Neutral Citation Number: [2020] EWHC 2562 (Pat)

Case No: HP-2019-000026
HP-2019-000003

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

Royal Courts of Justice
The Rolls Building
7 Rolls Buildings
Fetter Lane
London EC4A 1NL

Date: 29/09/2020

Before :

MR JUSTICE BIRSS

- -

Between :

(1) EDWARDS LIFESCIENCES CORPORATION **(2) EDWARDS LIFESCIENCES LIMITED**	**Claimants**
- and -	
(1) MERIL GmbH **(2) MERIL LIFE SCIENCES PVT. LTD.**	**Defendants**

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Iain Purvis QC, **Piers Acland QC**, **Kathryn Pickard** and **Mitchell Beebe** (instructed by **Powell Gilbert**) for the **Claimants**
Justin Turner QC and **Tim Austen** (instructed by **Kirkland & Ellis**) for the **Defendants**

Hearing dates: 20th - 24th, 28th, 29th July 2020

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Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

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MR JUSTICE BIRSS

Covid-19 Protocol: This judgment was handed down remotely by circulation to the parties' representatives by email, release to BAILII and publication on the Courts and Tribunals Judiciary website. The date and time for hand-down is deemed to be 2pm on 29th September 2020.

Mr Justice Birss:

1. This is a patent action. The claimants are respectively the proprietor and exclusive licensee of two patents: EP (UK) 1 267 753 entitled "Minimally-invasive heart valve" and EP (UK) 3 494 929 entitled "Low profile delivery system for transcatheter heart valve". The application for 753 was filed on 5th April 2001 claiming priority from a US filing on 6th April 2000. It was granted on 19th October 2005. The application for 929 was filed on 1st May 2009, claiming priority from three US filings, the earliest of which is 9th May 2008. 929 is a divisional. It was granted on 18th December 2019. The earliest claimed priority date relied on by Edwards for 929 is the second of the claimed priority dates, 23rd July 2008.

2. The claimant companies are part of the Edwards Lifesciences group, a leading international medical device manufacturer. The patents protect an established Edwards' product family of prosthetic heart valves called SAPIEN. The SAPIEN devices are aortic valves. They are delivered for implantation into a patient by a transcatheter approach. The current catheter delivery system used for SAPIEN is called Commander, which superseded the Novaflex. This field is called TAVI (Transcatheter Aortic Valve Implantation).

3. The defendants are members of the India based Meril Life Sciences group. Meril is another manufacturer of medical devices. Meril has recently obtained CE Mark approval for a TAVI product to rival SAPIEN. The product consists of a transcatheter heart valve called MvVal, and a catheter based delivery system for Myval called the Navigator.

4. Edwards contends that Meril's Myval and Navigator infringe the patents. In relation to 929, Edwards also relies, in the alternative, on the doctrine of equivalents (***Actavis v Lilly*** [2017] UKSC 48). Meril denies infringement and counterclaims for revocation of both patents on the grounds of obviousness, insufficiency and added subject matter.

5. For 753, Meril contends that the relevant claims are obvious in the light of published application WO 98/29057 ("Cribier") which was published on 9th July 1998 when read in conjunction with US Patent 5,411,552 ("Andersen US") which was published on 2nd May 1995. Andersen US is cross-referred to and discussed in the text of Cribier. There are also allegations of insufficiency and added matter.

6. For 929, Meril contends that the relevant claims are obvious in the light of US published patent application US 2008/0065011 A1 published on 13th March 2008 ("Marchand"), published application WO 2004/039273 ("Falwell") which was published on 13th May 2004 as well as on two prior used Edwards' products called Retroflex I and Retroflex II. There is no dispute that the Retroflex products were made available to the public. Marchand clearly relates to the same essential design as the two Retroflex products and whether the differences matter remains to be seen. There is also an added matter attack against 929.

7. The 753 patent case relates to the Myval valve device itself whereas the 929 patent relates to the Navigator delivery system. There are two alternative designs of part of the Navigator for which Meril seeks declarations of non-infringement. Edwards accepts Device A does not infringe but does not accept Device B avoids infringement.

8. This trial is the first of three technical trials of patent disputes between these parties concerning Myval and Navigator. The other two have been scheduled before the summer vacation in 2021. They relate to Edwards patents known as Levi 226, Benichou 930 and Benichou 464. There was a sixth patent in issue at one stage (EP (UK) 2 736 457) but that dispute has been settled. Meril also advances a public interest defence. The trial of that issue has been scheduled for autumn 2021.

Hybrid hearing

9. Following a triage hearing a few weeks beforehand and with the court's permission, the trial was conducted as a "hybrid" hearing using an audio/video system provided privately by the parties by a company called Sparq. For most of the time, present physically in court were up to six participants from each party, the usher, two staff from Sparq and me. All the other participants, including at various stages some junior counsel, solicitors, the transcriber, witnesses, individuals from the client companies and foreign lawyers instructed by the parties, attended by video conferencing, using a secure video link provided to them individually based on a list prepared in advance. Two witnesses attended in person to be cross-examined and the other four attended by the video conference system. Some participants were physically situated in England and Wales and others were overseas, including in the USA. The four remote witnesses were all in the USA. The remote witnesses were able to watch their counterparts give evidence. In addition, a small number of identified members of the public contacted the court and asked to attend, one by video and two in person. Since the court room was full, I permitted all three of them to be sent a video link which permitted them to watch and listen but not to speak. I made clear to those watching online, in a direction given at the outset of the trial, that recording or photographing the proceedings was prohibited. There was no broadcasting or livestreaming of the proceedings to unidentified persons. No breaches of the arrangements for the hearing took place.

10. I believe what took place was appropriate for the following brief reasons. Everything that took place was carried out only with the court's permission and under the court's control. No participant was provided with a video link without specific permission. Although the number of remote participants is different, the way in which this case was conducted is not different in principle from cases which have been carried out in the intellectual property courts for a long time, well before the pandemic. For example, international video conferencing was used in the Patents Court in 1999 in *Nutrinova v Scanchem* [2001] FSR 42 with witnesses in China. There are numerous other examples. The practice is well established. As part and parcel of this the remote participants, such as witnesses and lawyers, are able to see and hear what is taking place in the court room. This is a necessary part of their participation. It has always been something which requires the court's express permission and is under the court's control. It promotes access to justice and is often necessary for a fair trial since the physical attendance by overseas participants may otherwise have been impossible.

The claims

11. For the 753 patent, Edwards alleges that the Myval product infringes claim 1. Claim 1 divided into suitable integers is in this form:

Claim 1

A A prosthetic heart valve, comprising:

B a support stent including a tubular base along an inflow end and a plurality of generally axially-extending commissure posts disposed evenly around the tubular base on an outflow end thereof,

C wherein the base is expandable from a first size adapted for minimally invasive delivery, to a second, functional size that fits within a heart valve annulus; and

D a flexible tubular member having a prosthetic section attached to the commissure posts so as to define a plurality of prosthetic valve leaflets between the posts;

characterised in that

E the tubular member further comprises a fabric section connected to the tubular base and only the fabric section contacts the tubular base.

12. By the closing of the trial, none of the dependent claims were in issue in these proceedings. While Edwards initially asserted that the Myval device infringed claims 1, 2 and 3 of the 753 patent, it narrowed its case in its closing submissions to assert that only claim 1 was infringed. In response Meril indicated that its claim for revocation could be limited to claim 1.

13. For the 929 patent, Edwards alleges that the Navigator infringes claims 1, 3, 4, 5, 6, 8, 9, 12 and 13, while also alleging that claims 1, 2, 4, 5, 7, 8, 9, 11, 12 and 13 are independently valid.

14. Claim 1 of 929, divided into suitable integers, is in this form

A A delivery system for delivering a prosthetic aortic heart valve to a patient's native aortic valve, comprising:

B a balloon catheter comprising an elongated shaft and an inflatable balloon mounted at a distal end of the elongated shaft, and

C a flex indicating device comprising:

D a guide catheter comprising a handle portion and an elongated guide tube extending distally from the handle portion,

E the elongated shaft of the balloon catheter extending coaxially through the elongated guide tube;

F at least one pull wire connected to a distal end portion of the elongated guide tube;

G wherein the handle portion comprises a flex activating member, the flex activating member being coupled to the at least one pull wire such that manual adjustment of the flex activating member causes the distal end portion of the elongated guide tube to flex;

H the flex indicating device further comprising a flex indicating member,

I wherein manual adjustment of the flex activating member causes the flex indicating member to move relative to the handle portion to indicate an amount of flex of the distal end portion of the elongated guide tube,

J wherein the flex indicating device further includes indicia indicating the amount of flex of the distal end portion of the elongated guide tube, the indicia being provided at the handle portion,

K and wherein the handle portion comprises a slot for receiving at least a portion of the flex indicating member.

15. Far too many claims were maintained as independently relevant. If I had spotted this at the PTR, I would have restricted the number drastically.

The witnesses

16. Both parties have called expert witnesses in the fields of interventional cardiology and bio-engineering.

17. Edwards' expert witness in the field of interventional cardiology was Dr Sagar Doshi. Dr Doshi is a consultant cardiologist specialising in interventional cardiology, general cardiology and TAVI at the Queen Elizabeth Hospital, Birmingham. Dr Doshi has been a consultant since 2005 and Director of the TAVI programme since 2008.

18. Meril's expert witness in the field of interventional cardiology was Prof. Stephen Brecker. Prof. Brecker is an interventional cardiologist and Chief of Cardiology at St. George's University Hospital, London. He has been a consultant cardiologist since 1996.

19. In the field of bioengineering, Edwards called a different expert for each of the two patents. For 753 Edwards called Dr Ivan Vesely. Since completion of his PhD in Biophysics in 1987, Dr Vesely has spent the majority of his professional career dedicated to the study and development of cardiac valves: initially surgical heart valves but, for the past two decades, minimally invasive heart valves, including THVs.

20. For 929 Edwards called Mr Jonathan Rourke. Mr Rourke is a mechanical engineer, with a master's degree from MIT. He has worked in the field of cardiovascular medical devices since 1991 and has worked on numerous catheter-based devices and delivery systems.

21. In terms of engineering, the expert witness called by Meril was Dr Ronald Solar for both patents. Dr Solar finished his PhD in Metallurgy and Materials Science in the 1970s and from 1977 worked for a series of medical device companies, including ARCO, American Hospital Supply (then a division of Edwards), ACS, SciMed, Medtronic and others.

22. Each side criticised at least one of their opponent's witnesses (Edwards criticised Dr Solar and Meril criticised Dr Vesely). I will deal with specific points below but I reject any wider criticism. In my judgment all the expert witnesses in this case sought to give their evidence fairly, mindful of their duties to the court and trying their best to help the court. I am grateful to each of them for their evidence.

The skilled person and the common general knowledge

23. The identification of the person skilled in the art and the common general knowledge can conveniently be done in one go. It is applicable to both patents despite their different dates and subject matter. The common general knowledge relevant to the later 929 patent consists of all the same material as is relevant to the earlier 753 patent, plus further developments in the field, which I will address at the end of this section.

24. In this case the person skilled in the art is a team comprising at least an interventional cardiologist and a biomedical engineer. The only question I have to decide is whether the team would also include a cardiac surgeon. Essentially, Meril said it would and Edwards said it would not. In fact, there is less to this point than meets the eye. The debate is a proxy for an important argument about the common general knowledge relating to surgical heart valves. The point is that surgical heart valves are put into patients by surgeons carrying out open heart surgery. They are not delivered by transcatheter techniques. Although it is a little out of sequence, it is convenient to deal with both arguments now.

25. Interventional cardiology is a branch of medicine that emerged from the 1960s onwards. Interventional cardiologists use catheters to treat problems with the heart and associated vessels percutaneously. In that sense the field itself is an alternative to the field of open heart surgery practised by cardiac surgeons and so there is an inevitable and necessary relationship between the two fields. However that does not mean every technique in one field has an analogue in the other field either generally or at any given time. There was evidence of some rivalry, which I do not doubt may have existed between some individuals. However I do not accept, if suggested, that this evidence amounts to proof of a relevant prejudice in the minds of the notional persons skilled in the art who are members of the skilled team. The evidence was way short of establishing that. From the point of view of an uninventive team of persons skilled in the art, there is a close relationship at the medical and technical level between cardiac surgery and interventional cardiology.

26. In my judgment the knowledge of surgical heart valves which would be common general knowledge to a cardiac surgeon at the relevant time (the year 2000) was part of the common general knowledge of the skilled team. Analytically I prefer to reach that conclusion by finding that the skilled team itself did not include a cardiac surgeon, but that the team (of an interventional cardiologist and biomedical engineer) would be very familiar with the work of cardiac surgeons (so they would know who

to ask), would know in general terms that they installed prosthetic valves into patients, and would wish to have a detailed understanding of the construction, utility and performance of the current surgical valves if the team was thinking about delivering a prosthetic valve by an interventional technique. The reason the surgeon would not be in the team is because such a person would not be needed if a team was put together to design a TAVI valve at the time (other than to describe surgical valves). I am sure that the skilled team in this case would, as part of the common general knowledge, make it their business to know about surgical heart valves. The various kinds of surgical valves which were part of the common general knowledge by 2000 are mentioned below.

The heart and aortic stenosis

27. Turning to the rest of the common general knowledge: it would include the anatomy of the heart and the cardiovascular system. This case is concerned with the aortic valve. That is the valve at the outlet of the left ventricle of the heart. The left ventricle is the large part of the heart which pumps oxygenated blood into the main circulatory system in the body. The somewhat smaller right ventricle pumps de-oxygenated blood returning from the main circulatory system on into the lungs. Once that blood has been oxygenated in the lungs, it enters the left atrium, then passing into the left ventricle through the mitral valve. As the left ventricle squeezes inwards to pump blood, the mitral valve closes - stopping blood flowing back into the left atrium and towards lungs, and the aortic valve opens - allowing oxygenated blood to flow round the body.

28. The previous heart valve case I dealt with this year (***Abbott v Edwards*** [2020] EWHC 514 (Pat)) was concerned with devices used to treat problems with the mitral valve whereas this case is concerned with devices used to treat problems with the aortic valve The mitral valve devices in the previous case were used to treat regurgitation (i.e. a failure to close properly) whereas the aortic valve devices in this case are primarily used to treat stenosis (i.e. a failure to open properly).

29. Aortic valve stenosis is often caused by degenerative calcification. By 2000 the most prevalent valvular heart disease in the western world was aortic valve stenosis, affecting 2% of the population over 65 with the percentage increasing with age. In 2000, the only long-term treatment for stenosis was surgical valve replacement. However a large share (about 30%-60%) of patients with severe aortic stenosis were not eligible for surgery. For these patients the prognosis was poor. Half of them would die within 2 years.

30. Further aspects of anatomy are relevant. The aortic valve consists of an annulus (or ring) and three leaflets. The leaflets meet at their edges, away from the annulus, at what are called commissures. At the annulus the passage narrows somewhat. Just past the annulus in the wall of the aorta are small coronary “ostia”. These are holes where the arteries which deliver blood to the heart itself as an organ of the body branch off from the aorta. The cardiac arteries are relatively small as compared to the aorta at that point.

Surgical valves

31. Turning to the common general knowledge of the skilled team about surgical valves: they were implanted at the aortic annulus. They were directly sutured into the patient and could be positioned on the annulus after removal of the native leaflets. The standard design comprised a stent, stent posts, fabric and an occluder. The term occluder is sometimes conveniently used in this context because "valve" can mean the whole thing or it can refer to the structure which opens and closes in particular. Occluders could be of a ball and cage type or they could consist of leaflets to act as a prosthetic version of the natural valve.

32. Among the known surgical valves were the Carpentier-Edwards PERIMOUNT, the Hancock II, the St Jude Biocor, the Ionescu-Shiley (an early design), and the Mitroflow. These were all common general knowledge.

33. The frame of the surgical valves was non-collapsible, and its function was to provide the support structure for the occluder. It was usually made from a flexible plastic, such as Delrin. Other surgical valves had frames made from metal wire, such as stainless steel, formed in a non-collapsible mesh or frame.

34. The stent posts, or commissure posts, were projecting portions used with leaflet occluders. The occluder leaflets were attached at the periphery of their commissures. The posts were flexible such that they could bend inward to absorb any stresses on the leaflets caused by haemodynamic pressure against the valve.

35. The fabric component of surgical valves was often made of polyester, specifically Dacron. It was wrapped around the frame of the valve. The fabric layer also formed a surgical cuff (or sewing ring) which could be used to suture the fabric covered frame to the patient at the aortic annulus.

36. Focussing on leaflet occluders, there were various materials from which the occluder could be made. At the priority date, valves made of biological material were popular, so in the Carpentier-Edwards PERIMOUNT, the Mitroflow and the earlier Ionescu-Shiley valves, the occluder was made from bovine pericardium leaflets. Pericardium is tissue from the heart, albeit not actually valve tissue. Other bioprosthetic valves had occluders made from different biological materials: the Hancock II contained a whole porcine aortic valve and the St Jude Biocor had porcine aortic valve leaflets.

37. An image of the Carpentier-Edwards PERIMOUNT is as follows:

[as with many images in this judgment, this is clearer in colour]

Techniques

38. One of the main interventional cardiology techniques was balloon angioplasty, including the placement of stents. This is a way of treating blockages in the coronary arteries. It is an alternative to the surgical technique of a coronary bypass graft. Another interventional technique was atherectomy which is used to remove plaque from inside arteries.

39. At the priority date the idea of trying to treat aortic valve stenosis, especially in elderly patients unsuitable for surgery, by using a prosthetic valve delivered through the vasculature via a catheter was part of the common general knowledge of the skilled team, but the skilled team also knew (at 2000) that it had not been successfully done yet.

40. The work of Dr Andersen was part of the common general knowledge. Andersen published a paper in 1992 which described his work using a prosthetic heart valve in pigs. Andersen mounted a whole porcine aortic valve with 2mm of annulus tissue into a stent made from two cylindrical wire structures, one with extending commissure posts. Although the following diagrams are taken from the Andersen US document rather than the paper, they are a fair representation of the device Andersen used which would be part of the common general knowledge:

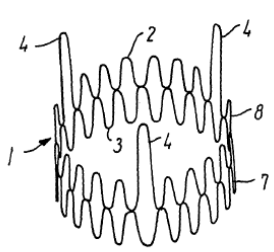


FIG.1

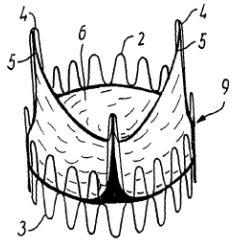


FIG.2

41. The stent with the two wire frames and commissure loops is shown in fig 1 and the whole device with the porcine valve installed is depicted in fig 2.

42. Also part of the common general knowledge as at 2000 would be that despite Andersen's work, which was considered ground breaking, nevertheless 8 years later, no transcatheter heart valve implantation procedure had taken place in a human.

43. Edwards emphasised various details of Andersen's work such as: the precise location of the implant (supra- and sub-coronary), the incidence of coronary occlusion (blockage of the coronary ostia) associated with the sub-coronary implantation leading to death of the relevant pigs, and the fact that Andersen viewed this as a possible treatment for aortic insufficiency rather than stenosis. I agree that these aspects would be part of the common general knowledge relating to 2000. However Edwards seeks to take these details too far. The most important thing about Andersen's work as a matter of the common general knowledge of the skilled team was at a more general level. Andersen had demonstrated that a prosthetic aortic valve with the same basic form as a surgical valve (in other words a stent frame with valve leaflets mounted to it) could be implanted without surgery. For the skilled team the general significance of Andersen's work was positive, not negative.

44. Meril submitted that the reaction to Andersen's work in the cardiology field was summarised in the 1994 edition of the Textbook of Interventional Cardiology by Topol. The work was one of a number of interventional cardiology textbooks available at the time. Topol has a chapter entitled Percutaneous Expandable Prosthetic Valves in which the idea of implanted catheter-based valve prostheses is discussed. The work of Andersen is summarised. The final paragraph of the chapter states:

> "The development of percutaneous techniques for treatment of cardiovascular diseases will continue to provide us with new methods of stabilizing and treating patients. It is extremely likely that one of these technologies will be percutaneously implanted heart valves. Most certainly the treatment of acute aortic insufficiency will be possible; treatment of other regurgitant lesions as well is likely. In 10 years we shall very probably look back on the pioneering work described above in the same way we respect the work of Hufnagel, Gruentzig, and Palmaz today. Certainly, heart valves will undergo radical changes in design in the decade."

45. I find that this reflected the view of the skilled team by 2000. The fact that by 2000 no human implant had been reported mitigated the enthusiasm a bit but not enough to matter. It was not a case of there having been early promise which had not borne fruit. The team regarded the concept as sound and as a potentially exciting new technique for interventional cardiology.

46. The skilled team would have appreciated in 2000 that the development of transcatheter prosthetic heart valve implants was likely to involve the marriage of two currently-available technologies: stent technology on the one hand, and surgical valve technology on the other.

47. Another technique which was part of the common general knowledge in 2000 was balloon valvuloplasty. This is an interventional cardiology technique whereby a balloon mounted on a catheter is manoeuvred to the site of the stenosed aortic valve where it is then inflated with the aim of opening the aortic valve and reducing the degree of stenosis. The technique was pioneered by Dr Cribier. Its introduction had been a phenomenon but by 2000, while it was a well-known technique, it was also known to result in rapid re-stenosis and was only used as a bridging treatment in patients waiting for surgical valve replacement or non-cardiac procedures.

Extra common general knowledge relevant to the 929 patent

48. The first successful TAVI procedure was carried out by Dr Cribier in 2002. This was a significant step, showing that patients with aortic stenosis who were unsuitable for surgery, could be successfully treated.

49. By July 2008 (the 929 priority date) two valve implants used in this field were on the market: the SAPIEN (balloon-expandable) and the CoreValve (self-expanding) devices.

50. There were two types of catheter for delivering the SAPIEN which were in public use up to the priority date: a non-steerable device for transapical delivery called Ascendra, and a steerable device for transfemoral delivery called Retroflex. There were two kinds of Retroflex (I and II) but in the end no relevant difference was identified and I will ignore the distinction. Due to the relatively large delivery profile of the Retroflex with SAPIEN, over half of SAPIEN procedures at that time were carried out via the transapical approach using Ascendra. The catheter for delivering the CoreValve is now and always was non-steerable.

51. Meril referred to a page from a CoreValve manual for details of the CoreValve delivery device at the relevant time. The device had a handle which included a slider labelled in the manual as "Macro Control (Cursor)" and a thumbwheel labelled "Micro Control (Thumb wheel)". The CoreValve implant is self-expanding. It is delivered in practice by placing it into the right position and then carefully withdrawing a sheath around the outside of the implant, allowing the cage material to spring outwards into shape inside the aorta. The sheath is controlled by a threaded rod in the handle and both the slider and the thumb wheel engage that same thread. The slider allows the operator to make large movements of the screw by riding on the thread while the thumb wheel allows fine control. As the slider rides on the thread it slides down the length of the handle. The result is that the position of the slider gives an indication of the degree to which the sheath has been pulled back at the distal end and so, says Meril, that is why it is called "cursor". I accept this CoreValve device and its mode of operation was common general knowledge. If it matters, I am not convinced the term "cursor" for the macro control slider was itself common general knowledge.

52. There was an issue about the extent of knowledge of other catheters and similar devices for probing the body. Dr Solar gave evidence about electrophysiology catheters, endoscopy devices and transoesophageal echocardiography probes. The issue is about detail. The interventional cardiologist member of the team would know of the existence and function of electrophysiology catheters in particular. They would have seen electrophysiology catheters in use by colleagues and as part of their training. However they would not know about any particular device. The interventional cardiologist would also know in general terms about the existence of the other devices (that is the endoscopy devices and transoesophageal echocardiography probes).

53. In terms of the internal mechanisms, the details of any electrophysiology catheters, endoscopy devices or transoesophageal echocardiography probes would not be common general knowledge for either the interventional cardiologist or the engineer. A team would know how to find out about the internal workings if they wanted to, but that would require a good reason to do so.

54. There was a dispute about whether some electrophysiology catheters or other devices at the time contained indicators which showed the amount of flex of the distal end of the catheter. Whether the examples relied on were truly relevant examples of that does not matter because I am not persuaded any particular device was common general knowledge, nor was it the case that these characteristics of those particular devices was itself common general knowledge.

55. The Retroflex was common general knowledge (in case it matters I include both Retroflex I and II, albeit II was introduced much closer to the priority date and only in very small numbers). In the relatively small but entirely international world of interventional cardiology the introduction of a second Retroflex device – the Retroflex II – would have been common general knowledge by the priority date.

56. Retroflex worked as follows:

    i) The distal end was steerable by adjusting a knob in the handle at the proximal end. Turning the knob on the handle clockwise increased flex. Turning the handle anticlockwise decreased flex;

    ii) Multiple revolutions were required for maximum flex;

    iii) There was a 'hard stop' which meant it was not possible to rotate the knob any further both when flexing and unflexing the device. The operator would know when turning clockwise the hard stop meant there was maximum flex, and conversely, when turning anticlockwise, that all flex had been removed.

57. The team would have been well aware of Retroflex and would have known that it was a steerable TAVI delivery system. The device they knew did not have any flexion markings on the handle.

58. There is a dispute as to whether or not the detailed designs or inner workings of the Retroflex devices would have formed part of the common general knowledge. Edwards sought to rely on the fact that the design drawings produced by Dr Solar were marked confidential. Edwards also sought to rely (i) on the fact that only a modest number of procedures using any version of Retroflex were carried out in the United Kingdom before the priority date, given the majority of the procedures with SAPIEN by that time had occurred transapically with the Ascendra rather than the Retroflex; (ii) on the fact that only a small number of interventional cardiologists in the UK would have implanted SAPIEN transfemorally using Retroflex I; and (iii) in the case of Retroflex II on the assertion that only 40 were ever used worldwide. I do not accept this means the inner workings of either device was not common general knowledge. Unlike the electrophysiology catheters, these devices were not just part of the common general knowledge as devices which happened to exist in a neighbouring field, these were key products for interventional cardiologists at the time. There was clearly a lot of excitement about the recent success of TAVI. The products were on sale. They were not confidential products. Edwards said getting them was not straightforward. Maybe not, but Edwards did not establish to my satisfaction that such a device could not be fully examined by a skilled team, including by being taken apart, if they wanted to. No doubt they cost a lot but that is irrelevant. While the legal burden of proof of invalidity is on Meril, on this point, not least because these are Edwards products, given that there is sufficient evidence from which to infer that the devices were freely available to the public, Edwards bears an evidential burden of proving they were not in fact available to be examined in full. It was not discharged.

59. I find that the inner workings of the Retroflex devices (I and II) formed part of the common general knowledge of a skilled team concerned with steerable TAVI delivery systems, in that the team would know how to find out anything they wanted to know

about the mechanisms inside and would know (correctly) that they would be able to do that if they wanted to.

60. It is common ground that the Skilled Cardiologist would know that the two main drawbacks of the Retroflex system were its (i) crossing profile and (ii) distal shape.

61. Edwards emphasised Dr Doshi's view that these drawbacks would be the focus of a skilled team's thoughts at the priority date. This issue overlaps with obviousness but it is convenient to address it now. I accept that the drawbacks were common general knowledge and the skilled team would have them in mind at the priority date. But I do not accept that this means the team would not also consider making any other improvements which might spring to mind as a matter of the application of their common general knowledge as persons skilled in the art. The fact that reducing the delivery profile of the device was an obvious thing to want to do does not mean there might not be other obvious aspects of the functioning of the device to be improved.

62. However I am not persuaded (if it was alleged) that the common general knowledge included the existence of any problem or drawback of the Retroflex devices themselves to which the inclusion of a flex indicating device of any type would be an answer. It seems that the problem of accidentally starting to withdraw the device when it was in a flexed state, which the indicator helps mitigate, was only widely appreciated in the field after the priority date. The evidence was that when a flex indicating device was first introduced (in the NovaFlex in 2010), its utility from the point of view of interventional cardiologists themselves only really became apparent through use.

The 753 patent

63. The 753 Patent is directed generally to expandable heart valves, especially for use as minimally invasive heart valves (para [0001]). At paras [0002] to [0007], the background section summarises the use of prosthetic heart valves, the basic technical features of surgical heart valves and the surgical technique. It goes on to discuss the developing field of minimally invasive surgery, which enables heart valve replacement without opening the chest but still requires the patient to go onto bypass, and gives examples of minimally invasive surgical heart valves.

64. The patent states that none of the prior art referred to discloses an optimum structure for tissue valves ([0007] ln20) and notes that one of the items of prior art (attributed to Dr Vesely) stops short of explaining how to construct the optimum valve (ln 26-27). The patent then places emphasis on the means of attaching leaflets to the stent, as follows:

> "the means of attaching the leaflets to the MIS stent is critical to ensure the integrity and durability of the valve once implanted. All the prior art MIS valves fall short in this regard.
>
> …
>
> In view of the foregoing, it is evident that an improved sewing ring that addresses the apparent deficiencies in existing expandable heart valves is necessary and desired."

65. At para [0008] the patent states that there is a need for an improved sewing ring which addresses the apparent deficiencies in existing valves.

66. At para [0009] a summary of the invention is set out, in the same terms as claim 1. Further details are referred to in the next paragraphs, including reference to a method of using the device, ending with a statement that the device can be delivered via the vasculature or by a minimally-invasive port in the patient's chest.

67. From para [0015] the document then goes on to describe the invention further by reference to the drawings and two specific embodiments. In the section introducing the two specific embodiments, the patent explains that the heart valves of the invention can be implanted in or adjacent the annulus. There was a suggestion that "adjacent" would be understood to mean immediately adjacent. I reject that. The skilled reader has no reason to read that simple teaching in such a narrow way. The passage also explains that the implants may be used in any of the four valve positions within the heart but are more likely to be used to replace the aortic valve.

68. Para [0017] includes a statement that the scope of the invention is defined solely by the claims. I doubt this statement makes any difference on any of the issues.

69. Para [0018] identifies the two specific embodiments which are depicted in Figs 1-5 and Figs 6-15 respectively. The paragraph highlights a difference between them in that the first is assembled prior to storage while for the second embodiment, the various components are stored separately and the valve is assembled just before use.

70. The description of the pre-assembled expandable heart valve starts at para [0019]. Figures 1 and 2 show it in an exploded and assembled form respectively. They are:

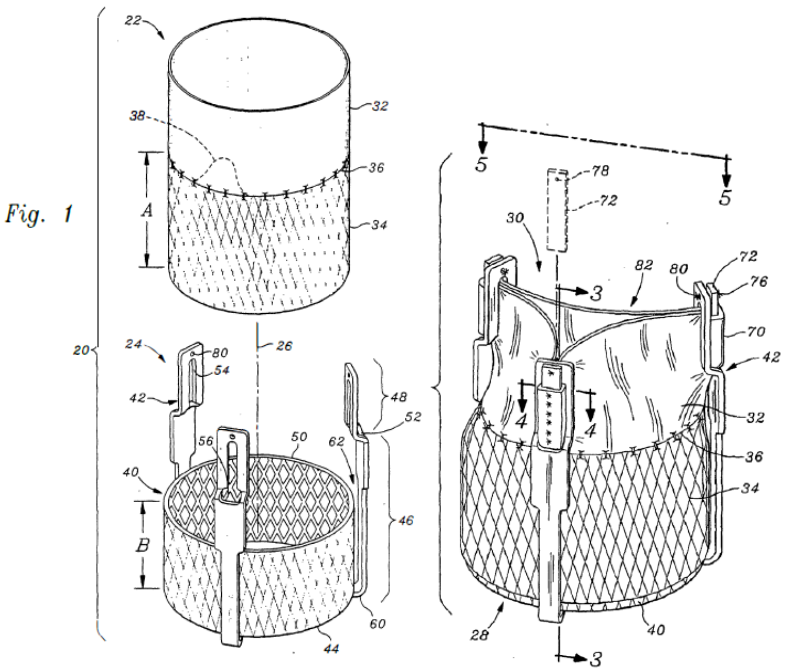


Figure 1 Figure 2

71. The key components are a support stent 24 and a tubular member 22. They are shown separated in fig 1. The support stent 24 has a tubular base 40 and three commissure posts 42. The tubular member 22 has a leaflet section 32 attached to a fabric section 34. To assemble the device the support stent and the tubular member are put together, as shown in fig 2. The tubular member fits in between the tubular base and the commissure posts. So in fig 2 at the lower half, the fabric section 34 is depicted inside the commissure posts 42. When the device is assembled this way the leaflet section is attached to the commissure posts. Also in the figure, the tubular base 40 is mostly not shown, because it is inside the fabric section, save at the very bottom where the connection between the tubular base and the commissure posts can be seen. The two ends of the device are referred to as the inflow end 28, at the bottom of the figures, and the outflow end 30 at the top.

72. Although the axial length of the support stent is a bit more than the axial length of the tubular member, nevertheless the axial length A of the fabric section is greater than the axial length B of the tubular base.

73. The tubular base is made of plastically expandable material like a conventional stent. The commissure posts are preferrably biocompatible elastic material such as stainless steel or Delrin. The fabric section can be made of woven polyester or other suitable sheet material and the leaflet section can be made of bovine pericardial tissue or other suitable biocompatible material such as synthetics.

74. There is a sentence in para [0021] (ln 20-23) which describes an option relating to the leaflet section. There was a dispute about its meaning which is best resolved in context below.

75. The patent explains at para [0029] by reference to fig 2 (and fig 5) that a plurality of leaflets are defined between the commissure posts. When the pressure differential is such that blood flows in the inflow end, the leaflets spread apart and the valve opens. When the pressure differential is reversed, the leaflets come together and the valve closes.

76. At para [0030] is a reference to the idea that the commissure posts may cantilever by a slight amount to accommodate the pressure when the valve closes. Meril submitted that this would be understood to mean that the ability of commissure posts to cantilever was mandatory (and so was imported into claim 1 by use of the term commissure post). The skilled reader would understand this cantilevering role but they would not understand para [0030] in that way. The patent does not teach that by definition commissure posts have to be able to cantilever.

77. Para [0031] refers to the problem of wear caused by dynamic contact between the stent and the leaflet. The device has features to address this. At col 8 ln38 the patent explains that the because axial length A is greater than B any contact between the flexible tubular member 22 and the tubular base 40 (at the outflow rim 50) is between fabric and the base. In other words, as the patent then states, the leaflet section 32 is not placed in contact with the base 40, thus increasing the life of the valve. This passage relates to the characterising portion of claim 1. The paragraph refers to other aspects which are designed to reduce rubbing but they are not important in the context of the issues in this case.

78. The description then turns to delivery of the device in paras [0032] – [0033]. Preferably the device is loaded on a balloon catheter in a delivery cannula. The catheter with the valve loaded on it is passed through the vasculature of a patient and once in position in the annulus, the balloon is inflated to cause the device to expand into contact with the annulus. The text in para [0033] first describes this as the tubular base being expanded into contact with the annulus and then clarifies that actually what ends up compressed against the annulus are the fabric section and commissure posts. The balloon is deflated and removed, leaving the valve in place.

79. The patent then turns to the second embodiment, the one which is assembled post-storage. Figures 6 and 7 show this second embodiment in a similar way to figs 1 and 2 for the first embodiment. Note that in fig 7 the outer fabric skirt 110 is not shown:

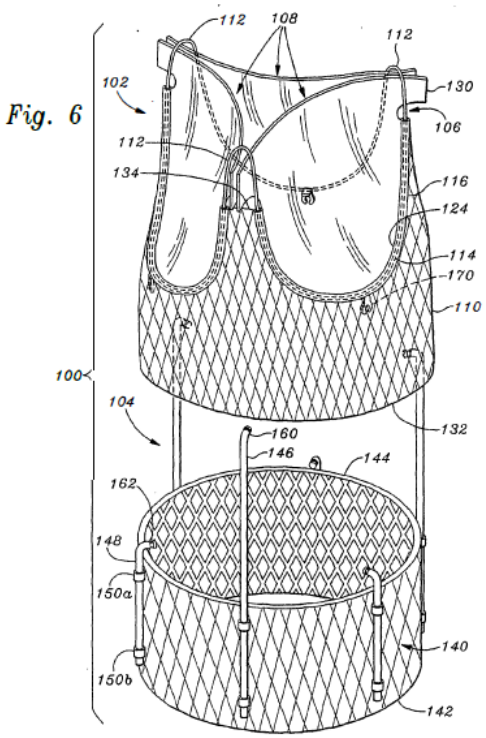


Fig. 6

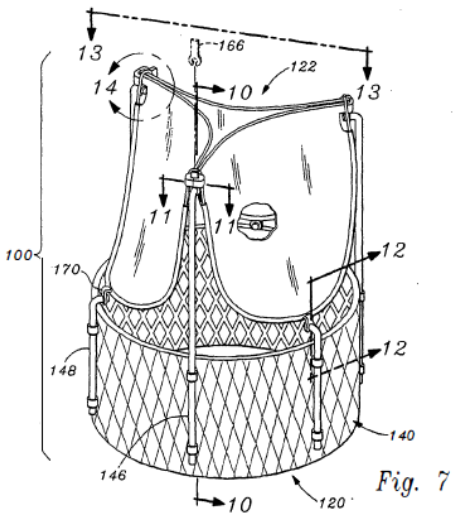


Fig. 7

80. In this device the two parts are called a leaflet sub-assembly 102 and a tissue engaging base 104. These two components are stored separately and connected just prior to delivery. The leaflet sub-assembly 102 comprises a wireform 106 supporting a plurality of prosthetic leaflets 108 and a fabric skirt 110. The tissue engaging base 104 has commissure posts 146 (as well as cusp posts 148) on the exterior of a tubular member 140. The wireform 106 has undulating commissures and cusps, 112 and 114 respectively. Each leaflet is attached to the commissures and along the entire arcuate cusp.

81. It can be seen from fig 7 that when assembled the bottom of the leaflets (at the cusps) is higher up than the top of the tubular member 140.

82. Although the lower part 104 is called a "tissue engaging" base, in fact it is clear that the fabric skirt 110 is sized to drape outside the tissue engaging base 104 and so, when the device is deployed the fabric skirt is captured between the tubular member

140 and the tissue and it is the fabric skirt which is actually in direct contact with the tissue (para [0054]).

83. There is no need to go into further detail about the second embodiment. What is apparent even from this brief introduction is that the language used to describe the second embodiment is different from that used to describe the first embodiment, particularly in relation to the upper component which in the first embodiment is called a tubular member whereas in the second embodiment it is called the leaflet sub-assembly.

84. The method of delivery of the valve is described in some detail from para [0049] onwards. The passage is mostly written by reference to the second embodiment but is sometimes expressed more generally (col 14 n13). At the end of this passage, para [0057] draws attention to a difference in the leaflets between the first and second embodiment in that the second embodiment has separate leaflets whereas the first has a continuous tube.

85. The final paragraph of the description ([0058]) expressly refers to both embodiments as being embodiments of the invention. I mention this because there are arguments about whether the second embodiment is within the claims.

Claim construction - 753

86. Claim 1 has been set out above. Broadly, it can be understood as a claim to a device – a prosthetic heart valve. The device has two parts – a support stent and a flexible tubular member. The support stent includes a tubular base which is expandable (feature C) and commissure posts. The flexible tubular member has a prosthetic section attached to the commissure posts (feature D in part). The characterising feature (E) is that the tubular member further comprises a fabric section connected to the tubular base and then crucially "only the fabric section contacts the tubular base".

87. Claim 1 is written in a pre/post characterising format. It is well settled that the skilled reader is taken to know about this sort of drafting approach and to take it into account. Paragraph [0005] expressly provides that the pre-characterising portion is based on WO 91/17720 which is the published international application corresponding to Andersen US.

88. There are two disputes on construction. The first can be addressed now but the second is best dealt with in the light of the arguments on infringement.

89. Meril contend that the claim only covers a device like the first embodiment in that the leaflet material is actually made from a single continuous tube and the valve leaflets only take shape as a result of the geometry of the attachment of the tube material to the metal structure. Therefore, Meril contends, a device like the second embodiment, in which the leaflets are formed from three distinct pieces, is not within claim 1. As a matter of construction the submissions are that the words "flexible tubular member" in claim 1 cover the first embodiment but not a device with separate leaflets like the second, and that the requirement in feature D that the prosthetic section is attached to commissure posts "so as to define" a number of valve leaflets between the posts, describes the first embodiment but not the second.

90. Edwards argued to the contrary, submitting that part of the foundation for the submission was an argument that the reader would think the second embodiment was not claimed, however that was wrong reading the document as a whole. Edwards also argued that in the assembled structure there is a flexible tubular structure regardless of whether the leaflets are composed of a single tube or of distinct pieces. Edwards also submitted that the language of feature D ("defining") is apt to cover both arrangements and does not exclude leaflets made of distinct pieces.

91. I agree with Edwards. First, the skilled reader would understand the patent as a whole to be written on the basis that both embodiments are embodiments of the invention, that is to say the invention claimed in claim 1. Mind you that cannot be taken too far. The skilled reader is not a fool. It would be apparent to that reader that for whatever reason claim 1 has been written using the language of the first embodiment and fits more naturally as a description of it. Reading the claim onto a device like the second embodiment creates puzzles, and the reader would not take the fact that the patent asserts that both embodiments are covered as a factor of such force as to override all other considerations.

92. Nowhere in the description does the patent describe the second embodiment as having a flexible tubular structure or a flexible tubular member. The corresponding element is the leaflet sub-assembly 102. Meril also drew attention to para [0057] as drawing a distinction between the first embodiment – as having a continuous tube, and the second – as having separate leaflets.

93. However the difference between the continuous tube of the first embodiment and the three separate leaflet pieces of the second is much more apparent when one focusses on the disassembled structure. I agree with Edwards that the claim relates to the assembled structure. When the two are looked at in that way, they both have a flexible tubular structure.

94. Moreover the characterising feature of claim 1, the presence of a fabric section in the tubular member which is connected to the tubular base, is a feature of both embodiments and so too is the requirement that only the fabric section contacts the tubular base.

95. In relation to feature D, a relevant point is that the claim is to a device and not to a method of making one; and moreover as before, it is to the device in the assembled state. The language is apt to read onto both embodiments and since the reader knows that that is what the inventors intended, from the document as a whole, there is no warrant to read feature D to exclude separate leaflet pieces.

96. Finally on construction, I turn to disputed para [0021] ln 20. The issue is as follows. One of the debates was about whether the patent would be understood to contemplate as within the scope of the invention a device in which the leaflets were not above the base. It will be recalled that in the two detailed embodiments the leaflets are above the base, in other words the lowest point of any leaflet material is higher up than the highest point of any base metal. As a point of construction of claim 1, in my judgment it is clear that the claim contains no such limitation. In other words the claim is capable of covering a device in which geometrically the bottom of the leaflets is at a lower point than the top of the metal base. Of course such a device would only

be covered by the claim if it also satisfies feature E (only fabric *contacts* the base), but that is another matter.

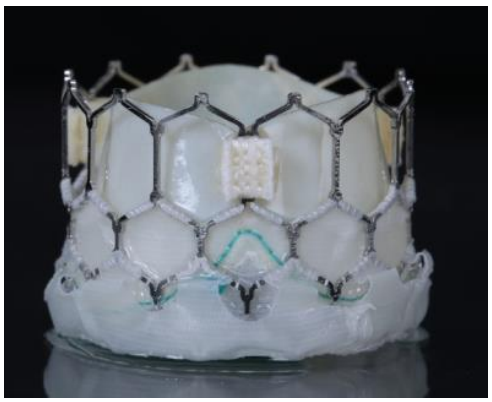
97. Edwards argued that the last sentence of para [0021] read in context amounts to a disclosure of an arrangement in which the leaflets were not above the base but nevertheless there was no contact between leaflet and base, and the only relevant contact with the base was by the fabric section. The issue of disclosure may have had something to do with sufficiency or added matter.

98. In cross-examination Dr Doshi drew the arrangement which he said the skilled person would produce if asked to put that teaching into practice. As a matter of what the document discloses, I do not accept that the arrangement drawn by Dr Doshi is disclosed having regard to para [0021] (or at all). It is not expressly described, nor is it necessarily implicit nor (if different) is such an arrangement clearly or unambiguously derivable. The passage only refers to the height of the leaflet section and to the fabric wrapping around. It does not say anything about avoiding contact and even if the reader assumes the patentee must have intended that to be done (which is not clear), it does not say how to do it. The passage is silent about the relationship between the leaflet and the tubular base.

99. At best Dr Doshi's diagram was just one possible thing a skilled person might make, but in my judgment they would most likely conclude that they do not know for sure what the inventor meant by this passage in para [0021].

Infringement

100. The Meril Myval device looks like this:



101. The structure is built from a single nickel cobalt alloy cage formed of hexagonal cells. The cells in the upper row are larger than the cells in the lower two rows. There are three preformed leaflets made of bovine pericardium stitched at their lower edge to a fabric skirt. The fabric skirt is attached to a frame. The fabric skirt is made of an inner skirt and an outer skirt. The commissures of the leaflets attach to slots in vertical struts which are part of the cage.

102. The first issue is "flexible tubular member". Edwards argued that when constructed, the pericardium leaflets and the inner skirt form a flexible tubular member. I agree. If I had accepted Meril's case on construction, which excluded separate leaflet pieces

then the outcome would have been different but I have already rejected that submission above.

103. Meril contends that the struts to which the commissures are attached are not commissure posts as required by claim 1 not least because they are not "posts" at all given that they are part of a rigid frame structure. Meril argues that this rigidity means that the struts cannot cantilever but since I have rejected that as a limitation in the claim it is irrelevant. Related to the commissure posts point is the question whether the Myval has a tubular base as required by claim 1 at all. Part of the argument is to submit that the stent part of the Myval device is a single structure whereas the claim requires a tubular base and, distinct from it, axially extending commissure posts.

104. Edwards does not agree with any of this, and contends that the Myval is a device within claim 1. The fact that there is extra material between the commissure posts as compared to the specific embodiments in the patent is irrelevant.

105. I agree with Edwards. Neither the fact that one can see three rows of cells in the Myval structure or that the top row of cells expands plastically in use, means that the struts to which the commissures are attached cease to be commissure posts. The term commissure post is not a term of art. In the claim it takes its meaning from its context. Although as a matter of ordinary English a post can refer to an independent free standing member, it does not have to be (e.g. in a post and rail fence). A row of posts is still a row of posts even if each post has a rigid connection to its neighbour. The fact that the designers of the Myval no doubt had good functional reasons to construct their device that way is neither here nor there.

106. There was an argument about whether the lower rows had greater radial strength than the top row, and Edwards levelled an unwarranted criticism of Dr Solar about that.

107. Dr Brecker characterised Edwards' division of the Myval frame into distinct zones with different functions as arbitrary and with no clinical or technical basis. In fact Meril themselves are content to divide the frame that way in technical marketing material and Dr Brecker agreed that there is a clinical basis for the different configurations of the upper row of cells and the two lower rows, the upper open row helps avoid occlusion of coronary ostia while the lower rows have higher radial strength.

108. I find that the lower two rows have smaller cells in order to have higher radial strength while the upper rows are more open so as to avoid occlusion. There is nothing arbitrary about considering these as distinct elements in the overall structure.

109. In terms of claim 1 the lower two rows of cells of the Myval amount to a tubular base while the three relevant struts are commissure posts extending axially and disposed around the tubular base.

110. In relation to feature E, there is no question that the Myval has a fabric section connected to the tubular base but Meril took the point that during deployment the leaflet material did make contact with the frame. Figure 50D of the PPD shows that when the valve is crimped on a balloon for deployment some of the leaflet material pokes through the hexagonal cells and is in contact with the metal. That is true but I

agree with Edwards that it is not what claim 1 is referring to. The contact which it is concerned to avoid is contact when the valve is in use, during the cycles of systole and diastole. The claim is not talking about deployment.

111. Accordingly the Myval infringes claim 1.

Validity

Obviousness over Cribier in the light of Andersen US

112. The skilled person and the common general knowledge have been identified above. In terms of inventive concept, there is no need to paraphrase the claim. To identify the differences I need to examine the prior art relied on.

113. Meril described their case as based on Cribier in the light of Andersen. When an obviousness argument is described in that way, there is a risk of mosaicing. If the argument had involved trying to put together passages buried in the Andersen patent (and not common general knowledge) with other less than central parts of Cribier, then the problem might have been significant. However in practice the argument does not suffer from that drawback for two reasons, first because the aspects of Andersen relied on were central to Cribier anyway and second because Andersen was common general knowledge.

114. Turing to the Cribier prior art document itself, it is entitled "Valve prosthesis for implantation in body channels". Although not limited to this, the first paragraphs of the document explain that it is focussed on a cardiac valve prosthesis to be implanted by a transcutaneous catheterization technique to treat aortic valve stenosis in elderly patients (p1 ln5-6, p1 ln20-23). The document describes the medical problem, the fact that many elderly patients are not strong enough for surgery, and explains (p2 ln 24) that "until now" the implantation of a valve prosthesis to treat aortic insufficiency was considered unrealistic since it was deemed difficult to superimpose an implantable valve on the distorted stenosed native valve without cutting away the native valve.

115. The advantages and disadvantages of the technique of valvuloplasty are described from p2 ln28.

116. Cribier turns to the prior art of catheter implanted prosthetic cardiac valves and cites (only) Andersen US, describing it as a collapsible valve introduced in a collapsed form and expanded in the right position by balloon inflation. Cribier then proceeds to critique features of the Andersen US design – from p4 ln8 to p5 ln2. I will address this critical passage below.

117. The next section of the document is the summary of Cribier's invention. This starts with the aims of the invention, the first being the provision of an implantable valve for aortic stenosis which is able to withstand the powerful recoil force in the aorta which the implanted valve will experience and also able to stand the forceful balloon inflation needed to deploy it (p5 ln6-10). This section also identifies using preliminary balloon inflation of the stenosed valve as an initial step in the procedure (in effect a valvuloplasty). Other aims and advantages are mentioned in this passage.

118. The particular device disclosed by Cribier is an implantable valve comprising an occluder set in a stent frame. The Cribier document does not use the word occluder, it refers to a valvular structure. The valvular structure is described by Cribier as a collapsible continuous structure which includes guiding means for stiffness. The specific examples all have a special shape referred to as a "truncated-hyperboloid". The frame must be strong enough to resist recoil. The device proposed is shown in fig 4b in its expanded form:

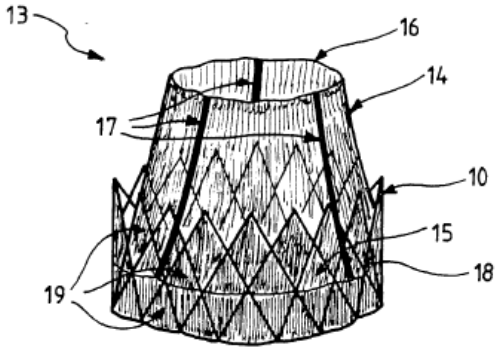


FIG_4b

119. The stent frame is item 10. The valvular structure 14 is continuous in nature. The material has stiffening struts 17. The valvular structure has a hyperboloidal shape. The hyperboloid is truncated at the upper end. An advantage of the hyperboloidal shape is said to be that the valvular structure can remain at a distance from the coronary ostia during systole as well as diastole (p19 ln22-26). Another advantage of this truncated continuous shape is said to be that it is stronger and has less risk of being destroyed or distorted by forceful balloon inflation at deployment. There is an internal cover 19 fixed to the internal wall of the frame which prevents passage of blood through the frame and strengthens the fastening of the valvular structure to the frame (p20 ln26-p21 ln3).

120. Fig 6 (a) to (d) shows different detailed examples of how to configure the lower part of the device and attach the valvular structure to the frame. They are:

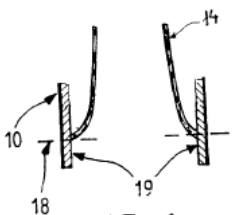


FIG_6a

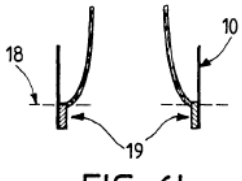


FIG_6b

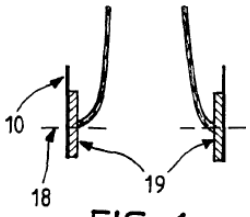


FIG_6c

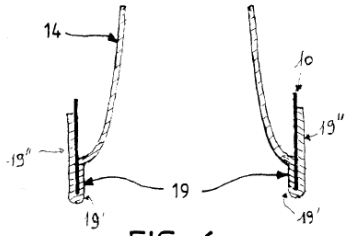


FIG_6d

121. Figures 6a to 6c differ as to how much the internal cover 19 covers the internal side of the frame. Fig 6d is like fig 6b but with the cover material going around the lower end and up the external part of the frame. The internal cover could be made from the same kind of material as the valvular structure but it does not need to be.

122. Another aspect of Cribier is the two step implantation technique. This consists of a preliminary dilation of the stenosed aortic valve using a regular balloon catheter, followed by implantation of a prosthetic valve which is mounted on a second balloon (e.g. p31 ln15 -p32 ln26).

123. Cribier does not contain the results of any experiment in which the proposed device(s) were tried out in practice either in an animal model or in humans.

124. That is a sufficient summary of Cribier for present purposes and I turn to identify the differences (***Pozzoli***) between what is disclosed in Cribier and claim 1 of 753. Owing to the way the argument was put, there was not much focus on this and I will come back to the way the argument is actually put, but at this stage it is useful to consider them.

125. Cribier discloses a prosthetic heart valve (feature A) which has feature C of claim 1. A major claim feature which is not disclosed in Cribier is commissure posts, because the truncated hyperboloidal valvular structure does not need them for attachment to the frame. For that reason only, features B and D are not disclosed by Cribier. Turning to feature E, in the arrangement shown in figs 6a to 6c, only the internal cover, and not the rest of the valvular structure, contacts the tubular base. However the internal cover of Cribier is not described as being made of fabric.

126. Thus the differences between Cribier and claim 1 are the lack of commissure posts and the use of fabric for the internal cover. There may be a question whether the arrangement of fig 6d falls within Feature E although this may not matter because if an internal cover was to be applied, in my judgment figs 6a to d are all equally obvious.

127. I will deal with fabric now. In my judgment there is nothing in this potential difference. Cribier does not specify in detail what to make the internal cover from but notes that preferably it could be made from the same material as the valvular structure itself. For the valvular structure Cribier proposes biocompatible materials such as Teflon or Dacron, polythene or polyamide or a biological material such as pericardium or porcine leaflets.

128. However else the skilled team chose to go forward from reading Cribier (if at all), no inventive step would be involved in the skilled team putting the internal cover of

Cribier into practice using fabric material. On this I preferred Dr Solar's evidence that the idea that using fabric was obvious given that the structure would need to be crimped and expanded, to that of Dr Vesely's, which pointed out that Cribier teaches that the material preferably is the same in the internal cover and the leaflet section. The team would understand Cribier's teaching but it would be an obvious step from that to make the material from fabric.

129. It is also convenient now to address fig 6d. With an internal material made of fabric, I am sure a skilled team which had decided to follow the fig 6d approach would make it in such a way that the fabric was attached to the frame and the leaflet material was attached to the fabric. The result would be an arrangement within feature E.

130. Pausing here and subject to the points of detail which I have just addressed, it is notable that Cribier essentially discloses feature E of claim 1, which is the characterising feature of the claim which distinguishes it from Andersen. So both Andersen and Cribier disclose different combinations of features and claim 1 is yet a further different combination of more or less the same features. New combinations of known features can most certainly amount to subject matter which involves an inventive step, but they may not. It depends on the facts and detailed circumstances.

131. Meril's main case is that an obvious thing the skilled team would do, having read Cribier and bearing in mind both their common general knowledge of Andersen and the discussion of Andersen in Cribier itself, would be to make a prosthetic heart valve based on the stent frame along the lines of Andersen, using a well-known three leaflet type occluder design such as the whole porcine valve or three pericardial leaflets as in some well known surgical valves, and incorporating an internal cover. The team might use the truncated hyperboloid instead but all three options – porcine valve, pericardial leaflets or the truncated hyperboloid were obvious. Using the three leaflet designs as in standard surgical valves, the leaflet commissures would be attached to the stent frame with commissure posts. Thus with an internal cover as well, this device would fall within claim 1 and so the 753 patent would be invalid for obviousness.

132. Edwards does not accept this, contending it is tainted with hindsight. A major plank of Edwards' case is that that it fails to face up to Cribier's criticisms of the Andersen design, which I have not yet addressed. Although other points were taken too, in my judgment it is the criticisms of Andersen in Cribier and their significance for the skilled team which is the key issue. The case turns on those. Other factors are insufficiently strong to carry the day either way.

133. I will mention only two of the "other" factors. First, Edwards referred to the fact that no-one had achieved a successful treatment of aortic stenosis in a human at the priority date. As the patentee is entitled to point out, (i) the invention is a device to treat that condition, (ii) that is something the art wanted, (iii) at the priority date the skilled team did not know of a successful way of doing this, and (iv) devices within the claims of the 753 patent are used today to treat the condition successfully. However this is not a case in which it can be said that the teaching of, or the technical contribution of, the 753 patent in suit is the solution to a particular technical problem which was itself the reason that the successful treatment of aortic stenosis in a human had not been achieved at the priority date. In this case therefore, this factor is not sufficient to make a difference if Edwards' case on the criticisms fails.

134. The second factor is the starting point. Meril's case is put on the footing that the team adds a cover to Andersen, rather than adding an Andersen type valve to Cribier. Normally for obviousness one considers a skilled person reading the relevant prior art and deciding (or not) to take a step by adding to or changing the device or process disclosed in that prior art. However on the facts of this case I think it is legitimate and realistic to consider a skilled team acting in the manner Meril contends. That is because of three cumulative factors. First Andersen is common general knowledge. Second Cribier is written based on a critique of Andersen itself, meaning that the team would be prompted to think about Andersen anyway. Third, while they are of course disclosed in the same document, I find that the truncated hyperboloid and the internal cover would be understood by the skilled team as distinct things, with their own properties and their own reasons to use or not. To the skilled team in 2000, the idea of the internal cover itself would be seen as having a value regardless of the details of the design of the occluder.

135. I turn to Cribier's criticisms of Andersen US. They start at p4 ln8. The valve of Andersen US is characterised as a semi-lunar design, tending to imitate the natural valve. It is convenient to take them as three criticisms.

136. The first criticism is that Cribier says of the Andersen US semi-lunar design that that type of design is inherently fragile and that such structures are not strong enough. The strong recoil will distort their weak structure and they will not be able to resist the balloon inflation used to install the valve. Note that as a matter of language this criticism appears to be directed to the valvular structure itself (from the sentence starting at p4 ln13 which refers to "this valvular structure" being attached to a metallic frame). Dr Vesely accepted in cross-examination that most likely what Dr Cribier was saying there was that the frame was not strong enough. In my judgment the reader would understand Cribier to be considering both the strength of the frame and the valvular structure in this passage.

137. Closely related is the point made in the paragraph starting at p4 ln23. This says that at the time of the maximum balloon inflation which will be needed to implant the valve, the implantable valve will be crushed between the strong aortic annulus and the rigid balloon with a risk of irreversible damage to the valvular structure of the implantable valve.

138. The second criticism relates specifically to the metal frame (from p4 ln13). It is said to be too weak to be forcefully embedded into the aortic annulus.

139. The third criticism is that there is a risk of "massive regurgitation" through the spaces between the wire frames, which makes it impossible to use in clinical practice.

140. I will deal with these individually in reverse order and then stand back and look overall. To the skilled team reading Cribier, the way to deal with the risk of massive regurgitation in an Andersen type design is to use the internal cover disclosed in Cribier. In other words this criticism of Andersen would actually make it all the more obvious to apply the internal cover disclosed in Cribier to an Andersen valve. In my judgment that is the simple and correct conclusion arising from this point. The experts called by Edwards Dr Vesely and Dr Doshi both sought to suggest that in effect there was no such problem with Andersen because Andersen was based on a whole porcine valve with the root (not just leaflets) and so the root tissue would

prevent any regurgitation. However in cross-examination Dr Vesely did accept that there were gaps to be seen in the Andersen design which might lead to the massive regurgitation referred to by Cribier. Dr Doshi also accepted that there was a risk of regurgitation albeit that the team would think they might be able to avoid it.

141. I find that the skilled team would understand this criticism of the Andersen design as described by Cribier. They would not see it as an inevitability – use of the root and precise placement of the valve might mitigate the risk somewhat. However they would regard the risk as sufficient to justify employing Cribier's solution. It would be obvious to consider employing an internal cover to address that risk.

142. A distinct argument was that adding the internal cover would make the Andersen device bulkier, such that it had a larger "crossing profile" and that the team would be concerned about this. The crossing profile is the size of the compressed valve. It matters for delivery of the valve through the body to the heart. To the extent the increase in crossing profile is a concern, it arises because of the combination of an internal cover and the valve root part of the whole valve used in Andersen. Meril contends the simple answer is to follow the pericardial leaflet approach. Dr Doshi accepted that the options for the skilled team would be pericardial leaflets, a whole valve or the Cribier truncated design. I find that all three would be obvious options for the skilled team reading Cribier. The first two are common general knowledge. I believe the team would appreciate that adding an internal cover could increase the crossing profile somewhat, and what they would do if they were concerned by that would be to follow the pericardial leaflet approach, all without any inventive step.

143. There was a point about placement of the Andersen valve and a point on occlusion of the ostia, but I am not satisfied these issues are relevant. The team would be concerned to place the valve in the annulus or as close as practical to it, bearing in mind in real stenosed valves the anatomy may be distorted. The team would also seek to place the valve in such a way as to minimise the risk of occlusion. These issues would not deter the team from taking the approach I have outlined so far.

144. Cribier does suggest that a specific advantage of the truncated hyperboloid would be to minimise the risk of ostial occlusion. However this would not cause the team to follow the truncated approach only and not follow up the leaflet based designs such as the pericardial approach which included commissures and commissure posts. The team would know that surgical valves using the same structure of pericardial valves did not have a problem with occlusion – albeit they would also know that surgical placement means the two situations are not completely comparable. A possible risk of occlusion would be something to watch out for in practice, but it would not be considered anything like significant enough as a reason not to go forwards with pericardial leaflets.

145. There was a complicated point of detail about the anatomy of the ostia and aorta in pigs and how that might account for the level of occlusion seen by Andersen such that if the skilled team knew about this detail of porcine anatomy (which made the risk higher for pigs) they would not be concerned about occlusion. I am not persuaded the skilled team would know the detailed point on pig anatomy nor am I persuaded that this is relevant.

146. I turn now to the second criticism made by Cribier about Andersen, namely the strength of the frame itself. Dr Vesely's evidence was that the skilled person would know how to set about improving the strength of the frame in Andersen. I accept that. I find that any issue about strength of the metal frame in an Andersen design, including its ability to withstand recoil and any distortion which might be caused, would not deter the team from going forward with an Andersen based device. If they were concerned about strength it would be obvious to a skilled team in 2000 how to address that.

147. That leaves the first criticism, namely that the valvular structure itself would be too fragile and would be damaged by being crushed against the annulus when the balloon is expanded. (I have addressed the recoil in the previous paragraph.)

148. It will be recalled that the purpose of the exercise is to treat aortic valves which are in a stenosed state. In other words one should not have in mind the idea of trying to open the implanted valve inside a normally functioning valve with leaflets which flap open and closed as the heart beats, and no doubt intuitively could be imagined to be able to be pushed aside fairly readily. The diseased valves which required treatment are heavily calcified. That is what is keeping them shut (albeit not 100%) against the force of the heart muscle trying to pump blood and push them open. The skilled team would appreciate that that was the task required. The team did not need to be told by Cribier that severely stenotic valves would resist expansion, that was common general knowledge.

149. As part of this submission, Edwards sought to deploy the reputation of Dr Cribier at the time, as the inventor of valvuloplasty and therefore someone with unrivalled knowledge of how much force is needed in a balloon to open a diseased valve. As a matter of principle it is legitimate to take into account the reputation of the author of a document as long as that forms part of the common general knowledge (as here) but this principle cannot be taken too far. What really counts for a skilled team in a technical field when evaluating an assertion is the evidence in support of it and its inherent scientific plausibility, not so much the reputation of the author. On this Edwards drew attention to the detailed data reported in the passage about valvuloplasty on p3 of Cribier. The skilled team would take that into account. However while the data, which is focussed on opening areas, supports the idea that Dr Cribier had indeed done tests of valvuloplasty (which the team would believe anyway), it is not data about the fragility of the valvular structure.

150. Meril appeared to suggest that the first criticism referred only to frame rather than the valvular structure, and I think cross-examined on that basis. As I have already held, although the words of the passage refer to the valvular structure and not the frame, the reader would think the issue related to both. If it matters, I reject the idea that the concern does not include a concern about the fragility of the valvular structure.

151. The skilled team would not be deterred by this concern in relation to frames because, as I have already held, they would be able to make a frame which was sufficiently strong to avoid being damaged and to resist recoil, without difficulty.

152. In relation to the valvular structure, while the team would take note of Cribier's concern about the fragility of the valvular structure in Andersen, it would not be sufficient to deter them from going forward, as one of the obvious options, with a

porcine valve or leaflets formed from pericardium. It would be a factor to look for, not a reason not to take the step. The team would think an approach based on a porcine valve or on leaflets formed from pericardium had a reasonable prospect of success because the skilled team knew as a matter of common general knowledge that while calcification was always significant, there were varying degrees in stenosed aortic valves. The team would think that there could be heavily stenosed valves for which this might be a problem but would also think that in less heavily stenosed valves there was a fair prospect of being able to deploy the valvular structure successfully without destroying it as part of the balloon expansion.

153. In any event the concern cannot be taken too far anyway for a different reason. Cribier itself proposes that while the preferred valvular structure is made from synthetic biocompatible material, it could also be made from pericardium, porcine leaflets or the like (p8 ln16-20).

154. Furthermore, if, contrary to my finding, the team was deterred by the concern about the risk of crushing the valvular structure caused by the force required for the balloon to open even a less heavily stenosed valve, Cribier itself presents another solution to this difficulty which the team would understand and would still mean the device – with a porcine valve or leaflets from pericardium – was obvious. That is the teaching to perform a balloon valvuloplasty first using a balloon which does not have a valve crimped on it, and then insert the valve into the now expanded valve as a second step. One way of doing that taught by Cribier would be to use the double balloon system. I find these were obvious approaches for a team concerned about the risk of crushing.

155. Dr Solar drew attention to this two step approach in his cross-examination and after an intervention from me, Edwards' counsel came back to it at the end of the cross-examination. The point being put at that stage was concerned with recoil. That is a different issue. The team would not see the two step process as addressing a need for strength to resist recoil. Recoil resistance comes from the metal frame. The two step process is one answer to a concern about the ability of the valvular structure to withstand the crushing forces at deployment.

156. Standing back, I find that claim 1 lacks inventive step. One of the obvious ways forward for a skilled team given Cribier in 2000 would be to construct an implantable valve with a metal frame and commissure posts, a valvular structure based on pericardial leaflets and an internal cover made of fabric based on any of figures 6a-d with the leaflet material connected to the fabric and not the metal base part. If, contrary to Edwards case, claim 1 had been limited to the continuous tube in the first embodiment of the 753 patent then it might well not have been obvious, but it would not be infringed by the Meril device. However given the width of claim 1 as I have construed it, the Meril structure falls within it, but the claim is invalid.

Insufficiency

157. The Supreme Court has recently addressed insufficiency in ***Regeneron v Kymab*** [2020] UKSC 27. Given the conclusion on inventive step, I do not need to spend time on insufficiency in this case. I find that the skilled team given the patent would have no difficulty constructing either specific embodiment, both of which are within claim 1. A point was raised about leaflets being in contact with commissure posts (para 3(c)

of the Grounds of Invalidity). I do not think it was pressed in closing but in any case, it is answered by the finding that both embodiments can be made.

158. Meril also ran a breadth of claim argument, arguing that if the claim covered the Meril device then it was insufficient. I do not propose to get into that because it is not necessary to do so. In case it matters later I will address what I think is the only potentially relevant finding of fact, having heard the evidence. I do not believe a skilled team given the 753 patent would make a thing like the Meril structure – that is to say an arrangement with either or both of (a) commissure posts built into a cage, with material running horizontally joining the tops of the commissure posts in a rigid frame or (b) fabric running all the way from the bottom of the leaflets inside the cage, around the bottom and up around the outside of the cage for an appreciable distance. These two aspects make the device a different thing from either embodiment. The device is covered by the claims of 753 but not disclosed by that patent. In other words, it is not clearly and unambiguously derivable from the specification. I doubt it is obvious either but even if it was, that would be a different point. Whether, given the Meril structure, the team might regard it as equivalent is another different point.

Added matter

159. The added matter argument is the submission that in the application as filed the feature forming feature E of claim 1 ("and only the fabric section contacts the tubular base") is only disclosed in relation to the first embodiment and by making it a feature of claim 1 on the footing that that claim is construed to cover both embodiments, as Edwards contend and I have found, then it is an intermediate generalisation and added matter.

160. I find there is no added matter. The reader of the application as a whole would understand that how the leaflets are attached is an important part of the teaching. The summary of the invention as set out in the application as filed at p2 ln25-p3 ln6 describes the invention as a product in which, amongst other things, the leaflets are attached to the commissure posts (and the cusp edge). Notably it does not say that the leaflets are attached to the tissue engaging base and the reader would not think that that was what was being suggested. When the document does refer to attachment to the base, the leaflets are not directly attached to the base, they are attached to the fabric section, which is itself attached to the base. It is true that the explanation of why one would attach the leaflet to the fabric section this way is given in relation to the first embodiment (p11 ln21-26) but the skilled reader would understand that to be generally applicable. Therefore there is no intermediate generalisation and no added matter.

The 929 patent

161. The relevant priority date for 929 is 23rd July 2008. By this time Dr Cribier's pioneering work in humans had been published and commercial TAVI products were on the market including the CoreValve and the Edwards SAPIEN valve delivered either by the transapical Ascendra system or the transfemoral Retroflex.

162. Although para [0001] of the 929 patent says the invention relates to implantable devices, the reader quickly sees that what it is really concerned with is the delivery system for such devices rather than the design of the implants themselves.

163. Para [0002]-[0004] is the background section. It explains transcatheter heart valve (THV) technology and notes that the diameter of the crimped profile of a transcatheter heart valve is an important design consideration – a smaller profile allows a wider population of patients to be treated using the preferred transfemoral approach (due to the diameter of the femoral artery). A published PCT, which is related to the Marchand prior art, is cited at para [0004]. The reader who looked at Marchand would recognise it related to the common general knowledge Retroflex system, indeed I think they would probably guess that from the description in para [0004] but it does not matter.

164. Para [0005] identifies a problem with prior art balloon catheters, in which the valve is crimped onto the inflatable balloon, namely that the thickness of the balloon material means that the valve cannot be crimped to its narrowest possible profile. Paras [0005]-[0006] go on to describe a concept known as off-balloon crimping, which is addressed in some detail in the 929 patent. In order to reduce the crossing profile the valve is first crimped on the catheter at a place away from the balloon, where it can be crimped down to a smaller diameter than it would have had on the balloon. The valve is then delivered through the somewhat narrow vascular route (which may include the relatively narrow iliac artery). Then, once the valve is in the aorta, which is relatively wide, the valve is moved onto the balloon (or the balloon is moved into the valve), widening the valve's diameter. The valve can then be implanted by balloon expansion.

165. However the next paragraph ([0007]) is a consistory clause. It does not mention off balloon crimping. It relates to the concept of a "flex indicating device". The consistory clause amounts to the same thing as claim 1, which has been set out above. The consistory clause is not worded in an identical way, and in some ways it is a bit clearer, but there is no need to set it out.

166. The point is that the known delivery device of Marchand is steerable (as para [0004] points out). The interventional cardiologist operating the device can turn a knob at the handle part of the system which causes the far end of the device to turn (i.e. "flex") so that it can be steered inside the patient's anatomy. The reason this is useful is simple. For example one conventional approach was to insert the catheter system into the femoral artery near the patient's groin, well below the heart. The device then passes upwards inside the patient towards the heart, but bearing in mind that the aorta also leaves the heart going upwards, it follows that the device will need to make a more or less complete 180° turn within the artery at the aortic arch to turn down through the aorta into the heart. The steering feature helps with that.

167. The flex indicating device provides an indication to the operator of the degree of flex which has been imparted to the delivery device. The patent does not state why this might be useful. In fact a particular advantage this provides is at withdrawal, after the procedure has been performed. At that stage the operator is in effect reminded that the device is in a flexed state before they pull it out after a valve has been implanted. This idea was not common general knowledge.

168. The next paragraph of the specification is para [0008]. This is again related to off balloon crimping. In fact off-balloon crimping takes up most of the remainder of the general section from now on, in paras [0008] to [0031] and [0035] to [0041]. Paras [0032] to [0034] relate to the flex indicating device but nothing turns on them.

169. The detailed description and figures start at para [0043]. This part starts with a general description of the delivery apparatus based on fig 1 from para [0045] to [0052].

170. Fig 1 shows the delivery device overall:

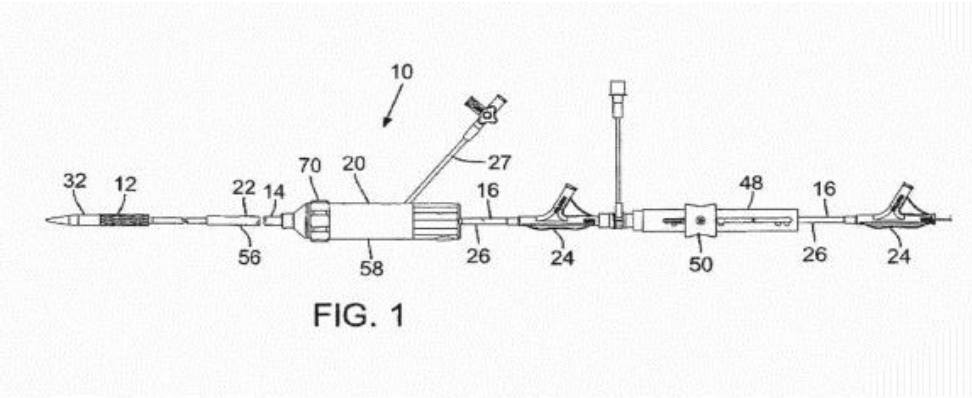


FIG. 1

171. The prosthetic heart valve 12 is just proximal to the nose piece 32. There is a balloon catheter 16 which extends through a guide catheter 14, and there is a handle portion 20.

172. Off-balloon crimping is then addressed extensively: in figs. 3 to 7, discussed at paras [0053] to [0066]; paras [0067] to [0070] (Figs. 8-12); paras [0075] to [0078] (Figs. 16-17); paras [0085] to [0086] (Fig. 20); and paras [0123] to [0129] (Figs. 39A-39C). There are also other features such as a flex adapter (see fig 22 and para [0087] et seq). There is no need to get into any of this at this stage although some parts may have a bearing later.

173. The detailed description of the flex indicating device starts at para [0108] and runs to [0122]. It is in the handle portion. Figure 31 shows the handle portion and Fig 36 shows the internal parts of the handle:

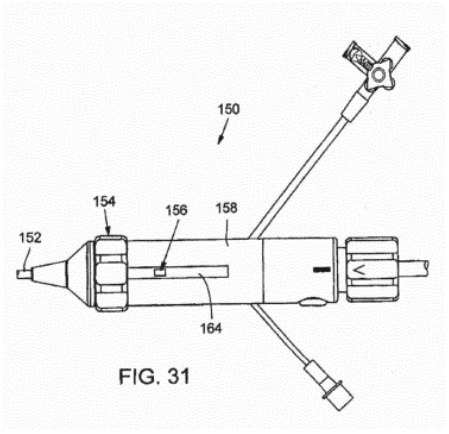


FIG. 31

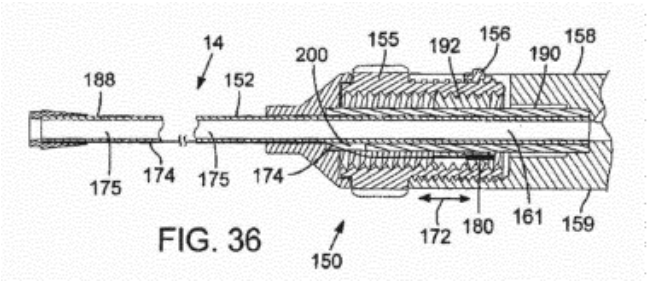


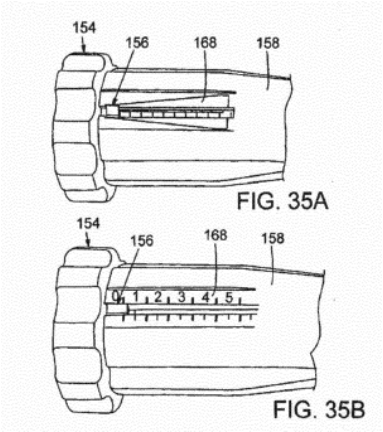
FIG. 36

174. In fig 31 the handle portion has a flex activating member 154 which includes a rotating knob (155 in fig 36) which is turned to cause flexing. The degree of flex is indicated by a pin 156 which moves in slot 164.

175. Turning to fig 36, the knob 155 has an internal thread and an external thread. The internal thread engages with a threaded slide nut 192 which in turn engages the pull wire 174. The pull wire is attached to a distal part of the guide tube (14). The external thread engages the indicator pin.

176. As the knob turns, the internal thread drives the slide nut proximally, pulling the pull wire and flexing the guide tube. At the same time, as the knob turns the external thread drives the indicator pin, allowing the position of the pin to indicate the degree of flex.

177. Figures 35A and 35B show indicia (168) present on the housing of the handle portion that indicate the amount of flex as the indicator pin 156 moves in the slot. In fig 35A the indicia are a triangular marking system and in fig 35B the indicia depict the amount of flex with numbers. This is described in para [0113] which contains a typo, referring to fig 36 instead of fig 35B. Nothing turns on that. The figures are:



Claim construction 929

178. Turning to claim 1, the claim is addressed to a delivery system with certain features. The system is for delivering a prosthetic valve to a patient's aorta. The system comprises a balloon catheter with certain features (claim 1 feature B) and a flex indicating device (C) with certain features. All of the remaining features of the claim (D to K) are features of the flex indicating device. A small point is that the way the claim has been type set in the published B specification could be accidentally misleading but nothing turns on that.

179. The flex indicating device comprises a guide catheter which itself comprises two things - a handle portion and an elongated guide tube extending from the handle. This is feature D. Feature E requires that the elongated shaft of the balloon catheter extends coaxially through the guide tube. Feature F requires that there is a pull wire connected to the distal end of the guide tube.

180. The claim then focusses on the handle portion. Feature G provides that the handle portion comprises a flex activating member. This is coupled to the pull wire so as to allow flex to be imparted to the distal portion of the guide tube. An adjustable knob would be an example of a flex activating member.

181. At feature H the claim then provides that the flex indicating device comprises a flex indicating member.

182. Feature I requires that manual adjustment of the flex activating member (e.g. the knob) causes the flex indicating member to move relative to the handle portion to indicate an amount of flex of the distal portion of the guide tube.

183. Feature J then requires that the flex indicating device includes indicia indicating the amount of flex. The indicia are provided at the handle portion.

184. Finally feature K provides that the handle portion comprises a slot for receiving at least a portion of the flex indicating member.

185. Before turning to the points in issue, it is worth noting that claim 1 has been carefully drawn to refer to various similarly named but distinct things: the flex indicating device, the flex indicating member (which is different from the flex indicating device), and the flex activating member. For example when I first read the claim I misread feature J as if it was an aspect of the flex indicating member, but as drafted it is a characteristic of the flex indicating device. And when you think about it, that makes sense. It also bears noting that the claim is drafted so that the guide catheter, including the handle and the guide tube, the pull wire and the flex activating member are all aspects of the flex indicating device. I doubt the skilled reader would think that really made sense but the claim can be understood well enough without being concerned by this.

186. There are three points on the construction of claim 1 worth highlighting now. The main two are: (i) balloon catheter/guide catheter and (ii) indicia. The third point is about feature K and the slot.

187. The balloon catheter / guide catheter issue can only be fully understood with an eye on infringement, which includes an issue of equivalents, but I will deal with construction at this stage.

188. As a matter of construction of the specification, without an eye on infringement, I believe the reader would understand the patent as a whole, and the claim itself, to be referring to two distinct elements – a balloon catheter and a guide catheter. They are different things and perform different functions. Contrary to Edwards' case, I hold that they would be understood to be separate and distinct.

189. A particular point relates to relative movement. As described in the specification the balloon catheter slides inside the guide catheter. That feature has particular significance in relation to off-balloon crimping and so Edwards sought to say that since the claim does not refer to relative movement between the two catheters, and since the claim is clearly not concerned with off-balloon crimping, so therefore it follows that the reader would not think the two things needed to be quite so distinct as they would if they had to move relative to one another or if off-balloon crimping was required.

190. That argument goes too far. For one thing the relative movement of the two pieces is not only described as an aspect of off-balloon crimping, it is discussed in the common

part of the detailed description at paragraph [0046] to facilitate delivery and positioning of the valve.

191. Furthermore, while I do agree that the reader would not read claim 1 as positively requiring the balloon catheter to be free to move longitudinally inside the guide catheter, that absence does not mean the reader would think the person drafting the patent had used the words of claim 1 to make a specific point about the relationship between the balloon catheter and the guide catheter, which are otherwise disclosed as distinct things in the specification, as if to imply that they did not have to be so distinct after all. That is to read too much into the language.

192. The fact that, as the skilled person would know as a matter of common general knowledge, in the Retroflex the two catheters were fixed one relative to another during the guiding phase, does not assist Edwards. Apart from anything else, while they were fixed at that phase, they could be moved at other times.

193. Meril submitted that guide catheter and balloon catheter were terms of art, and that the former by definition has a lumen which allows for insertion of the latter through it. I have not taken that submission into account in reaching the conclusion. But if it was necessary to do so, I would hold that based on Dr Doshi's evidence the expressions are terms of art and the skilled person would understand those expressions to refer to separate and distinct things. That would also support Meril's case and undermine Edwards' submission.

Indicia

194. I turn to indicia. Edwards submitted that the requirement for indicia would be satisfied by any means which allows the amount of flex at the distal end to be identified. This is said to be supported by wide words in para [0113] that the indicia can indicate the amount of flex in any of a variety of manners.

195. Meril did not agree with Edwards' construction, submitting that it effectively did away with the concept of indicia because it meant that any flex indicating device would do. There was an attempt in closing to refer to the EPO prosecution file to show that feature J (and feature K) were added because the examiner took the view that the Marchand prior art did disclose a flex indicating device and in particular a flex indicating member in the form of a lever which was moved to cause the flex, and which indicated the degree of flex simply by the position of the lever. What that did not have was graduated markings on the housing such as are shown in the 929 patent in figures 35A/35B and are called indicia.

196. I do not propose to get into the EPO file issue. The flaw in Edwards' case, put at its broadest, is that it seems to make feature I and J duplicative but the skilled reader would think that the patentee had gone to the trouble of using words in that way – to have both features – for a reason. A flex indicating member is claimed in feature I whereas the requirement for indicia comes in feature J. The reader would understand it to be a distinct requirement over and above feature I. Sometimes the skilled reader will conclude that words in a patent claim are surplusage but it would not be a natural conclusion here.

197. It is clear what the reference to indicia in feature J refers to – they are the visual markings on the housing shown in fig 35A/35B. The indicia can identify the amount of flex "in a variety of manners" - so for example the indicia do not have to indicate a graduated scale, but not having any indicia at all is not what the claim is talking about.

198. I have not found this easy but I have decided that the reference in feature J to indicia would be understood to convey to the reader that the indication of flex must be a visual one. In fact, the pin moving in the slot on its own, without a graduated scale, also provides a visual indication. However, feature I on its own, without feature J, could be understood to include other ways of indicating flex, aside from a visual indication.

199. The idea of a non-visual indication of flex is not as fanciful as it might seem at first sight. The operator imparts flex on the distal portion of the device by turning the knob. The knob itself is featureless and so one cannot just glance at it and know how much the distal end is flexed relative to the straight line. However this knob does give some tactile indication of the flex. That is because turning the knob in the same direction will ultimately reach a stop, so that the operator will feel that the knob cannot be turned any further. One stop indicates that the guide catheter is straight and the other stop represents the fully flexed state. That is a simple tactile indication of the amount of flex (all or nothing) and so the knob itself as it turns relative to the handle portion, seems to me to fall within feature I. But there are no visual indicia in the example just given (which corresponds to the common general knowledge of Retroflex). Feature J is not satisfied by the tactile feedback provided by the knob.

200. Therefore I find feature J does add something to feature I, it provides (or if you will confirms) that the claim as a whole requires a visual indication of the amount of flex by means of some indicia.

201. In reaching this conclusion I have skipped over another point on construction on this topic which needs to be drawn attention to. The issue is whether the requirement in claim 1 to indicate an "amount" of flex can be satisfied by a means which can indicate whether the device is fully flexed, not flexed at all, and somewhere in between (as I have held above) or whether it must be able to indicate intermediate degrees of flex in between fully flexed and not flexed – as the graduated marks and the triangular marks do. I believe Meril's case is that the claim is so limited. I do not agree. I can see a grey area if for example a system was able to indicate no flex or some flex but never how much, but it seems to me that a device which can indicate both no flex and full flex is providing an indication of the amount of flex sufficient to satisfy the claim even if it cannot distinguish different intermediate cases.

The third point on construction - the slot

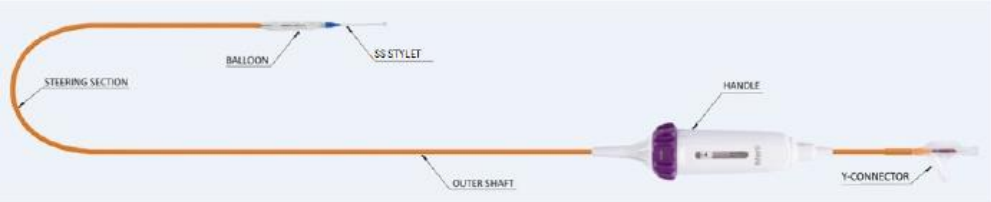
202. The third and final point is about feature K – the slot. Edwards argued that the slot referred to was the one in which the flex indicating member could be seen to travel so as to provide the indication of the amount of flex. No doubt the reader would identify that slot in the specific embodiment as being one which satisfies feature K, however this submission is an attempt to read words into the claim which are just not there. It is a common but illegitimate approach to construction to say that because the claim refers to a thing (a slot) and because the slot in the detailed description has certain features which happen not to be mentioned expressly in the claim (the flex indicating

member can be seen to travel in it so as to indicate flex) therefore it nevertheless follows that despite their absence from the claim, the claim is still to be understood in context as being limited by reference to those features. At this stage the traditional remark of a judge in a patent case is to refer to one of the key observations in ***Catnic***, that a patent is a unilateral declaration by a patentee in words of their own choosing. It is not always true, but in this case with this specification it is the case that, from the point of view of the skilled reader, if the patentee had wanted to limit the claim in that way, that could have been done. Feature K simply requires that there is some slot somewhere, and all it has to be able to do is receive some portion – of any kind – of the flex indicating member. It does not have to be on the outside nor does it have to be visible.

203. Any issues of construction of the other relevant claims will be dealt with in the context of infringement.

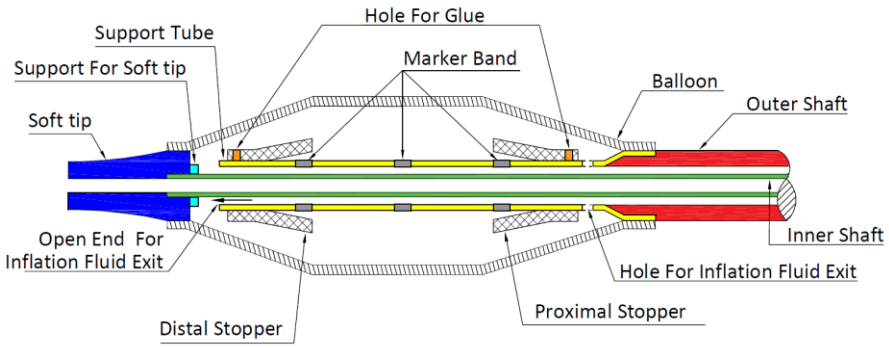
Infringement

204. The Meril Navigator is the delivery system used to deliver the Myval device. Edwards contend it infringes. An overall picture of the whole thing is:



205. Although the words are a bit unclear in the picture, what one can see is that there is a balloon at one end, a steerable section proximal to the balloon at the far left of the picture, and a proximal handle. The handle has a rotatable knob which imparts flex to the device to allow it to be steered.

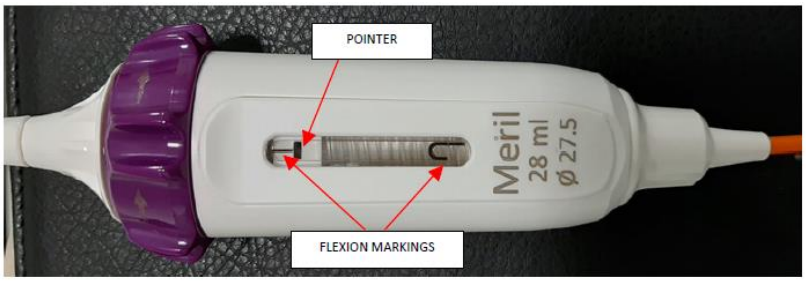
206. A more detailed drawing of the balloon section is shown here:



207. The outer shaft shown here (in red) is also visible in the overall picture above. There is an inner shaft inside and a soft tip at the distal end (left hand side). The fluid to inflate the balloon passes in the space between the inside of the outer shaft and the outside of the inner shaft. In use there will be a guide wire running inside the inner shaft but that is not shown.

208. At this diagrammatic level, what is shown here would be regarded by the skilled person as a balloon mounted on a balloon catheter. The inner and outer shaft together make up the balloon catheter.

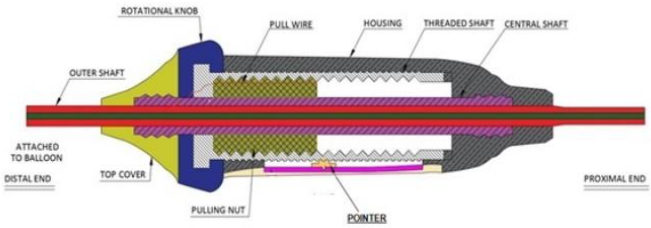
209. The close up picture of the handle is as follows:



210. The purple knob is clear on the left. As it is turned to cause the distal portion of the structure to flex, a white pin moves along inside the window from left to right. There are markings at either end of the window to indicate no flex on the left with a kind of T shape, and full flex on the right with a hockey stick shape.

211. I find that these visible markings – the T shape and the hockey stick – are indicia as required by claim 1. Coupled with the pointer, they indicate the amount of flex, as I have construed those terms in the claim.

212. The internal workings of the handle are shown in the following diagram:



213. As the knob is rotated, the threaded shaft (in grey) turns with it. The inner thread engages with a pulling nut and drives it to the right. The pulling nut is attached to a pull wire.

214. The pull wire runs in a passage inside the material which forms the outer shaft. At a distal point not far from the balloon, the wire is attached to a metal ring in the outer shaft material. The passage is close to the inner lumen inside the outer shaft and so, as the wire is pulled, the outer shaft structure bends, i.e. flexes. If the tension on the pull wire is released by turning the knob the other way, the outer shaft structure tends to return to its straight form.

215. Overall therefore, it is clear that at least at first sight, there is simply no guide catheter at all. The handle is attached to a balloon catheter and the pull wire flexes the balloon catheter by acting on the outer shaft part of that catheter. That is one of Meril's non-infringement points. Edwards contends there is infringement even on the construction

of claim 1 I have adopted and also relies on infringement by the doctrine of equivalents.

216. Edwards submitted that it was not put to Dr Doshi that there was no guide catheter in the Navigator device. I will assume that is so without going back over the transcript. It does not preclude the court from reaching a conclusion that there is no guide catheter. The issues on infringement and construction were gone into extensively in cross-examination and even though the detailed composite structure of the outer shaft emerged late, I am quite sure each witness was able to express their opinions to me on the relevant issues.

217. Edwards' case on infringement based on the normal construction of claim 1 is directed to the detailed composition of the outer shaft. In fact it is made of three components, an orange plastic outer layer, an inner plastic liner and a mesh layer in between. This detailed information only emerged close to trial. The pull wire extends through the outer layer.

218. Based on these layers, Edwards argued that the balloon catheter is made up of the inner shaft and the inner liner (as well as the soft tip and the balloon). It may also involve elements at the proximal end but they do not matter. The fluid used to inflate the balloon passes in the space between the inner shaft and the inner liner. Edwards then argues that the guide catheter is the proximal handle and the outer shaft, excluding the inner liner. It is that part of the outer shaft which extends to and includes the metal ring. The elongated guide tube of the guide catheter is the outer layer and the mesh layer. The inner layer and the inner shaft extend coaxially through that elongated guide tube so defined. On this basis Edwards argues that there are two catheters, both physically and functionally distinct and so the claim is satisfied.

219. I do not agree. The simple answer in my view is that the skilled person would regard the outer shaft of the Navigator device as a single composite structure. No reader of the patent would think it made sense to divide up such a single composite structure in that way to try and make it fit within the claim.

220. Edwards also maintained that there was infringement on a normal construction on the basis that the balloon catheter and guide catheter of the Navigator simply share a structure – the outer shaft - which serves both purposes. I do not accept that approach. As a matter of normal construction the claim would be understood to require two distinct catheters. This argument is a polite way of pretending it does not. I find that the Navigator does not satisfy claim 1 on a normal construction.

221. The questions to be answered to address equivalents are posed by the Supreme Court in ***Actavis v Lilly*** [2017] EWHC 48 as follows:

> Question 1: does the variant achieve substantially the same result in substantially the same way as the invention?
>
> Question 2: Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?

> Question 3: Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

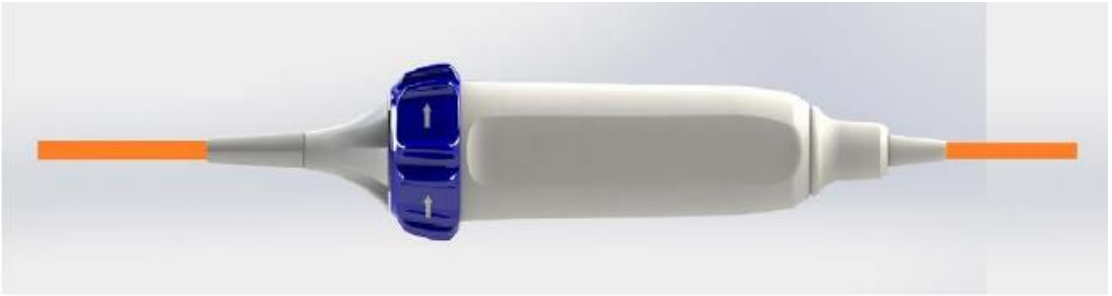
222. Also relevant is that in ***Icescape v Ice-World*** [2018] EWCA Civ 2219 the Court of Appeal considered how to approach the first ***Actavis*** question (which the court called the first ***Improver*** question). Kitchin LJ at paragraphs 58-67 explained that part of what is required to answer it is to identify what is the "inventive concept" or "inventive core" of the patent:

> "The first Improver question, whether the variant has a material effect on the way the invention works, was addressed by Lord Neuberger at [60]. He thought this was generally satisfactory but the court must focus on "the problem underlying the invention", "the inventive core", or the "inventive concept". In effect the question is whether the variant achieves the same result in substantially the same way as the invention".

223. In other words one should examine what is the problem underlying the invention and how does the patent solve that problem. Since it will be necessary to deal with the inventive concept when addressing equivalents, I will address equivalents after addressing obviousness.

224. I now turn to claim 1 in relation to the variant products about which Meril seek a declaration of non-infringement, and then the dependent claims.

225. Device A looks like this:



226. There are clearly no indicia, no flex indicating member and not really a flex indicating device (even though there is a flex activating member). Edwards accepts this device does not infringe.

227. Device B looks like this:

228. Infringement turns on the issue of construction I have already decided. As I have construed the claim this infringes. It provides a visual indication. The indication is of the amount of flex because the user can see how much flex is imparted by the distance of travel in the slot. The fact the end of the slot which corresponds to straight or to fully flexed is not indicated by a special graphic does not avoid infringement.

Dependent claims

229. The dependent claims said to be infringed are 3, 4, 5, 6, 8, 9, 12 and 13.

230. They are all dependent on claim 1 and so unless that claim is infringed, none of the other are. For this purpose I will assume the Navigator is within claim 1. I believe the only dependent claims which are in dispute on infringement are claims 6, 12 and possibly 4. It is helpful to address them all briefly.

231. Claim 3 (the flex activating member comprises a rotatable member) is infringed by the Navigator with its rotatable knob.

232. Claim 4 relates to the internal arrangement in the handle driven by the rotatable knob. It requires the rotatable member to have two threaded surface portions – internal and external. The internal thread receives a slide member, i.e. the pulling nut. The slide member is connected to the pull wire. The external thread receives an "extending portion" of the flex indicating member. In other words the flex indicating pin has a lug which engages the external thread.

233. Dr Solar maintained that in the Navigator handle (see internal diagram above) the rotatable knob did not have an externally threaded portion albeit he accepted that turning the knob did turn the thread. I think his evidence was based just on the difference in colour of the two parts in the diagram (purple and grey). In my judgment that is no basis for a finding of non-infringement. It is manifest that they are firmly fitted together in some way so that they act as one piece and turning the knob either way turns the thread appropriately. If there was more to it than that then the burden was on Meril to bring forward proper evidence. In truth, as depicted in the internal diagram, the Navigator handle has all the features of claim 4.

234. Claim 5 depends on claim 4 and is a long way of saying that the various parts defined in claim 4 have to move in the manner they move in the patent – turning the knob moves the pulling nut and that changes the amount of flex and at the same time turning the knob also causes the indicator pin to move in the slot to indicate the amount of flex. The Navigator satisfies claim 5.

235. Claim 6 requires the handle to have a lumen which receives "a proximal end portion" of the guide tube. This stands or falls with claim 1. If claim 1 was infringed then the Navigator would satisfy this claim.

236. Claim 8 is dependent on claim 6 (or 7). It relates to an inner sleeve on which the slide member (i.e. the pulling nut) can slide. The Navigator has this. The inner sleeve is labelled "central shaft" in the diagram of the internal workings of the Navigator handle.

237. Claim 9 depends on claim 8. It spells out that the slide member (i.e. the pulling nut) has an external thread which mates with the internal thread of the rotatable member required by claim 4. This is also satisfied by the Navigator.

238. The next relevant claim is 12, which needs to be seen with claim 11 on which it depends. The arrangement claimed is a mechanism to prevent relative rotation between the slide member (i.e. the pulling nut) and the inner sleeve, while permitting the slide member to slide along the inner sleeve. This works by having two sets of grooves which line up. One set of grooves is in the slide member and the other set is in the inner sleeve. That is claim 11. There is an elongated rod which fits into both grooves. That is claim 12. With the elongated rod in the grooves the relative rotation between the two parts is prevented. This allows the slide member to pull the pull wire instead of just spinning as the knob is turned.

239. There is a pin and groove arrangement in the Navigator (see fig 37A of the PPD) but it is configured in a slightly different way. Edwards contended it infringes claim 12 on the doctrine of equivalents.

240. The difference is that although in the Navigator the slide member (pulling nut) has grooves, the inner sleeve (aka central shaft) does not. Instead the inner sleeve has a pair of elongated ribs or "guide rails". These ribs stick out from the inner sleeve and fit into the grooves on the slide member. They prevent relative rotation between the two parts while allowing one to slide relative to the other. So instead of a system of one groove on each part and an elongated rod which fits in both grooves as claimed, there is a groove in one part and an elongated rib sticking out of the other part. In my judgment if claim 1 is infringed (e.g. under the doctrine of equivalents) then this claim too would also be infringed via its own equivalents analysis. The Navigator's arrangement does not satisfy claim 12 on a normal construction but the variant is that the elongated rod or pin has been fixed to the inner sleeve, from where it can still run in a groove in the sliding member. That makes no difference to the way this invention (in claim 12 dependent ultimately on claim 1 etc) works and that lack of a difference would be obvious to a skilled person. The skilled person would not read the claim language as showing any intention to deliberately exclude such an arrangement. I conclude that if claim 1 is infringed, so is claim 12.

241. Claim 13 (retaining pin securing the pull wire) is also infringed.

Obviousness

242. The skilled person and the common general knowledge have been addressed above. In terms of inventive concept, the claim has been construed above but it is helpful to identify what a skilled person would regard as the concept underlying it. What claim

1 really amounts to is an improvement on what was then a well known steerable transcatheter delivery system for prosthetic aortic valves, the improvement being means to give the operator a visual indication of the amount of flex at the distal end using a flex indicating member and indicia in the proximal handle of the delivery system.

243. Various starting points for obviousness were relied on by Meril. Two distinct arguments arise over Marchand and it is worth distinguishing between them. One relates to the embodiment in Marchand which is basically the Retroflex system whereas the other is focussed on an alternative embodiment in the Marchand document. The various cases I will address are:

i) Marchand – alternative embodiment

ii) Marchand – Retroflex embodiment

iii) Falwell

Marchand

244. Part of Marchand describes what was the then common general knowledge Retroflex system. For example, figure 1 looks like this:

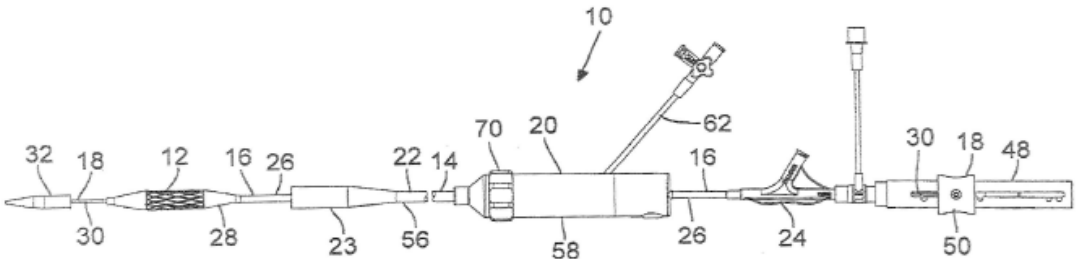


FIG. 1

245. That is Retroflex. Note also its similarity to figure 1 of the 929 patent. The user imparts flex on the distal portion by turning the knob. As I have construed the claim, this does provide an indication of the amount of flex but does not provide indicia because the tactile feedback provided by the limits on turning the knob is not visual.

Marchand – alternative embodiment

246. However, Marchand contains an alternative embodiment shown in figs 11-18 and uses a lever on the handle. A representative image is fig 18A:

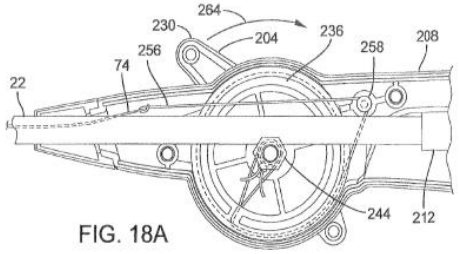


FIG. 18A

247. The description of this embodiment starts at para [0098]. There is an adjustment lever 230 connected to the handle portion which can be pivoted distally and proximally to adjust the curvature of the shaft 22 (which is the guide catheter). When the adjustment lever is forward, the steerable section is in its normal non-deflected state (e.g. straight or slightly curved). Paras [0103] to [0105] describe the features of the lever relevant to this case. When the lever is in its rearward-most position, this corresponds to the fully curved position of the steerable section of the shaft. The pull wire is wound around a pulley in the handle which holds the pull wire taut, and the rotation friction of the pulley can be varied. Marchand anticipates that a user might pull back the guide catheter inadvertently while there is still flex in the catheter. It suggests that the friction on the pulley is such that the pulley can rotate towards the forward-most position to allow the steerable section to straighten out as it is pulled through. Marchand also discloses that the adjustment lever provides substantially 1:1 deflection of the steerable section in response to movement of the lever. Importantly it then states:

> "In this manner, the adjustment lever 204 provides the operator tactile feedback of the curvature of the steerable section to facilitate tracking through the vasculature"

248. Meril submitted that the lever itself is a flex indicating device. I agree. Dr Doshi acknowledged that a 1:1 deflection approach would be more desirable and that the position of the lever would indicate the degree of flex. In fact as I have construed the claim such that the Meril Navigator and Navigator Device B systems infringe, this falls within claim 1 regardless of 1:1 deflection (subject to slot feature K - see below). However on Meril's case these systems do not infringe, and Meril's argument is that it would be obvious to add some graduation markings beside the lever. In case I am wrong on construction I will deal with Meril's obviousness case.

249. Meril submitted that graduation markings (what Meril called indicia) are common place in medical devices and whereas they may not be required universally one can think of almost no circumstances where they would not be obvious to add. In cross-examination Dr Doshi agreed that putting some numbers down the side of the lever would not be a particularly clever or inventive thing to do. Dr Solar also said in cross-examination that he thought that putting markings on the handle of Marchand to indicate whether or not the tip was flexed was a pretty obvious idea.

250. Meril also relied on Dr Brecker's evidence about the utility of a visual indication. I accept his evidence about safety being the bread and butter of interventional cardiology but I am not so sure his particular views about the utility of a visual indication of flex in the abstract, are free from hindsight knowledge of the utility of that indication in the Edwards commercial systems which put the 929 patent into practice.

251. Nevertheless in my judgment these aspects of Dr Doshi's and Dr Solar's evidence represent the thinking of the uninventive skilled team when applied to the alternative embodiment in Marchand. No hindsight is involved here because the device already provides a visual indication of flex by the position of the lever. I find that it would be an obvious improvement, and indeed a trivial modification, of the alternative device in Marchand to place numbers or some other visual scale beside the lever 204.

Therefore on Meril's case as to the true scope of claim 1, subject to the slot, it would be obvious.

252. That leaves the slot question. Edwards argued that feature K was not satisfied by the alternative embodiment. Meril contended that it was, because the lever sits on a shaft, or slot, marked 244 in Figure 14 of Marchand. I agree with Meril. As disclosed in Marchand there is a slot in the handle which receives a portion of the lever (the lever is the flex indicating member). The slot is buried inside the handle and is not visible but that does not matter from the point of view of feature K.

253. Therefore claim 1 is invalid. On my construction it in fact lacks novelty but even on Meril's case on construction which is intended to lead to non-infringement of its devices, the claim is obvious.

Marchand alternative embodiment –the dependent claims

254. The dependent claims said to be independently valid are 2, 4, 5, 7, 8, 9, 11, 12, and 13.

255. Meril summarised its case on the dependent claims as being that they related to trivial engineering and had no inventive subject matter in the event that claim 1 was obvious. However things are not that simple for various reasons. First the starting point is critical. At the moment I am considering a device based on the alternative embodiment in which labels such as numbers have been put beside the lever. I will call it the "Labelled Marchand Alternative". I do not believe Meril really advanced a detailed case aimed at the dependent claims based on the Labelled Marchand Alternative. Also in terms of evidence directed to these issues, the cross-examination was focussed on making changes to a system like the Retroflex embodiment with a knob as the flex activating member. I will address that below. Another way of putting the case was, I think, that a skilled team who had made or at least conceived of the Labelled Marchand Alternative would, in order to make a better system, start taking forward the mechanism of the Retroflex embodiment instead. I reject that. It is unreal and loaded with hindsight.

256. Claim 2 would fall with claim 1 based on the Labelled Marchand Alternative. Using numbers as the visual marking beside the lever is obvious.

257. Claims 4 and 5 are plainly distinct from the Labelled Marchand Alternative. It would not be obvious to make modifications to the Labelled Marchand Alternative itself which arrived within claims 4 or 5. Although I have accepted in the previous paragraph that the lever could be a rotatable member, these claims relate to an entirely different kind of rotatable member (the knob).

258. Meril contended that claim 7 (which is dependent on claim 6) requires a side arm which was present in Retroflex. I am prepared to accept that but it does not establish the claim is invalid over this alternative embodiment. Absent any other point, I hold claim 7 would not fall with the Labelled Marchand Alternative.

259. Claims 8 and 9 would not fall with the Labelled Marchand Alternative, nor would they be obvious. They relate to a different internal arrangement in the handle, based

on the flex being imparted by rotation of a knob, not pulling a lever. Since claims 11, 12 and 13 are dependent on claim 8 or 9, they would not fall for obviousness either.

Marchand – Retroflex embodiment

260. Although I have taken this second, this is really the occasion to consider the argument over Marchand as a whole. Given their common general knowledge the skilled reader would recognise the first embodiment of Marchand as Retroflex. They would appreciate that the document may not correspond in every detail to the commercial device – there may be features of the commercial device not in the document and vice versa, but the correspondence would be apparent.

261. In fact this obviousness case is the same as the obviousness case over Retroflex as a prior use. The difference between Retroflex and claim 1 of 929 is that there is no visual indication of flex, i.e. no indicia. As I have interpreted claim 1 the stops at the end of the rotation of the knob provide a tactile indication of the amount of flex but not a visual one. The approach said to be obvious by Meril and supported by Dr Solar and Dr Brecker's evidence would be that the idea of a visual indication of the amount of flex such as is provided by the pin moving in the slot of the 929 patent, was obvious. Analytically this involves two things – the idea of wanting this kind of indicator at all and working out a way to do it, but they interact.

262. I was not persuaded by this obviousness case. When one knows about the 929 patent, the indicator pin in slot mechanism looks simple. And when Meril's case was put to Mr Rourke, it was put at a high level of generality. However the flaw was exposed in the cross-examination of Dr Solar. It sounds simple to say that if you wanted a visual indication you could just put a slot in the handle in order to see the slide nut. However in fact the slide nut is inside the shaft with its internal thread which is part of the knob. See fig 3B of Marchand:

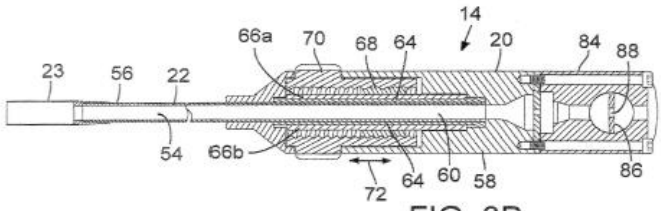


FIG. 3B

263. Dr Solar's clear view was that installing a visual indication of flex was obvious but he had clearly not thought the mechanics through. The simple proposal does not work.

264. When the question was put, Dr Solar suggested making the shaft from some form of transparent material. I agree a skilled team might do that, but in my judgment this amounts to a hindsight driven step by step analysis which is unfair to inventors.

265. The other aspect of this issue is whether the team would think of embarking on the provision of a visual indication of the amount of flex at all. I was less convinced by Edwards' case on this. At a conceptual level I doubt there is anything inventive in the idea, if it could readily be done, of providing such an indication. It is not inventive to think that the operator of a tool would like as much information as possible about the configuration of the device which would otherwise be hard to discern. However I

reject as too simplistic, an approach which says that the skilled team would decide they wanted this sort of visual indication, by any means, and then set a task for the engineer to provide it. In some cases the advantages of a goal will carry forward a development exercise even if the skilled team does not immediately know how to achieve it. But for the skilled team with the common general knowledge in July 2008 this idea is not that worthwhile. For the uninventive skilled team in this case, the idea of providing a visual indication, and feasible mechanism to provide it, go hand in hand. If the thought occurred to the team in the first place, unless a feasible mechanism presented itself, the idea would not be taken forward. There was no obvious feasible mechanism.

266. Another proposal was to change the gearing of the knob so that it was a single turn between fully flexed and unflexed. The relevance of this depended on a construction of claim 1 different from the one I have adopted. However in any case I was not persuaded it was an obvious thing to do. The only motive is hindsight.

267. Finally, in case it matters, I will say that if the team did construct a flex indicating mechanism along the lines proposed, it would be obvious to put a graduated scale or some other visual marking on it.

Marchand – Retroflex embodiment – dependent claims

268. I have rejected the attack on claim 1 based on the Retroflex embodiment. Nevertheless I will consider the dependent claims said to be independently valid. They are 2, 4, 5, 7, 8, 9, 11, 12, and 13.

269. The features of claims 7, 8, 9, 11, 12 and 13 are in Retroflex. Therefore these claims stand or fall with claim 1.

270. If, which I have rejected, the skilled team did come up with the idea of cutting a slot in the handle to see the slide nut and then making the internal shaft transparent, adding graduated scale markings like numbers on the handle beside the window would be obvious. Therefore claim 2 would be obvious if claim 1 fell for that reason.

271. However even if the skilled team came up with that idea (cutting a slot and making the internal shaft transparent to see the nut), that does not bring the device within claims 4 and 5. The mechanism in those claims is a neat practical engineering solution to the problem of how to show what is going on inside the handle. Instead of showing the operator the slide nut itself, a second external thread is put around the internal shaft in order to mount an indicator pin which will act as a proxy and indicate what is going on inside. Mr Rourke called it a clever mechanism.

272. In cross-examination the idea of putting an external thread on the shaft was put to Mr Rourke. His answer was that it was "somewhat less straight forward" than the idea of cutting a slot to see the slide nut and then, as Meril are entitled to emphasise, he did agree when pressed that it was "a technical option". I did not interpret Mr Rourke's testimony overall as a concession that he thought the approach was an obvious one for the skilled engineer. His answer was expressed with a degree of understated courtesy. He was accepting that it could be done but that was all. (The transcript shows that the question mistakenly suggested the external thread was to go on the slide nut but I am

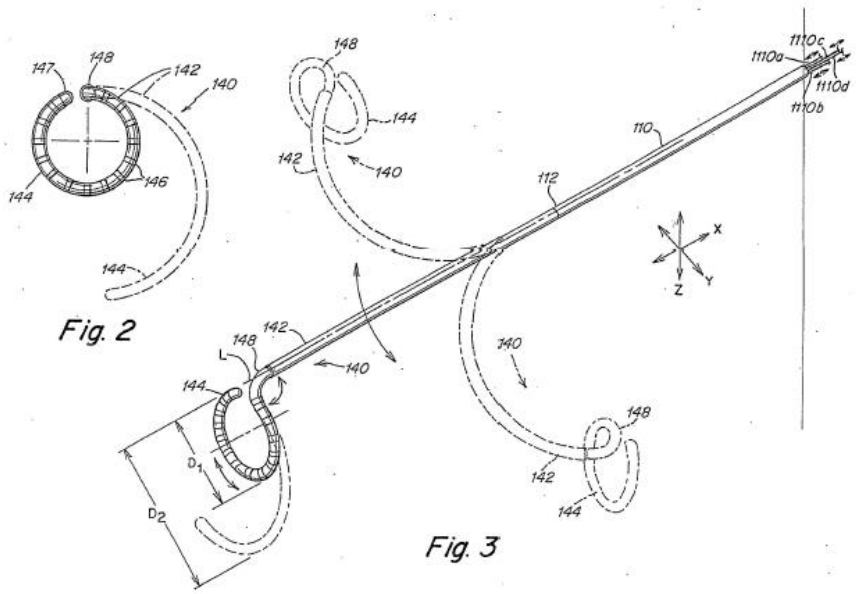
sure Mr Rourke understood what was intended – that the external thread goes on the shaft.).

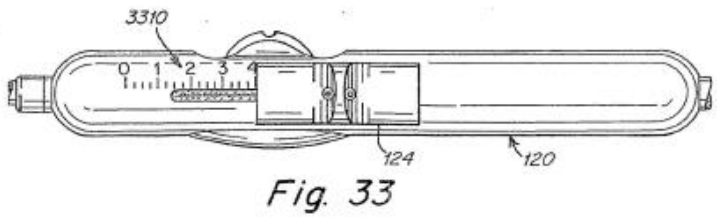
273. I agree with Edwards that this does not prove there is nothing inventive in these claims. The fact it could be produced is necessary but not sufficient to establish obviousness in this case. No example of a similar mechanism in any other medical device was drawn to my attention. I am not satisfied it would be obvious for a skilled team, even if they had decided to come up with some kind of visual indication of flex to be added to a Retroflex type delivery system, to think of the mechanism in claim 4 (and therefore necessarily claim 5).

274. In my judgment claims 4 and 5 are independently inventive over claim 1 starting from Retroflex or the Retroflex embodiment of Marchand.

Falwell

275. The Falwell patent is concerned with electrophysiology catheters. The following images from Falwell are sufficient:





276. The tip of the catheter device is shown in figs 2 and 3. An example of a handle for the operator is shown in fig 33. The shape of the tip is adjustable. In fact it is adjustable in two senses, shown by the dashed images in figs 2 and 3. The adjustments are made using actuators in the handle (e.g. slider 124). Whether these movements amount to "flex" within claim 1 of the 929 patent does not matter. I would hold that they were but even if not, the skilled team, bearing in mind the common general knowledge of steerable delivery systems for prosthetic heart valves

(Retroflex) and reading Falwell with interest, would identify the simple analogy that adjustments via fittings on the handle in Falwell control the configuration of the distal end, just as adjustments via fittings on the handle in Retroflex do the same. Fig 33 is not the only example of a handle in Falwell but the skilled team would see that the handle in fig 33 has a slider and a thumb wheel. The slider also has a graduated scale, therefore the handle provides a clear visual indication of the degree of adjustment imparted to the distal end.

277. The skilled team given Falwell and having Retroflex in mind as part of their common general knowledge might consider adopting the slider approach (with the graduated scale) to control the steering of the Retroflex. However I do not believe Dr Solar thought it was obvious, his evidence was in fact based on taking the graduated scale but not the slider. I find this option (adopting the slider) was not obvious, mainly because there is just no obvious reason to do it. The fact the slider itself provides a visual indication would not be a sufficient reason to abandon the fine control of flex provided by the knob in Retroflex.

278. In case I am wrong, even if the knob on the Retroflex was replaced with the slider of Falwell, with its graduated scale, then I suppose that would produce a device which would fall within claim 1 (the slider will side in a slot). It would not be within claim 3 (the slider is not a rotatable member) nor claims 4 or 5 (no threads), nor claim 8 (no inner sleeve) or later. It would I think be within claim 6.

279. The alternative case was that the graduated scale in Falwell would be seen by the skilled team and they would think it was worth adding such a visual indication to Retroflex. To the extent that is said to take the team down the same path as in the case over the Retroflex embodiment of Marchand, I reject it for the same reasons. Seeing the scale in Falwell would not give the team sufficient motivation to overcome the practical problems identified with that case above. To the extent that the argument over Falwell is that the graduated scale would lead the team to think about putting in visual indicia related to the knob itself, which I think is what Dr Solar actually thought, I am not persuaded that is obvious because the knob in Retroflex rotates through more than one cycle. One would have to think of limiting the travel of the knob to a single cycle to make this work. That could be done in theory but it would not be obvious.

280. I reject the case over Falwell.

Added matter

281. Three grounds for added matter were advanced. The first was about the indicia feature. This was said to have been disclosed in a specific context in the application as filed (related to figs 35A and 35B) but then generalised by being added to claim 1. The second was more or less the same point but in a different way, namely that flex indicating devices with indicia were only disclosed in the context of devices which could perform off balloon crimping and not in a broader context equivalent to claim 1.

282. I reject both grounds. The only specific features Meril identified which relate to the specific context in which the indicia are disclosed are off balloon crimping (A) and the ability of the balloon catheter to slide relative to the guide catheter (B). The skilled reader reading the application as filed would not think the indicia had any

relevant technical relationship with either or both of A or B. Therefore putting that feature into a generalised claim like claim 1, which is not limited to A or B, does not add matter. There is no intermediate generalisation. There are no other specific features aside from A or B which merit consideration.

283. The third ground is contingent on a construction of claim 1 I have rejected. The argument is that in the application as filed the balloon catheter and guide catheter are disclosed as distinct things and so, if the claim properly construed covers a system in which they can be the same thing, there is added matter. Even if I had construed claim 1 as Edwards urged on this topic, I would reject the added matter argument. It fails because at best the claim on Edwards construction would be wide enough to cover such a system, but it would not provide a new teaching disclosing such an arrangement (see ***AC Edwards v Acme***).

Equivalents

284. The issue of infringement by equivalents was left over to be addressed once I had dealt with obviousness, since that involves consideration of the inventive concept and problem(s) to be solved.

Actavis question 1

285. The variant is that instead of a separate and distinct guide catheter and balloon catheter, the Navigator device has a single structure which acts both as a balloon catheter and also can be flexed by the pull wire actuated from the handle.

286. The inventive concept relevant to claim 1 is an improvement on what was then a well known steerable transcatheter delivery system for prosthetic aortic valves, the improvement being means to give the operator a visual indication of the amount of flex at the distal end using a flex indicating member and indicia in the proximal handle of the delivery system.

287. In my judgment the Navigator provides the same advantages as the claimed invention and in the same way. The fact that the pull wire is attached to part of the balloon catheter and so there is no need for a separate guide catheter makes no difference to the way the invention of claim 1 works. The fact the Navigator does not take advantage of the benefit of a separate guide catheter, such as the ability to have relative movement between guide catheter and balloon catheter during deployment, does not matter because that feature is not germane to the way the invention works. The fact there is no facility for off-balloon crimping does not matter.

288. There was a suggestion that Edwards' evidence was lacking because while Dr Doshi had handled the Navigator, he had not used it in practice. In a different case that might be important, but given the nature of the devices and the issues, the evidence as a whole in this case and the education into the technology that the expert evidence has provided, allows the court to draw the necessary inferences.

Actavis question 2

289. The skilled person is treated as knowing that the variant achieves substantially the same result as the invention. The question is whether it is then obvious to them that

the variant achieves that result in substantially the same way as the invention. This criterion is satisfied in this case.

Actavis question 3

290. I do not believe the skilled reader would conclude that the patentee intended that strict compliance with the literal meaning of the claim language which provides for a guide catheter (and its elements) was an essential requirement of the invention so as to exclude a case in which the pull wire is attached inside the balloon catheter so that it is the balloon catheter itself rather than the guide catheter which is flexed. The reader would see that the inventor described the invention by reference to what was then a conventional set up with a balloon catheter and separate guide catheter. The reader would see that the inventor recognised that off-balloon crimping – which does require both catheters and relative movement – was not an essential feature of the flex indication invention and so claimed the flex indication invention separately from it.

Equivalents - conclusion

291. I conclude that the Navigator would infringe claim 1 (if valid) under the doctrine of equivalents.

292. Although I have concluded claims 1 and 2 are invalid, the dependent claims found valid are 4, 5, 7, 8, 9, 11, 12 and 13. Of these, claims 4, 5, 8, 9, 12 and 13 have been found to be infringed already, assuming claim 1 was satisfied. There is no reason to revisit my conclusion in the light of the equivalents analysis applied to claim 1. There is no reason not to find infringement by a double but distinct application of equivalents to claims 1 and 12.

Conclusion

293. In summary my conclusions are that the Meril Navigator device infringes valid claims of EP (UK) 3 494 929 whereas the only relevant claim of patent EP (UK) 1 267 753 is invalid.

294. In more detail:

i) The Myval product falls within claim 1 of patent EP (UK) 1 267 753.

ii) Claim 1 of the 753 patent is invalid for obviousness. The other grounds of invalidity of that claim which were relied on are rejected.

iii) Claims 1 and 2 of patent EP (UK) 3 494 929 are invalid in the light of the alternative embodiment of Marchand. Claims 4, 5, 7, 8, 9, 11, 12 and 13 are independently valid and so the 929 patent is partially valid.

iv) The other grounds of invalidity relied on against the 929 patent are rejected.

v) The Navigator product infringes the 929 patent because it infringes the following independently valid claims: 4, 5, 8, 9, 12 and 13 as they are dependent on claim 1. The literal infringement of claims 1 and 12 was not established but Navigator infringes each of them on the doctrine of equivalents.

vi) Device B proposed by Meril infringes the same claims of 929 as the Navigator and a declaration of non-infringement is refused. Undisputed Device A does not infringe.