides a complete solution to a technical problem unambiguously recognisable from the application.

59 It follows that it is not permissible to introduce into a claim a feature taken from a specific embodiment unless the skilled person would understand that the other features of the embodiment are not necessary to carry out the claimed invention. Put another way, it must be apparent to the skilled person that the selected feature is generally applicable to the claimed invention absent the other features of that embodiment.

60 Ultimately the key question is once again whether the amendment presents the skilled person with new information about the invention which is not directly and unambiguously apparent from the original disclosure. If it does then the amendment is not permissible."

289. In the extract above Kitchin LJ refers to case law of the EPO. The approach of the EPO is similar to that of the UK courts. As explained in T 1644/11 JOHNSON CONTROLS / Battery, where a technical feature has originally been described only in combination with other features, it is nevertheless admissible to claim that technical feature separately, provided that it is apparent to the skilled person that the isolated technical feature on its own enables the object of the invention to be achieved.

Allegation of added matter against '254 Patent

290. §3 Re-Re-Re-Re-Amended Particulars of Invalidity sets out two added matter attacks against the claims of the '254 Patent. The first is an intermediate generalisation attack, made against all of the claims. The second is a specific added matter attack made against claim 6 only.

Intermediate Generalisation

291. The attack here is that the claims of the '254 Patent combine features of the embodiments described in the Fig 32-34 Embodiment and the Fig 107

Embodiment where the significance of those features have not been disclosed in the Application and would not have been apparent to the Skilled Team.

292. A similar attack has been made at the EPO. However, despite the EPO being notoriously strict when it comes to added matter attacks, the Opposition Division has indicated that the majority of this attack should fail and only one element is, on a preliminary view, arguable.

293. Given the Preliminary Opinion of the EPO, we will focus here on the only point that the EPO indicated might have any merit. That point related to the omission of the feature "anchor foreshortens" from claims 1-8 which, it was indicated, was an impermissible intermediate generalisation because the Application taught a clear functional relationship between the anchor foreshortening and the seal bunching up. In fact, the EPO was wrong to conclude that there was such a clear functional relationship disclosed in the Application:

a. The description of Figs. 32-34 at p34 / 26-31 does not require a causal relationship between the bunching up of the fabric seal and the anchor foreshortening: all that it requires is that *"when deployed…fabric seal bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets"*. The later description of Figs. 32-34 (at p86/22-32) is a more specific description of the manner in which the fabric seal may bunch up when it is being used in conjunction with the Fig 107 apparatus. But that more specific description does not detract from the earlier general teaching.
b. Given the object of the invention is to provide a seal, the Skilled Team would recognise that it is the bunching up to create fabric flaps and pockets that enables the object of the invention to be achieved. The manner in which that bunching occurs is neither here nor there. Indeed, the patentee goes on to teach at p34 / 30-31 that the bunching could occur "*particularly when the pockets are filled with blood in response to backflow blood pressure"*.

c. Active foreshortening in the claims of the Application is always claimed separately: the dependencies are such that there can be a pleated seal with or without active foreshortening (see claims 101, 103, 119, 120 and 122, 125, 139 and 140).

294. It was therefore wrong for the EPO to reach the preliminary view that it did.

295. However, if contrary to our primary position, the absence of any requirement that the anchor foreshortens during deployment in the claims does constitute an intermediate generalisation, it does not invalidate all of the claims of the Patent. That is because claim 9 is to the apparatus of any of claims 1-8 wherein "*the anchor foreshortens during deployment*". Furthermore, as the anchor of the S3 device foreshortens during deployment, infringement is still made out[315].

296. We wait to see what other, if any, points on intermediate generalisation Edwards pursues in its skeleton argument.

Claim 6 of '254 Patent

297. The attack here is that the Application nowhere discloses that the fabric seal may bunch up only in response to backflow blood pressure.

298. This attack is bad. The Application teaches that, when deployed, the fabric seal bunches up *"particularly when the pockets are filled with blood in response to backflow blood pressure"* [at p34/26-31]. The same teaching is found in the '254 Patent [at column 16 / 20-25]. Whatever "in response" means, it is clear that it means the same in both the Application and the Patent. There is therefore no basis for this added matter attack.

[315] Buller 1, §215

Allegation of added matter against '766 Patent

299. Again there are two added matter attacks against the '766 Patent. Both of these were introduced by late amendment in the Re-Re-Re-Re-Amended Particulars of Claim. The first is an intermediate generalisation attack. The second attack appears to be some form of squeeze argument based on infringement. At this stage, the relevance of the second argument is not understood. We will therefore wait to see how, if at all, Edwards develops it in its skeleton argument for trial.

300. As to the intermediate generalisation attack, this is misconceived. It is clear from p32/29 – p33/13 Application that the various arrangements described in Figs. 14 – 16 are illustrative only. They are examples of the way in which the problem of Type 3 PVL (described in the section immediately preceding this at p32/23-28 Application) can be addressed. The Skilled Team would not consider that the various features of the illustrative embodiments described in Figs. 14 – 16 did not have any general application to the invention. To the contrary, the Skilled Team would recognise that given the purpose of this aspect of the invention, the concept of the use of sacs disposed around the exterior of the anchor which were capable of being filled with ambient blood, was an entirely general one.

Conclusions

301. Both Patents are valid and infringed.

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