

IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 31/07/2009

Before :

MR JUSTICE MANN

Between :

OCCLUTECH GmbH

Claimant

- and -

AGA MEDICAL Corp

Defendant

And

DOT MEDICAL Ltd

Third Party

MR. P. PRESCOTT Q.C. (instructed by **Messrs Marks & Clerk Solicitors**) for the
Claimant.

MR. M. HOWE Q.C. (instructed by **Messrs Hogan Hartson**) for the **Defendant.**

Hearing dates: 24th, 25th, 26th March, 6th & 7th April 2009

Judgment

Mr Justice Mann :

Introduction

1. This is a patent action in which the claimant (“Occlutech”) seeks a declaration of non-infringement in respect of some of its products, and the defendant (“AGA”) counterclaims for infringement and joins the third party (Occlutech’s importer) for that purpose. Occlutech also seeks the revocation of the patent on the grounds of obviousness. The revocation grounds have been narrowed since the commencement of action (and indeed since the beginning of the trial) by the dropping of certain pieces of prior art and attacks based on them. The dropping of one of those pieces of prior art has also led to the abandonment of an application to amend the patent. The result is that there is now only one piece of prior art which is said to found an obviousness attack.

The patent in suit

2. The patent in suit concerns medical devices. What is said to be one of its principal benefits is in the field of the occlusion of blood vessels and other bodily tubes, though the claims do not confine its application to that or indeed to any particular medical use. The device is made of braided metal fabric, typically made of nitinol (a nickel-titanium alloy) which has a good “memory” for shape. If a tubular structure made of nitinol fabric (typically braided) is heated while being moulded to the desired shape, when it is subsequently deformed it will tend to spring back to its moulded shape. That lends itself to being introduced through spaces in a squashed-up way, and it can then be released so that it springs out into its desired larger shape. Thus it can be initially shaped into a shape and size which is desired to block a vessel, squashed into a roughly tubular form which enables it to pass down a catheter, guided down the catheter and then released at the end, at which point it springs out to adopt its (larger) desired form, lodges there and starts occluding the vessel (or fulfilling another purpose). The general shape of the device when deployed is described as dumbbell-like, as illustrated in figure 5 of the patent which is reproduced in Appendix 2 to this judgment.

The claimant’s products

3. This action started life as a claim for revocation of the defendant’s patent, and for declaratory relief in respect of two of the claimant’s products - their “old” and their “new” devices. It sought a declaration (under the inherent jurisdiction, not under section 71 of the 1977 Act) that its two products did not infringe. In due course, and in accordance with established procedures, the claimant served product and process descriptions (“PPDs”) in respect of each of its two products. The old type was said to have been no longer manufactured. The evidence was that it was last manufactured in January/February 2008. Occlutech also provided what it said were samples of each of those products. However, at that stage there was an error. Instead of providing one of each type, it turned out that it provided two old types. A new type was not provided until towards the end of the trial. An investigation of that sample demonstrated that it accorded with the PPD for the new type, but Mr Howe submitted that there was no evidence that a version of that was ever sold in the UK, and that I should refuse a declaration of non-infringement in relation to it.

4. The evidence called by Occlutech of its manufacturing process and procedures was less than clear about the production line provenance of the sample new product, and unnecessary confusion was caused by the attempts of Occlutech to provide samples. However, Occlutech have pleaded importation of the new device, and we have had a trial about it. In the light of that pleading and the way the trial went, it would be an odd thing to do to decline to decide the point on the basis suggested by Mr Howe, and I shall not accede to his submission. I will determine the declaration point in relation to both the old and new products.
5. I should, however, provide a little more clarification of what those products are for these purposes. The evidence I heard referred to two sorts of devices to which this technology can be applied. The first are called PFO (patent foramen ovale) occluders and the second are ASD (atrial septum defect) occluders. PFO occluders are intended to be used in heart defects where there is an undesirable gap in the atrial wall in the heart caused by an overlap of the wall without proper fusion. This is remedied by a PFO occluder in which one disk sits in each atrium with a relatively thin middle section situated in the gap. An ASD occluder is intended to remedy a hole in the atrial septum. Again, each disk sits in each atrium respectively, but this time the connecting central section is relatively wider, sometimes being almost as wide as the defect itself (so that it fills it). These occluders are also used where the defect is a fenestration - several "holes". In this case the disks are sized to cover more than one hole, with the central section occupying one of the holes.
6. Because of their different anatomical situations and purposes, the difference between these two types of devices is in the relative sizes of their central sections - PFO narrower than ASD. They both, however, share one characteristic which differs from some of the modus operandi contemplated by the patent in suit. Those modus operandi (not reproduced in the claims) are those involving the positioning of an occluder in a vessel. In that position the rings of the dumbbell exert an outward force, pushing against the walls of the vessel in order to lodge there. The dumbbell shape is intended to stop tumbling (patent para 0053). The PFO and ASD devices are not positioned or fixed in the same way. They are held in place by the natural inward "pinching" forces which the disks exert along the axis of the device, those forces holding each disk against its proximate atrial wall. For that purpose the central section is said (by Mr Prescott) to be shorter than would be the case for a vascular occluder, and the appropriate metaphor would be yo-yo, not dumbbell.
7. The difference between PFO and ASD devices is relevant to one limited aspect of this dispute. The claim for a declaration of non-infringement is pleaded as relating to devices that Occlutech provided to AGA. After some confusion at the trial, it became apparent that those two devices were PFO devices. Since then some ASD devices were provided to AGA. There was some debate as to the devices to which any declaration should relate. As a result of that debate, and bearing in mind the circumstances in which the later devices were supplied (which included confusion as to which generation they were) I determined that any declaration would relate only to the PFO devices supplied (one old, one new) and not to any other devices. By the same token, I shall deal with infringements in relation to those devices. However, the debate in this case also applies to ASD devices that I was provided with. As far as I can see, there is no material difference between them and PFO devices for the purposes of this action, and while they may technically not be the subject of the

pleaded case, in my view their fate (in terms of infringement and non-infringement) is exactly the same.

8. The products in respect of which declarations of non-infringement are sought are described in a process and product description and the same description can be taken as applying to all the allegedly infringing products if different from those which are the subject of the declaration. The old and new are essentially the same apart from the method of fixing the loose strands of the devices. The common elements are as follows:
 - i) A braided fabric formed from monofilament nitinol wires is used.
 - ii) It is formed into a sock. The distal end (farthest from the open end of the catheter) is closed; the proximal end is open and terminates in some loose wires which are not braided, or not braided to the extent that they form a fabric.
 - iii) The sock is placed into a mould conforming to the shape of the final intended product. The end with the ends of the strands protrudes through a hole at one end of mould.
 - iv) The mould is then heated to a temperature sufficient to make the nitinol keep its desired shape. That shape in the picture is of two saucer like disks, one slightly smaller than each other, separated by a wider mid-piece, though the actual products that I have seen do not reflect that difference in shape. Nothing turns on that.
 - v) The newly shaped product is then removed from the mould.
9. At this point the old and new products depart. The next stage, according to the description, is the fixing of the loose ends of the device - what was formerly the open end of the sock. According to the description, but as supplemented by further oral evidence, the following steps take place in relation to the old Occlutech device.
 - i) A copper wire is round around the loose ends of the strands at their ends to gather them together for the next phase.
 - ii) Then a nitinol sleeve in the form of a hollow cylinder and having an internal diameter slightly larger than the diameter of the bundle of nitinol wires is slid up the gathered wires and the assembly inverted to stop the sleeve falling off. Then the copper wire is removed. The wire is sufficiently loose to be able to be slipped off.
 - iii) The protruding wires are cut flush with the proximal end of the sleeve, by a laser beam. The assembly is retained in the inverted position.
 - iv) The bundle of wires is then subjected to microplasma welding to fuse the wires together and to the nitinol sleeve. "The ends of wires have been merged together with each other and with the proximal end of the sleeve to form a welded clot of nitinol."

- v) An adaptor “for delivery purposes” may then be fitted. It is cylindrical and its distal end is of a size to mate with the nitinol clot; the proximal bore is internally threaded. It is pushed over the clot of nitinol and spot welds applied by laser beam to deform inwardly the inner and outer walls of the adaptor. The adaptor has an internal thread at its proximal end for fixing it on to the delivery wire.
10. It should be noted from this description that only one end of the device is subjected to this welding and sleeving process. The other end is the former closed end of the sock - the fibres pass continuously around it.
11. For the new device the sock and moulding processes are essentially the same. The differences come after the moulding process.
12. At this point the device is put in a template which has a hole through which the loose ends of the device protrude. Then the following steps take place:
- i) The loose ends are cut almost, but not quite, flush with the face of the template, by using a laser beam. Short lengths are left protruding.
 - ii) The loose ends are subjected to microplasma arc welding to fuse the wires to each other. They form a welded nitinol clot.
 - iii) At that point the device is in its final configuration save for the addition of an adaptor for delivery purposes.
 - iv) As with the old devices, the adaptor is a sleeve which fits over the clot and is threaded at the proximal end. It is pushed over the clot and weld spots are applied radially by means of a laser beam. This deforms the inner and outer walls of the adaptor.
13. Accordingly, as with the old devices, the welding and other operations go on at one end of the device only. The other end is still the closed end of the sock, formed by the fibres passing round and returning to the originally “open” end.
14. This method of fabrication raises questions of construction to which I will have to return. The points are whether there is any clamp at all in this device, and if so whether it is at one end or both ends.

The patent in suit

15. The claims which are relevant to this action are set out in appendix 1. The relevant parts of the description are as follows. (I omit most of the cross-references to the figures where they are not necessary for the purposes of this exposition.)
16. Paragraph 1 of the description describes the invention in general terms:

“The present invention generally relates to intravascular devices for treating certain medical conditions. The devices in accordance with the invention are particularly well suited for delivery through a catheter or the like to a remote location in a

patient's vascular system or in analogous vessels within a patient's body.

0002 A wide variety of intravascular devices are used in various medical procedures. Certain intravascular devices, such as catheters and guidewires, are generally used simply to deliver fluids or other medical devices to specific locations within a patient's body, such as a selective site within the vascular system. Other, frequently more complex, devices are used in treating specific conditions, such as devices used in removing vascular occlusions or treating septal defects and the like.

0003 In certain circumstances, it may be necessary to occlude a patient's vessel, such as to stop flow through an artery to a tumour or other lesion. Presently, this is commonly accomplished simply by inserting e.g. Ivalon particles....and short sections of coiled springs into a vessel at a desired location. These 'embolisation' agents will eventually become lodged in the vessel, frequently floating downstream of the site at which they are released before blocking the vessel. In part due to the inability to precisely position the embolisation agents, this procedure is often limited in its utility."

17. The next two paragraphs deal with balloon catheters and their disadvantages – they may be insufficiently filled or rupture and release undesirable substances into the bloodstream. Paragraph 0006 refers to other mechanical embolisation devices which have been proposed which were said to be expensive and time-consuming to manufacture. They often had to be hand-built. The description then goes on:

"0007 Accordingly, it would be advantageous to provide a reliable embolisation device which is both easy to deploy and can be accurately placed in a vessel.

0008 According to the present invention, a collapsible medical device comprises a metal fabric formed of braided metal strands, the device having a collapsed configuration for delivery through a channel in a patient's body and a generally dumbbell-shaped expanded configuration with two expanded diameter portions separated by a reduced diameter portion formed between the opposed ends of the device, and clamps for clamping the strands of the opposed ends of the device."

18. This is the consistory clause. The reference to clamps should be noted – a question of construction arises thereafter in relation to them.
19. The description goes on:

"0009 A collapsible medical device having a dumbbell-shaped expanded configuration is disclosed in the international application WO-A-94/12136.

0010 Such devices of the invention are formed of a metal fabric and have an expanded configuration and a collapsed configuration. The devices are collapsed for deployment through a catheter and, upon exiting the distal end of the catheter in a patient's channel, will resiliently substantially return to their expanded configuration.

0011 The device of the present invention can be formed from a metal fabric formed of a plurality of resilient strands, with the wires being formed of a resilient material which can be heat-treated to substantially set a desired shape. The fabric is then deformed to generally conform to a moulding surface of a moulding element, and the fabric is heat-treated in contact with the surface of the moulding element at an elevated temperature....after the heat treatment, the fabric is removed from contact with the moulding element and will substantially retain its shape in the deformed state. The fabric so treated defines an expanded state of a medical device which can be deployed through a catheter into a channel in a patient's body.

0012 The present invention will be described, by way of example, with reference to the accompanying drawings, in which:

Figures 1A and 1B depict a metal fabric suitable for use with the invention;

...

Figures 5A and 5B are a side view and an end view, respectively, of a medical device in accordance with the invention.”

20. Figure 1A seems to show a braided structure. Figure 1B shows what has been described as a woven structure. Its presence is said to be relevant to various construction issues which arise and to which I will return. Figure 5A demonstrates the dumbbell shape which is referred to in the specification and the claims. This is the fully expanded shape. In order to get this into the body, the ends are pulled apart so that the whole thing becomes stretched and capable of being manoeuvred down a narrow catheter. As it emerges from the open end in the relevant part of the patient's body, it assumes the sort of shape shown in figure 5A because that is the shape in which it has been forced by the moulding and heating process and which it now prefers to adopt. The two end parts labelled 15 should be noted; they are later described as “clamps” on which a major infringement point turns.
21. I can now return to the specification. Paragraph 0013 again refers to figures 1A and 1B:

“Figures 1 A and 1B illustrate two examples of metal fabrics which are suitable for use.

0014 In the fabric of figure 1A the metal strands define two sets of essentially parallel generally helical strands, with the strands of one set having a ‘hand’, i.e. a direction of rotation, opposite that of the other set. This defines a generally tubular fabric, known in the fabric industry as a tubular braid.

....

0018 Figure 1B illustrates another type of fabric which is suitable for use. This fabric is a more conventional fabric and may take the form of a flat woven sheet, knitted sheet or the like. In the woven fabric shown in figure 1B, there are also two sets 14 and 14’ of generally parallel strands, with one set of strands being oriented at an angle, e.g. generally perpendicular (having a pick of about 90°) with respect to the other set.

....

0023 In preparation of forming a medical device in keeping with the invention, an appropriately sized piece of metal fabric is cut from the larger piece of fabric which is formed, for example, by braiding wire strands to form a long tubular braid. The dimensions of the piece of fabric to be cut will depend, in large part, upon the size and shape of the medical device to be formed therefrom.

....

0025 In such untreated NiTi fabrics, the strands will tend to return to their unbraided configuration and the braid can unravel fairly quickly unless the ends of the length of braid cut to form the device are constrained relative to one another. One method which has proven to be useful to prevent the braid from unravelling is to clamp the braid at two locations and cut the braid to leave a length of the braid having clamps (15 in figure 2) at either end, thereby effectively defining an empty space within a sealed length of fabric. These clamps 15 will hold the end of the cut braid together and prevent the braid from unravelling.”

The reference there to figure 2 is plainly a mistake; it is obviously a reference to figure 5A.

“0026 Alternatively, one can solder, braze, weld or otherwise affix the ends of the desired length together (e.g. with a biocompatible cementitious organic material) before cutting the braid. Although soldering and braising of NiTi

alloys has proven to be fairly difficult, the ends can be welded together, such as by spot welding with a laser welder.

0027 The same problems present themselves when a flat sheet of fabric such as the woven fabric shown in figure 1B is used. With such a fabric, the fabric can be inverted upon itself to form a recess or depression and the fabric can be clamped about this recess to form an empty pocket (not shown) before the fabric is cut. If it is desired to keep the fabric in a generally flat configuration, it may be necessary to weld the junctions of the strands together adjacent to the periphery of the desired piece of fabric before that piece is cut from the larger sheet. So connecting the ends of the strands together will prevent fabrics formed of untreated shape memory alloys and the like from unravelling during the forming process.”

22. These provisions are said to be relevant to a question of construction involving the words and expressions “clamps” and “clamped”.
23. Paragraph 0041 again refers to clamps:

“0041 As noted above, the ends of the tubular braid should be secured in order to prevent the braid from unravelling. Each end of the metal fabric 10 is desirably received within a cavity 46 formed in one of the two end plates 40 [of the mould]. If a clamp (15 in figure 2) is used, the clamp may be sized to be relatively snugly received within one of these cavities 46 in order to effectively attach the end of the fabric to the end plate 40.”

It is not necessary to follow the details of the relationship between the “clamp” and the mould.

24. Paragraph 0043 elaborates a little on “dumbbell”:

“0043Accordingly, when the moulding element 20 is completely assembled, the metal will tend to assume a somewhat ‘dumbbell’ shaped configuration with a relatively narrow centre section disposed between a pair of bulbous, perhaps even disk-shaped end sections, as best seen in figure 4.

0044 It should be understood that the specific shape of the particular moulded element shown in [the patent figures] is intended to produce one useful medical device in accordance with the present method, but that other moulding elements having different configurations could also be used. If a more complex shape is desired, the moulding element may have more parts....

.....

0053 The sizes of the tubular middle section and the expanded diameter portions can be varied as desired. In this particular embodiment, the medical device is intended to be used as a vascular occlusion device to substantially stop the flow of blood through a patient's blood vessel. When the device was deployed within a patient's blood vessel, as detailed below, it will be positioned within the vessel such that its axis generally coincides with the axis of the vessel. The dumbbell-shape of the present device is intended to limit the ability of the vascular occlusion device 60 to turn at an angle with respect to the axis of the blood vessel to ensure that it remains in substantially the same position in which the operator deploys it within the vessel.

0054 Although the illustrated embodiments of this invention only have two expanded diameter portions, it should be understood that the device could have more than two such expanded diameter portions. For example, if the device has three expanded diameter portions each expanded diameter portion is separated from at least one other expanded diameter portion by a tubular portion having a smaller diameter. If so desired, the diameters of each of the expanded diameter portions can be the same, but they need not be the same.

0055 In order to relatively strongly engage the lumen of the blood vessel, the maximum diameter of the expanded diameter portions ... should be selected so that it is at least as great as the diameter of the lumen of the vessel in which it is to be deployed, and is optimally slightly greater than that diameter The device is desirably longer along its axis than the dimension of its greatest diameter. This will substantially prevent the vascular occlusion device from turning within the lumen at an angle to its axis, essentially preventing the device from becoming dislodged and tumbling along the vessel with the blood flowing through the vessel.

0056 The relative sizes of the generally tubular middle portion and the expanded diameter portion of the vascular occlusion device can be varied as desired for any particular application. [Certain ranges are set out] Although these dimensions are suitable if the device is to be used solely for occluding a vascular vessel, it is to be understood that these dimensions may be varied if the device is to be used in other applications, such as where the device is intended to be used simply as a vascular filter rather than to substantially occlude the entire vessel or where the device is deployed in a different channel in a patient's body.

.....

0057 The aspect ratio (i.e. the ratio of the length of the device over its maximum diameter or width) of the device illustrated in figures 5A and 5B is desirably about 1.0 with a range of about 1.0 to about 3.0 being preferred and an aspect ratio of about 2.0 being particularly preferred. Having a greater aspect ratio [sic] will tend to prevent the device from rotating generally perpendicularly to its axis, which may be referred to as an end over end roll. So long as the outer diameter of the expanded diameter portions of the device is large enough to seat the device fairly securely against the lumen of the channel in which the device is deployed, the inability of the device to turn end over end will keep the device deployed precisely where it is positioned within the patient's vascular system or in any other channel in the patient's body. Alternatively, having expanded diameter portions which have natural, relaxed diameters substantially larger than the lumen of the vessel in which the vessel is deployed could also suffice to wedge the device in place in the vessel without undue concern being placed on the aspect ratio of the device.

....

0060 The clamp may serve to connect the device to a delivery system (not shown). In this case, the clamp may be generally cylindrical in shape and have a recess for receiving the ends of the wires to substantially prevent the wires from moving relative to one another, and a threaded outer surface....

....

0071 While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptations and modifications may be made therein without departing from the invention and scope of the appended claims.”

The skilled addressee

25. There was no material dispute as to the skilled addressee to which the patent should be taken as being addressed. I find it to be a team consisting of a medical devices engineer and a clinician.

Witnesses

26. The following witnesses were called.
27. **Professor David Williams.** He is currently a Professor at the Wake Forest Institute of Regenerative Medicine, North Carolina and is an expert in biomaterials with a

degree in metallurgy. As he put it, he is an engineer not a clinician. He was called by Occlutech to give evidence as to the content and meaning of certain aspects of the patent in suit, including some of the science, the skilled addressee, and common general knowledge. He also dealt with prior art, including the one piece that survived to the end of the trial. Having seen him cross-examined, it seems to me that his written report was over-condensed in some respects with the effect that some distinctions that needed to be drawn were not drawn (see below as to obviousness and the prior art). I think that he was being too brief in some of his descriptions so that he did not have to point up some matters which operated against his client's obviousness case. That is an unsatisfactory way of going about preparing an expert's report. However, in cross-examination he was forthcoming about these missing matters and was not evasive about them.

28. **Dr William Drasler.** He was called by AGA to give evidence about the technology of the patent, and certain points going to its construction. He had a background in chemical and biomedical engineering, including experience with medical devices. He too dealt with prior art. He was an extremely thorough and careful witness.
29. **Dr Stephen Brecker.** He is a consultant cardiologist who gave evidence for AGA which was said to go to infringement and obviousness. He was able to give evidence of the actual use of the sort of devices which are the subject of the patent in suit, and he was obviously very keen on devices similar to those in the patent (in that they were collapsible devices which could be introduced and repositioned, made in a way similar to those described in the patent in suit) and has used them for treating septal defects. He called them "Amplatz devices" (Amplatz being the named inventor in the patent in suit). He compared these devices to the prior art devices, though not in any depth. He gave some limited evidence, from the user's point of view, about obviousness and, also told me about the effect (or lack of it) of a clamp at the distal end. His evidence about the actual use of these things was extremely interesting, but some of it was rather limited in its relevance. He was, however, a straightforward and unbiased witness. It is necessary for me to make this last point because Mr Prescott QC, for Occlutech, started his cross-examination with some strong suggestions that Dr Brecker's impartiality was impaired by virtue of certain payments received by him. This cross-examination turned out to be based on a misunderstanding of the nature of the payments, and all imputations against his impartiality were fulsomely (and very properly) withdrawn by Mr Prescott. It is only fair to Dr Brecker to record this withdrawal in this judgment.
30. **Dr Kathrin Schmidt.** She is a manager of quality control at Occlutech and was called to prove certain features of the manufacture of the Occlutech products. She gave her evidence honestly and straightforwardly.

The claims and the disputes

31. The principal material disputes (ignoring subsidiary disputes and squeezes), in their diminished form by the end of the evidence, were as follows:
 - i) Does the patent fall to be revoked for obviousness over one particular piece of prior art?

- ii) If the patent is valid, are the claimants entitled to declarations of non-infringement in relation to the two products provided to AGA in conjunction with the PPD?
 - iii) Have AGA made out a case for infringement in relation to those Occlutech products?
32. The patent has been the subject of litigation in both Holland and Germany, where infringement by Occlutech was alleged. Infringement was found in Germany but not in Holland. I shall consider the first of those decisions in due course, but will first consider the issues without reference to them.

Prior art - “Boston Scientific”

33. By the end of the trial only one piece of prior art was relied on. It is an International Patent Application filed by a US company, no WO 94/12136 – “Boston Scientific”. It describes the following.
34. The title is: “stents for body lumens exhibiting peristaltic”. The Abstract is as follows (omitting cross-references to a diagram):
- “A stent for reinforcement of the lumen of a peristaltic organ, and methods for forming, shaping and heat-treating of such a stent. The stent is formed by knitting preferably a nitinol wire into a pattern of overlapping loops selected such that from a relaxed state each row of loops may shift axially relevant to and independently of the rows on either side. A stent is also shown which comprises two resilient cylindrical mesh layers and a semi-permeable compliant membrane such as expanded polytetrafluoroethylene, sandwiched between. A method is also shown of manufacturing a delivery system for a resilient tubular device such as a stent so that the device can be inserted into the body of a substantially reduced diameter.”
35. The background of the invention refers to stents whose function is to maintain open a body lumen, for example, a passageway occluded by a tumour. Typically the stent is to be delivered inside a catheter in a compacted form, and upon reaching the relevant site it is expanded so that it engages the wall of the lumen. Reference is made to doing this by the inflation of a balloon carried by the catheter. Particular reference is made to strictures of the oesophagus, where the theoretical advantages of placing a plastic stent to restore a patient’s ability to swallow have been offset by technical difficulty of placement, morbidity and mortality associated with the procedure, and poor long-term prosthesis performance. In particular, previous stents have transmitted the force and deformation of peristaltic waves inappropriately, sometimes causing the stent to creep towards the stomach, perforate the oesophagus or rupture the aorta.
36. The Summary of the Invention is as follows:
- “In a first aspect, the invention features a method for providing reinforcements to the lumen of a peristaltic organ. The stent is

formed by knitting a filament into interknit loops, the pattern of the loops selected such that from a relaxed state each row of loops may shift axially relative to and independently of the rows on either side. The local lengthening and shortening allowed by the shifting allows the stent to accommodate the peristalsis of the organ without migrating within the organ.”

Figs 1 and 1C are said to be perspective views of a stent according to the invention. They are set out in Appendix 3 to this judgment. In fact, Fig 1C is used to show how the knitted loops move against each other when peristalsis is taking place. The description makes it plain that the knitted structure of this device is important because of the way knitted loops move relative to each other so that the device gives and expands under peristalsis. Nitinol is one of several preferred materials. After the stent is cut to its final length, the loops at the end which would otherwise unravel are fixed with a drop of urethane to prevent unravelling. In order to be delivered, the stent is elongated and narrowed by wrapping a copper wire round it. It is then further fixed in this position by soluble gelatine and the wire is removed. This assembly is then inserted through a catheter and deployed in the body. The gelatine dissolves, allowing the stent to expand under its own elastic restoring force.

37. The description goes on:

“The shape of the stent can be selected to have a variable diameter such as a flare at one end that helps anchor the stent in a lumen that has inherent physiologic lumen wall movements such as peristalsis....the stent can also be shaped to complement the varying diameter of a body lumen.... For use in the colon, the stent can have a flare at both ends, to affix the stent to a lumen wall at both ends.”

38. Both want of novelty and obviousness over this patent were originally pleaded, but by the time of final speeches this had become an obviousness attack only, advanced as a squeeze, and taken pretty shortly.

39. There are three important points of distinction between Boston Scientific and the patent in suit that would have to be overcome by obviousness (see the test in *Pozzoli Spa v BDMO SA* [2007] FSR 372). They are knitted vs braided fabric, whether Boston Scientific discloses a dumbbell shape or whether it would be obvious to move to one, and principally open ended to allow flow through (Boston Scientific) vs clamped at both ends.

40. So far as the first is concerned, in his report Prof Williams said that the Boston Scientific device could be made equally with knitted or braided or woven structures, and would achieve the same result. That suggests that the knitted nature does not matter. Later, when addressing the question of whether the skilled person, reading Boston Scientific, would want to use a braided metal fabric instead of the disclosed knitted construction, he said:

“As noted above, I do not believe that it would make any significant difference if the device were braided or knitted, but

I do not see any particular incentive to change to a braided fabric.”

It might be thought that he was implicitly saying that it would be obvious to try a braided fabric. Certainly this is material on which the court was invited to act in finding obviousness (and indeed want of novelty, on the pleaded case). In cross-examination his position was elaborated. In sum, he said that if you used an appropriate material, with appropriate elasticity or flexibility, and braided it in an appropriate way (with the fibres a significant distance apart), you could get a device which would deform to accommodate peristalsis as the Boston Scientific device does. There are a lot more qualifications in this evidence than his report suggests. He did not express a view favouring Occlutech’s obviousness case and overall his evidence puts a significant amount of distance between Boston Scientific and the patent in suit. Dr Drasler was clear that it was not obvious to move from this knitted stent to a braided occlusion device. I accept his view on that, and on this evidence, I do not find that it would be obvious to use a braided fabric.

41. Mr Prescott sought to belittle this difference by describing the prior art as referring to a feature which is convenient but not always required - ie it is optional - and he relied on *Gillette Safety Razor Company v Anglo-American Trading Company Ltd* in support of this approach. Using knitted fabric was described as “going the extra mile” to get the flexibility required of this device. In my view this seeks to present a false picture of Boston Scientific. A knitted fabric lies at the heart of the invention - it is not some sort of optional extra. Occlutech cannot overcome this difference in this way.
42. Next, there is dumbbell-shaped. Dr Drasler’s report disputed that the Boston Scientific stent had bulbous ends appropriately described as dumbbell-shaped. In doing so it did not refer to the fact that the patent in suit itself described a dumbbell shape as being disclosed in Boston Scientific (see para 0009). Were it not for the fact that the patent describes it in this way, I would have had considerable sympathy for Dr Drasler’s view. Boston Scientific generally discloses an extended cylinder or tube, with a flared end. The only time it refers to something which might be termed dumbbell shaped is in describing a device which needs a slimmer waste, between two flared ends, in order to sit across somewhere like a sphincter. It does not look like a dumbbell to me. However, the patent suggests that it does have that shape. But even so, this allusion is some way from the sort of dumbbell shape, with its stated purpose, referred to in the patent. It forms a further bar to obviousness. I accept Dr Drasler’s underlying point that this is not something that would be bridged by obviousness.
43. Last, there is the presence of clamps in the patent, and the open ends of Boston Scientific. Actually, the point is a wider one than this. The whole purpose of the stent is to keep a lumen open, apart from one reference which refers to its being closed until pressure allows a desired opening (in effect, a valve). The principal (though not in express terms the sole) purpose of the invention in the patent in suit is to have closed ends to form a blockage. Dr Drasler said it would not be obvious to close off the Boston Scientific device by placing a clamp over the end. I agree with him. Mr Prescott said that if clamps means anything which holds the ends of the strands together, which he says is what AGA says clamps can mean, then that sort of clamp is disclosed in Boston Scientific because urethane is used to stop unravelling. I do not think that he summarises AGA’s case correctly, and anyway “clamping” is not

what happens in Boston Scientific. Urethane is used at the end of loops as a sort of glue in the holes of the end loops. It is very, very far away from any form of clamping of ends to form a closed loop, even on a definition which would include welding or simply having a closed sock-end (which are issues which I will have to resolve when I come to infringement). Therefore in this respect too Boston Scientific is too far away from the patent for the patent to be obvious over it.

44. If it needs saying, I would also find that a combination of all those elements produces an overall effect which makes it even more impossible for obviousness to be a bridge between Boston Scientific and the patent in suit.
45. Accordingly, this obviousness attack fails. There is no other obviousness or want of novelty attack, so the patent survives this attempt to have it revoked.

Infringement

46. Questions of construction arise in this area. Since all construction points arise in a particular factual context, or for a reason, rather than in a vacuum, it will be useful to indicate the context in which they arise in this case. In summary they, and their relevance to the case, are as follows:
 - i) What do “clamps” and “to clamp” mean in the patent? Are the Occlutech devices clamped within the meaning of that word in the patent, given that they are fixed by welding? This point also has a relevance to the Boston Scientific prior art, identified above.
 - ii) What does “to clamp the strands at the opposite ends of the device” mean? Are the Occlutech devices clamped at the opposed ends of the device, given that at one end the fibres wrap around and there are no loose strands to fix?
 - iii) What does “dumbbell shaped” mean? Are the Occlutech devices dumbbell shaped?

Other points which might be described as construction points arose in this case, but it is not necessary to deal with them in this section of this judgment (or, in the light of my conclusions on the main points, at all).

Clamps

47. The most authoritative correct approach to construction is the relatively recently decision in *Kirin-Amgen Inc v Hoescht Marion Roussel Ltd* [2005] RPC 9. In that case Lord Hoffman said:

“34 ... The question is always what the person skilled in the art would have understood the patentee to be using the language of the claim to mean. And for this purpose, the language he has chosen is usually of critical importance. The conventions of word meaning and syntax enable us to express our meanings with great accuracy and subtlety and the skilled man will ordinarily assume that the patentee has chosen his language accordingly. As a number of judges have pointed out, the specification is a unilateral document

in words of the patentee's own choosing. Furthermore, the words will usually have been chosen upon skilled advice. The specification is not a document *inter rusticos* for which broad allowances must be made. On the other hand ... there will be occasions upon which it will be obvious to the skilled man that the patentee must in some respect have departed from conventional use of language or included in his description of the invention some element which he did not mean to be essential. But one would not expect that to happen very often.

“35 ... The courts of the United Kingdom ... certainly discourage, if they do not actually prohibit, use of the patent office file in aid of construction. ... It is however frequently impossible to know without access, not merely to the file but to the private thoughts of the patentee and his advisors as well, what the reason was for some apparently inexplicable limitation in the extent of the monopoly claimed. One possible explanation is that it does not represent what the patentee really meant to say. But another is that he did mean it, for reasons of his own; such as wanting to avoid arguments with the examiners over enablement or prior art and have his patent granted as soon as possible. This feature of the practical life of a patent agent reduces the scope for a conclusion that the patentee could not have meant what the words appear to be saying. It has been suggested that in the absence of any explanation for a restriction in the extent of protection claimed, it should be presumed that there was some good reason between the patentee and the patent office. I do not think that it is sensible to have presumptions about what people must be taken to have meant but a conclusion that they have departed from conventional usage obviously needs some rational basis.”

48. Previously Lord Hoffman in the Court of Appeal in *STEP v Emson Europe Ltd* [1993] RPC 513 at page 522 had said:

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

49. From those extracts I discern and apply the following principles:

- i) The language of the patent is the starting point and is critical though not finally determinative.

- ii) If there is a conventional meaning of a word or expression, either in the eyes of the skilled team, or in everyday language if the words have no special meaning to the team, then a conclusion that it has some unconventional meaning requires a rational basis.
- iii) Even if a given limitation looks odd, in the sense that one cannot see why the patentee would have included it, there may nevertheless be an undisclosed reason for that oddity and one cannot assume that the oddity is unintended and betokens an unconventional meaning for words, or that the limitation should be disregarded.

50. With those points in mind I turn to the meaning of “clamps” in claim 1 (and its dependent claims). No expert suggested that this was a term of art in the field of medical devices, and Prof Williams said that he understood that the common meaning would be what the skilled addressee would take from the word, so that in a general sense “a clamp is some object that exerts force upon two or more other objects in order to keep the latter objects together”. This coincides with dictionary definitions - for example Webster’s Third New International Dictionary:

“A device (as a band or brace) designed to bind or constrict two or more parts together so as to hold them firmly in their relative position.”

Other definitions have the same import.

51. Something held together by soldering, welding, gluing or similar mechanisms would not naturally, or at least not immediately, fall within that meaning. However, one has to consider whether the patent has an extended meaning going beyond physical compression by a particular object. In my view it is plain that, on the wording of the patent, it does not. This is apparent from the following:

- i) There is a small indication from the words in claim 1 itself - “clamps are adapted to clamp the strands”. The repetition tends to suggest that the word is used in its normal sense. By itself, however, this is not strong.
- ii) The point begins to look stronger because the claim contains a cross-reference to figure 5 A via the numerical reference to “(15)”. That figure appears in Appendix 2 to this judgment. It shows something which is fairly clearly representative of a clamp.
- iii) The more one reads the description and the embodiments the clearer this view becomes. This is particularly apparent from paragraphs 0025 and 0026, set out above. Paragraph 0025 refers to “clamps (15 in figure 2 [should be 5A]) ... [which] will hold the ends of the cut braid together ...”.
- iv) This is put pretty much beyond doubt by paragraph 0026 which in terms distinguishes other techniques, - “Alternatively, one can solder, braze, weld or otherwise affix the ends ...”. Thus clamping is said not to indicate these alternative methods of fixing.

- v) Other references to clamps support this. Thus paragraph 41 suggests how a clamp can be sized. It is hard to see how this can refer to anything other than a clamp in the ordinary sense of the word, which excludes such things as soldering or welding.
52. Mr Howe's argument sought to turn these textual references on their head. He said that soldering, brazing and so on were taught in paragraph 0026 as "alternative methods of achieving [the objective of preventing unravelling] to clamping. Thus, this is a case where the Patentee has made a 'dictionary definition of his specification' and the word 'clamp' in the claims is to be construed as embracing these alternative disclosed methods of securing the ends of the strands." I am afraid I do not follow this reasoning. The juxtaposition of paragraphs 0025 and 0026 demonstrate that the patentee has not provided a sort of dictionary definition of "clamp". He has referred to clamps, and then referred to alternatives to clamps. I do not understand how this amounts to defining clamps to include those other "not clamps" (as it were).
53. I therefore find that clamps means clamps - that is to say that it connotes fixing the strands together by means of an object which exerts a physical fixing and binding force on the strands of the fabric so that they do not unravel. It does not include the other methods of fixing referred to in paragraph 0026 (and perhaps other things as well, but that does not matter for the purposes of this case).
54. It is, of course, the case that other methods of fixing are envisaged by the description, and it is not at all apparent why the patentee should intend to exclude those from his claims. However, the drafting is so clear that the actual wording cannot be ignored for these purposes, and the relevant words cannot be extended beyond their natural wording, and it may be a case where the reasons for the more limited wording are unascertainable but could well exist, in line with the dicta and principles set out above. It may even, I suppose, be a mistake, but the words say what they say. There is no apparent rational basis for forming another conclusion in the light of the guidance given by the specification.
55. This reasoning makes it unnecessary to consider whether, and to what extent, I should look at the application to help construe the patent. There was some dispute as to this. It was Mr Prescott who said I could and should. However, since I have ruled in his favour on this point of construction without it it is unnecessary for me to go into those additional documents or to consider the propriety of my doing so.
56. Having thus decided, it is necessary to consider whether any of the Occlutech devices contain clamps in the sense which I have found the word to carry in the patent.
57. The method of construction is set out above. So far as the old device is concerned, there is a fixing of the strands by welding. First the strands are gathered together by a copper wire, for the purposes of the next phase. That, in my view, is not clamping for two reasons. First, the force is not applied with a view to fixing permanently, which the patent envisages. Second, the force is not sufficient to amount to clamping. The word "gathering" is mine (the process is not described in the PPD, because it only emerged in oral evidence, so there is no word for me to take from the PPD), but I have deliberately used a word which carries the correct connotations so far as the evidence of its function is concerned. It gathers them together so that the nitinol ring can be slid over them. This is not a clamping force.

58. Then the nitinol ring is slid over the strand ends. This does not apply a clamping force at all – it is so loose that gravity would make it fall off if the device were inverted. The purpose of the ring is not to act as a clamp in the sense referred to above. It is more of a collar than a clamp. The next phase is the welding process which fuses the strands to each other, and the strands to the ring. The result of this is not that the ring exerts an inward force to fix the strands. The result of this is that the strands are stuck to each other, and they are all stuck to the ring, and thus prevented from unravelling. This is a welding operation of the kind specifically identified in the patent but which did not find its way into the claims. Claim 1 provides for “clamps ... adapted to clamp the strands”. The ring does not clamp the strands, contrary to the arguments of Mr Howe.
59. Nor does Mr Howe’s alternative argument succeed. He says the welding itself amounts to clamping. For the reasons given above, clamping in the patent does not include welding, so this welding in the old Occlutech device does not amount to a clamp. This conclusion is reinforced by paragraph 0060, which refers to “The clamp”, and describes it in terms which are inconsistent with a soldering process and seems clearly to envisage a separate part having a clamping effect.
60. Mr Howe’s last point on the old Occlutech device was that the steel adaptor was a clamp. He relied on evidence that it would hold the end of the wires and would prevent them from straying. It was fixed by crimping (ie squeezing through spot lasering), which was said by him to be clamping on any view. The lasering process would result in indented regions on the adaptor exerting an inward force on the nitinol strands. These regions would not constitute a complete circumferential ring around the top of the adaptor; rather they would amount to a series of spots. Mr Howe’s case was that this method of fixing the adaptor amounted to a clamp.
61. In one sense this argument of Mr Howe is more promising than his others. There is something exerting a real inward force, which is a major part of what a clamp does. However, it is still not clamping in the manner required by claim 1. The relevant words (to return to them) are: “characterized in that clamps (15) are adapted to clamp the strands” (my emphasis). What is meant by clamping the strands is fixing them so that they do not unravel - see paragraph 0025. That is not what this adaptor does. They have already been fixed so that they do not unravel - that is what the welding does. The inward pressure does not clamp the strands in any relevant sense even though inward pressure is exerted. The purpose and effect of the inward pressure is to secure the adaptor, not to clamp the strands. So this facet does not constitute an infringing clamp either.
62. It therefore follows that the old Occlutech device does not infringe.
63. Accordingly, the old Occlutech device does not infringe claim 1, because of the absence of a clamp. For the same reason it does not infringe claim 16 either. Mr Howe sought to mount an alternative argument under claim 16 based on the use of the copper wire. The copper wire was a temporary clamp, even if it was superseded by something that was not within the claims. He sought to say that such clamping was a process within claim 16, and that the importation of an article created by such a process was an infringement under section 60(1)(c) of the 1997 Act.

64. The short answer to that point is that the copper wire is not a clamp. That is not its purpose, and that is not its effect. It does not exert enough force - see above. Furthermore, the clamping integer on its true construction is one which describes the final product, not an intermediate step. It is still necessary to have a final product with clamping in order to infringe, and in this respect the old Occlutech device does not infringe. There are other answers as well, but I do not need to go into them.
65. I can deal with the new Occlutech device more quickly. It is even clearer that this does not infringe on the footing that there is no clamp. Here there is no wire, and no nitinol ring. Welding cannot be clamping - see above. And although again the adaptor has indentations which exert inward pressure on the strands, it is not a clamp for the same reasons as those just discussed in relation to the old device.
66. Accordingly the new Occlutech device does not infringe either.
67. Those conclusions are sufficient to deal with the infringement claims, and to entitle Occlutech to its declarations. However, other reasons were advanced for there being no infringement and I should deal with those. Those arguments, and their disposal, apply equally to both the old and the new Occlutech devices.

Clamps at opposite ends of the device

68. The next argument is as to the number of clamps. AGA say that there are clamps at both ends of the device. Occlutech says that even if there is a clamp at the welded end of the device, there is not one at the distal end (the toe end of the sock), where the strands wrap around and return to the proximal end. In its final written submissions AGA accepts that “The Occlutech Devices have no clamp at the distal end”, but says that the strands pass back to the proximal end where they are all clamped; and “the single clamp serves the purpose of the ‘clamps’ referred to in the literal wording of claim 1”. This is said to raise the question of whether literal fulfilment would be viewed by the skilled reader as required when the same result can be achieved by this single clamp.
69. AGA relies on the well-known *Improver* questions (*Improver Corp v Remington Consumer Products Ltd* [1990] FSR 181 in its approach to this point:

“If the issue was whether a feature embodied in an alleged infringement which fell outside the primary, literal or acontextual meaning of a descriptive word or phrase in the claim (“a variant”) was nevertheless within its language as properly interpreted, the court should ask itself the following three questions:

(1) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no?

(2) Would this (ie that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes?

(3) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

On the other hand, a negative answer to the last question would lead to the conclusion that the patentee was intending the word or phrase to have not a literal but a figurative meaning (the figure being a form of synecdoche or metonymy) denoting a class of things which include the variant and the literal meaning, the latter being perhaps the most perfect, best-known or striking example of the class.”

70. Mr Prescott disputes the applicability of these questions. He says the construction of the patent is clear - it requires (a) clamps which are (b) at each end. If that is right then that is an answer to the point, and one does not revisit the point via the *Improver* questions - see the approach of Lord Hoffman in *Kirin-Amgen*.
71. As Lord Hoffman observed in *Kirin-Amgen* at paragraph 52, there are some cases in which these questions do not work very well, and they are in any event guidelines and not binding principles of construction. Later in his speech he went on to consider the practical workings of the *Improver* question in cases which concerned questions where measurements or figures were involved, and other cases. At paragraph 66 he said:

“No doubt there are other cases, not involving figures or measurements, in which the question is whether a word or phrase was used in a strictly conventional or some looser sense. But the present case illustrates the difficulty of applying the Protocol [*Improver*] questions when no such question arises. No one suggests that an exogenous DNA sequence coding for EPO can have some looser meaning which includes ‘an endogenous DNA sequence coding for EPO’. The question is rather whether the person skilled in the art would understand the invention as operating at a level of generality which makes it irrelevant whether the DNA which codes for EPO is exogenous or not. That is a difficult question to put through the mangle of the Protocol questions because the answer depends entirely upon what you think the invention is. Once you have decided that question, the Protocol questions answer themselves.”

Later he said:

“69. I shall say in a moment why I agree with the Court of Appeal, but I want first to emphasise a point I have already made about the use of the Protocol questions. The determination of the extent of protection conferred by a European patent is an

examination in which there is only one compulsory question, namely that set by article 69 and its Protocol: what would a person skilled in the art have understood the patentee to have used the language of the claim to mean? Everything else, including the Protocol questions, is only guidance to a judge trying to answer that question. But there is no point in going through the motions of answering the Protocol questions when you cannot sensibly do so until you have construed the claim. In such a case - and the present is in my opinion such a case - they simply provide a formal justification for a conclusion which has already been reached on other grounds.

70. I agree with the Court of Appeal that the invention should normally be taken as having been claimed at the same level of generality as that at which it is defined in the claims. It would be unusual for the person skilled in the art to understand a specification to be claiming an invention at a higher level of generality than that chosen by the patentee. That means that once the judge had construed the claims as he did, he had answered the question of infringement. It could only cause confusion to try to answer the Protocol questions as well.”

72. So it is entirely appropriate to start by construing the patent itself, and considering the level of generality at which the invention is claimed in the claims. The wording is specific and not particularly general, so far as clamps and ends are concerned. There are to be clamps, and they are to be at opposite ends of the device. It does not say at opposite ends of the strands, even though that would amount to the same thing. Does it mean what it says? Apart from one point, everything in the specification suggests that it does. There is a picture of a product with clamps at each end. There are various references to tubes, which would obviously require clamping at both ends. Thus it refers to a “tubular braid such as that shown in figure 1A” (paragraph 0017), a description repeated elsewhere; paragraph 0025 refers to one method to prevent braid unravelling is “to clamp the braid at two locations and cut the braid having clamps (15 in Figure [5]) *at either end*, thereby effectively defining an empty space within a sealed length of fabric”; paragraph 26 refers to alternative methods of fixing “the ends of the desired length”. Figure 1A plainly shows a tube, probably braided, with two open ends. Other material can be cited; it is unnecessary to set out each and every piece of this supporting material.
73. Various related reasons are put forward for suggesting that a “purposive” construction should be adopted, which construction is said not to require clamps at each end. The first is based on the first two *Improver* questions – having a closed sock end does not affect how the invention works. But it depends on what one describes the invention as being for these purposes, and what one means by “works”. If the invention involves having clamps at both ends, then it does not work in that sense at all if there is clamp at one end only. What this submission amounts to is that there is a device which is capable of providing the same functionality as the invention, even though differently finished off at one end. That may be true (I do not need to make a finding about it) but, in the light of the wording of the patent, that is irrelevant. The patent claims one thing; the other device is another thing. To adopt this approach is not successfully to

adopt a purposive construction of the patent; it is to go way beyond what seems clearly to be a specific limitation, deliberately included, even though one cannot glean why that limitation might be there.

74. The other reasons turn on paragraph 27 of the patent, and its reference to making a pocket and clamping one end only. Mr Howe says that this supports his argument that the patent envisages that the function of the distal clamp can be fulfilled by running the fabric round the end. One can and should determine the scope of the claim in the light of this, and if one does then a product within paragraph 27 would be treated as clamped at both ends.
75. This argument is similar to one that succeeded in the German proceedings, and I shall return to it in that context. For present purposes I find that it fails for the following reasons. Paragraph 27 is not couched in terms of an embodiment of the invention. It refers to “the same problems” as are dealt with in the preceding paragraph, but the link with the invention is otherwise more tenuous. It refers to a device made of a woven fabric, which the patent seems to distinguish from braided fabric (the subject of the claims) for these purposes. Although paragraph 0012 seems to refer to such a fabric as being suitable for use with the invention, it is apparently not the fabric described in the claims. There was some evidence, and some debate before me, as to whether there was any real difference between a woven fabric and a braided fabric, and whether woven fabrics were merely braiding with a 90 degree pick angle (the angle with which one fabric meets another). I do not need to deal with that particular point. It is sufficient for present purposes that the patent seems to draw some distinction, and it limits the claim to one of the methods of construction (braiding). All this seems to be another demonstration of the patent disclosing one thing (here, the pocket alternative, with a woven fabric, clamped at one end) in order to present it as an alternative to another (the braided tube, clamped at two ends) and then only claiming the latter. In the light of the way that they are both separately disclosed in the specification, it is impossible to read the selection of just one of them in the claims as intended to refer to both. The selection of a braided material, requiring clamping at both ends, seems to be deliberate, even if the reason for it is not readily apparent. As Lord Hoffman has pointed out in *Empson*, there may be still be reasons that the patentee had for doing this. Nothing in the expert evidence requires a different conclusion. All Dr Drasler said in his report was that if you had a device with one end, you only need to clamp at one end. That is, of course, true, but ultimately not relevant.
76. I therefore regard it as plain, looking at the patent, that the claims require two ends each of which is clamped. If one poses the “variant” contained in the Occlutech device, namely one end clamped, the other end enclosed by the strands themselves, and asks whether it is within the patent, it is plainly not - there is nothing amounting to a clamp at the distal end (even if welding would be clamping). It is unnecessary to get out what Lord Hoffman would have called the mangle; the thing is dry enough already. But if one wanted to ask the *Improver* questions one would reach the same conclusions on the same reasoning when one came to the third question. I shall therefore not consider the other two.
77. Since the Occlutech devices all have a clamp at one end only, and an end enclosed by the strands at the other, then for that reason, too, the Occlutech device does not infringe.

Dumbbell shaped

78. Last, there is the “dumbbell-shaped” point. Mr Prescott says that the Occlutech devices are not dumbbell shaped because the central portion is too short. The essence of a dumbbell is that it has a central bar that is wide enough to accommodate a hand, and while the use of the expression in the patent is to some extent figurative, it is not broad enough to cover Occlutech’s products whose central portion is short (because of their function - their function is to pinch or exert inward forces, so the central portion has a pulling-in function rather than a separation function).
79. The expression has no specialised meaning to the skilled man, so the words bear their ordinary meaning. The wording of claim 1 is generalised, so it is a generalised figure of speech – “a generally dumbbell shaped expanded configuration”. It is a broad concept in the specification too:
- i) It is said that Boston Scientific discloses such a shape. It does so only in a loose way, in that (as referred to above) the relevant shape is tapered down to a thinner middle portion on each side of it.
 - ii) Figures 4 (not reproduced hereafter) and 5A do indeed show the sort of shape that Mr Prescott relies on.
 - iii) Paragraph 43 refers to the moulding elements and finishes with the words set out above – note the word “somewhat”, and the apparent quasi-definition which expounds a narrow central section and more bulbous end sections.
 - iv) Paragraph 53 refers to variations in the relative sizes of the middle and outer sections, as desired. This suggests a wide range of variations. On the other hand, the reference in the same paragraph to limiting the ability of the device to turn within a vessel suggests a significant distance between the outer elements (more than in the Occlutech devices) because, as a matter of physics, the two outer elements have to have a decent spacing to be able to prevent the turning (or tumbling). At the same time, it must be noted that the claims do not confine themselves to an occluding device in a blood vessel - that is merely one use.
 - v) The anti-tumbling element is reinforced by paragraph 0055 and its sentence: “The device 60 is desirably longer along the axis than the dimension of its greatest diameter.” (The “60” is the device shown in figure 5.)
 - vi) Paragraph 0056 shows a significant range in the relative proportions of the middle element, and goes on to say that even those preferred ranges may be departed from if a different use requires it.
80. One cannot arrive at an answer to this question by some rigorously logical process. It is a question of ascertaining just how figurative the key expression is intended to be. Is it intended to describe two outer wider portions and a thinner central portion (however short), or is it intended to describe something with a wide enough central section to get one’s metaphorical hand on? In my view the former is correct. It is describing a shape in a generalised way, without seeking to ascribe limits on the proportionate length of the central section. One does not get that from the claim, but

one gets it from the overall thrust of the paragraphs in the specification to which I have referred. In this sense the Occlutech devices are dumbbell shaped. Mr Prescott says that these devices demonstrate a yo-yo shape, not a dumbbell shape. He may be correct to the extent that yo-yo would be a better description of some of the devices (though it would not be particularly apt for the PFO devices because the central portion is very thin on those), but that is not the point. The fact that another metaphor might be more appropriate for a given device does not determine whether or not the patent's metaphor is itself, and on its true construction, inappropriate for that device. That latter question has to be determined by construing the patent, not by a "best metaphor" selection process.

81. So I find that the Occlutech devices (both those in the PPD and the other devices I was shown) are dumbbell-shaped for these purposes. That being the case, Mr Prescott has one further line of attack on the patent. He says if that is correct (which it is) then there is added subject matter. If dumbbell-shaped includes a yo-yo whose discs do not expand to fill the lumen, but instead occlude a septal defect by touching inwardly against the septal wall, no such device was disclosed in the application as filed. Mr Prescott did not take long on this point, and did not even take me to the application as filed to make it good. He asserted that the reference to dumbbell shape was not in the original application claims. That may be true. But he did not conduct any other comparative exercise. In my view the point fails. In my view the reference to dumbbells is a reference to a shape which is referred to in the specification. It has not been demonstrated that all those references did not appear in the application as filed. It seems to be included in the claim as a form of summary. There is no additional disclosure in the patent. The claim refers merely to a medical device. The specification refers to a range of uses. It has not been demonstrated that the application disclosed only anti-tumbling devices, so that somehow the possibility of a septal-pinching device being referred to in the patent is added matter to that. All in all this was a confused point, shortly taken, and it fails.

The German and Dutch decisions

82. So far I have decided the construction points that arise without reference to the decisions of the German and Dutch courts which have already been delivered on the points. The German court has delivered a decision which supports AGA on the clamping points of construction. The Dutch court has delivered a decision the other way. Mr Howe says I should give great weight to the former, because it is a court which has decided the same points and because Lord Hoffman in *Kirin Amgen* has recorded that the German courts were applying a *Catnic* construction process (see paragraph 65), but he accepts I am not bound by it. He takes the position of making the reasoning in the German decision part of his own submissions. I therefore have to consider that decision, and in any event since I have reached a different decision from that of the German court and I should at least explain why.
83. The decision is that of the Düsseldorf Higher Regional Court, and is dated 22nd December 2008. It is common ground that it is considering the same patent as the patent in suit in this case and considers it against the old and new Occlutech devices. It considered that both devices infringed. The court did not have a point before it on "dumbbell-shaped", but it did consider the question of clamping and clamping at both ends. It concluded that the Occlutech devices contained clamps, and that they were

clamped at both ends for the purposes of the patent. (It considered other points as well, but they have no parallel in points taken in the proceedings before me.)

84. So far as the presence of a clamp anywhere is concerned, it appears from the judgment that that was not fully in issue. It appears from page 25 of the translation that Occlutech sought to raise the point that there was no clamp, because welding was not a clamp and the nitinol sleeve did not amount to a clamp either. However, it was not allowed to raise that contention. The judgment records:

“All four defendants conceded in the first instance that embodiment 1 has a clamp...”

and the court declined to allow them formally to raise the point. However, it went on:

“Even if one were to assume in favour of the defendants that prior to welding the nitinol ring can be easily slipped on to the wire bundle without encountering any major resistance, as in the presented sample, this would not help to stay outside of the scope of the patent. The defendants cannot seriously deny that the Nitinol ring receives the ends of the wires and holds them together, even if it is initially only loosely slipped on to the bundle. With that, the spatial arrangement and physical configuration of this ring, corresponds to what claim 1 and 16 of the patent in suit disclose with respect to the clamp. Having said this, it is no longer necessary to contemplate whether the identical features of the attacked device fulfil the same purpose and have the same function as those of the patent in suit....It does not matter whether the Nitinol sleeve of the attacked device is additionally welded, and if it is the welding which keeps the wire filaments together, especially since the patent in suit does not rule out that the ends of the strands are welded, in addition to providing the clamp.”

85. Then the court ruled against the submission from Occlutech to the effect that since the device brought together the wires at one end, instead of at two ends, it did not infringe, in other words the “clamped at both ends” point. It said:

“One must agree with the defendants that claims 1 and 16 of the patent in suit seen from the philological point of view, teach several clamps (plural) and in addition to that prescribe that these clamps are adapted to **clamp the strands at the opposed ends of the device**. This describes configurations in which one clamp each is presented at the proximal end and at the opposed – distal end. Yet the average skilled person will not content himself with this mere linguistic understanding. He will understand that the ends of the **strands** are supposed to be bundled with the help of the clamps, which is why feature 2(e) of claim 16 – as the plaintiff rightly pointed out in the oral hearing before the present court – refers to a clamping of the opposed ends of the strands, and not of the device, regardless of whether the strands are left lying flat or if the

ends are placed on top of each other by folding, because just by taking this measure, the two ends of the strand do not cease to exist. Since the method described therein is supposed to result in a device of the type *inter alia* protected by claim 1, the skilled person will assume that the technical meaning of claim 1 also includes embodiments in which both strand ends are placed on top of each other and are bundled at one end of the device only. The fact that the patent in suit comprises such configurations is confirmed by the patent specifications in paragraph [0032] in conjunction with fig 1B – which the Regional Court rightly referred to – where the manufacture of an occluder from a flat piece of fabric is described which after its inversion forms an empty pocket as an intermediate product. This function that the clamps are supposed to have according to the invention, does not necessarily require a flat embodiment with two clamps as shown in fig 5A of the patent document as a preferred embodiment. First and foremost, the clamps are supposed to hold together the ends of the wire strands and secure them against unravelling. The fact that it is also possible to attach them to the catheter for deploying the device, is not mentioned until independent claim 2, and is only required with respect to one of the clamps. The additional possibility of pulling the clamps apart manually to stretch the device into a collapsed state...is explicitly mentioned as an example only of how the device can be introduced into the catheter. None of the competent parties held the view that the latter two functions are of absolute necessity for the technical teaching of the patent in suit, and rightly not. In the embodiment according to paragraph 0032, it only makes sense technically, in view of the function of the clamping which is to prevent the strand ends from unravelling, to provide clamps where free strand ends are present. Since this is only the case on one side of the device, and all strand ends can be grasped at once with one – single – clamp, only one and not several clamps are required. The plural “clamps” used in the claim does not stand in the way of this view. The skilled person does not glean from the wording that several clamps should be used in any case; in view of the embodiment described in paragraph 0032, he will understand the term “clamps” as a generic term which specifies which type of device – i.e. clamps – is supposed to be used in order to prevent the strand ends from fraying. The regional court has therefore rightly assumed that the skilled person will understand feature 5 and 2E [i.e. the feature of being clamped at both ends] in a technically meaningful way, i.e. to say that as many clamps – one or several – are to be provided as are necessary and meaningful given the chosen basic design.” (The emboldened words are emboldened in the translation.)

86. The decision then goes on to consider whether fig 1B (which the flat woven metal fabric which is the one which is turned into the open-ended pocket) should be treated as deleted from the patent and not used to determine the technical meaning of the claims. It rejects that case. It goes on to observe:

“To understand that patented technical teaching, the skilled person has to resort to the specification of the patent in suit in its published version; and looking for anything that may help him to understand the teaching, he is able to consider all parts of the description and must not mask out the parts of the description which in the opinion of the defendants should have been deleted from the description, because patent claim 1 was amended.”

87. This reinforces the impression that the presence of the open-pocket device was an important factor in leading the German court to the conclusion that one did not need clamps at both ends of the device.

88. So far as the Occlutech new device is concerned (described as embodiment II), the court observed that it applied the same answer to the “not clamped at both ends” objection. It went on to consider the absence of the nitinol ring:

“There is only one difference in that the wire ends of embodiment II are welded together without a nitinol ring, and that a steel sleeve is pulled over the welded ends in order to connect them to a guide wire. In this respect, the considerations above relating to embodiment I apply analogously, because the clamp described in claims 1 and 16 is also physically and spatially present in the form of the steel sleeve which receives the wire ends and holds them together simply by receiving them, so that it is not necessary to discuss here whether the steel sleeve has the same function as the clamp taught in claim 1 of the patent in suit...the fact that it at least holds together the wire ends follows from the fig 4 submitted by the plaintiff [in its brief] from which it can be seen that the steel sleeve has a narrowing which is pushed over the bulge of the strand ends formed by welding, so that the enlarged portion is also received in a slightly enlarged-diameter portion of the sleeve. The narrower portion prevents the steel sleeve from being pulled off the welded end.”

In other words, it held that the steel adaptor was a clamp because of its physical position and because it received the strand ends and held them together.

89. It therefore appears that the German court did not fully consider whether or not there was clamping in the Occlutech old device, but if it had had to it would have concluded:

- i) that the nitinol ring was a clamp, because of where it is in relation to the strands, and

- ii) welding amounts to clamping because the patent does not rule out the possibility of welding.

90. I am afraid that, with all due respect, I agree with neither conclusion. For the reasons I have given above, the ring is not, in my view, a clamp. It does not operate as a clamp either before or after welding. Before welding it is too loose to perform the vital function of securing the strands, and after welding it performs its function not by the mechanical force of pressure, but by the adhesive force of welding. So far as the welding is concerned, it is true that the specification itself does not rule out the possibility of welding – indeed, it obviously rules it in, as a technique – but it specifically, and in terms treats it as an alternative to clamping. I am afraid I have real difficulty in understanding how a patent which in terms draws a distinction between clamping on the one hand and welding (and other techniques) on the other can be treated as if it were treating them as the same.
91. So far as the requirement for clamps at opposed ends is concerned, the court seems to have relied heavily on the “pocket” alternative, and concluded that it only made sense to clamp this at one point with a single clamp, which is obviously correct in terms of the physical requirements. This is said to indicate to the skilled man that you have to use as many clamps as are necessary and meaningful for any given design. Again, as a piece of logic that is correct. However, it seems to me to overlook the fact that the “pocket” alternative is presented as another aspect of a problem, and not as a clear embodiment of the invention, and is distinguished from tubular braids. The question is: what does the claim refer to? It is apparently a device with two ends, so it cannot be the “pocket” device. The central finding on this part of the decision seems to be that “first and foremost, the clamps are supposed to hold together the ends of the wire strands to secure them against unravelling, and that this is what the skilled addressee will understand.” Again, that is obviously correct - if you have got loose strands they will need to be fixed. What the reasoning fails to give proper effect to, in my view, is the actual wording of claim 1 (and, because of the cross-reference in the opening words of claim 16, that later claim 16) in that there are clamps to clamp the strands at the opposite ends of the device (even though those words are emphasized in the judgment). In other words, the claim does not merely refer to clamping. It tells the reader where those clamps are to go, and that is at the opposed ends of the device, not the opposed ends of the strands. It presupposes two ends to the device, and that is backed up by my analysis of the specification appearing above. On the evidence that I heard I do not accept that a skilled person would understand “clamp the strands at the opposite ends of the device” to mean “clamp the device at whichever ends of the device there are loose strands which need securing”. Again, therefore, my reading and construction of this patent differs from the Higher Regional Court.
92. I do not think that claim 16 assists in the manner suggested by the German court. Of course, claim 16 might assist in construing claim 1, but the opening words of claim 16 demonstrate that one starts with claim 1, not claim 16, because it refers to a method of forming “a medical device according to any one of the preceding claims”, and then describes the method. All of the preceding claims have their roots in claim 1. So the device is one in claim 1 – two clamps, one at each end of the device. In that context paragraph (e) cannot be taken as altering that requirement, even though it refers to opposite ends of the strands, not the opposite ends of the device. Bearing in mind its

starting point (a claim 1 device) they amount to the different ways of describing the same thing, not different things.

93. Last, there is the question of whether the steel adaptor can be a clamp in the new Occlutech device. I have considered this point myself, and arrived at a different conclusion. By the time the adapter is applied the strands are already restrained, and neither its avowed function, nor its physical effect, is to provide additional clamping force. So again, and with respect, I differ from the analysis of the German court.
94. The Dutch decision is a decision of the District Court of The Hague. Since it finds the same way as I do, I do not need to consider it further.

Conclusions on infringement

95. The infringement claim therefore fails. I have considered it principally in relation to claim 1, but none of the later claims is materially different for purposes (not even claim 16, for the reasons given in my consideration of the German judgment), so I do not need to consider them separately.

Other points

96. Other points, including an insufficiency point, were made, but in the light of my decisions above they do not fall for decision, and I say no more about them.

Conclusion

97. In the circumstances I find as follows:
- i) The claim for declarations of non-infringement in relation to devices constructed in accordance with the PPDs and constructed in the same manner as the two PFO occluders produced by Occlutech to AGA succeeds.
 - ii) The claim for revocation of the patent in suit fails.
 - iii) The claim for infringement fails.

Appendix 1

The principal claims in the patent in suit

1. A collapsible medical device (60) comprising a metal fabric formed of braided metal strands, the device (60) having a collapsed configuration for delivery through a channel in a patient's [body], and has a generally dumbbell-shaped expanded configuration with two expanded diameter portions (64) separated by a reduced diameter portion (62) formed between opposed ends of the device, characterised in that clamps (15) are adapted to clamp the strands at the opposed ends of the device.
2. The medical device (60) of Claim 1, wherein at least one of the clamps (15) configured to be releasably attached to a delivery device.
3. The medical device (60) of Claim 2, wherein at least one clamp (15) includes a threaded portion for threaded attachment to the delivery device.
4. The medical device (60) of any one of the preceding claims, wherein each of the expanded diameter portions (64) and the reduced diameter portion (62) are all integrally formed from a single piece of metal fabric.
7. The medical device (60) of Claim 5, wherein the thrombogenic agent comprises a thrombogenic fabric.

9. The medical device (60) of any one of the preceding claims, wherein the reduced diameter portion (62) has an outer diameter which is no more than about one-third of an outer diameter of at least one of the expanded diameter portions.

14. The medical device (60) of any one of the preceding claims, further comprising a third expanded diameter portion and a second reduced diameter portion being disposed between the third expanded diameter portion and one of the other two expanded diameter portions.

16. A method of forming a medical device according to any one of the preceding claims, the method comprising the steps of:
 - (a) providing a metal fabric formed of a plurality of braided strands, the strands being formed of a metal which can be heat treated to substantially set a desired shape;
 - (b) deforming the metal fabric to generally conform to an internal wall surface of a moulding element;
 - (c) heat treating the metal fabric in contact with the surface of the moulding element at an elevated temperature, the temperature and the duration of the heat treatment being sufficient to substantially set the shape of the fabric in its deformed state;
 - (d) removing the metal fabric from contact with the moulding element
 - (e) clamping the opposite ends of the strands of the device with clamps

Appendix 2

Figures from the patent in suit

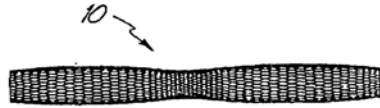


Fig. 1A

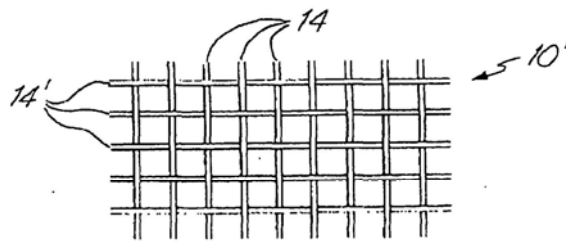


Fig. 1B

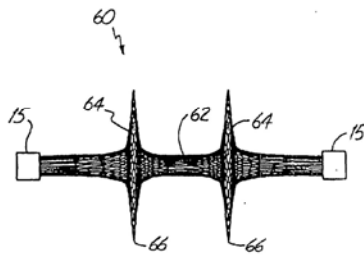


Fig. 5A

