Neutral Citation Number: [2011] IEHC 128

**THE HIGH COURT**

**COMMERCIAL**

**2008 10436 P**

**BETWEEN**

**MEDINOL LIMITED**

**PLAINTIFF**

**AND**
**ABBOTT IRELAND AND ABBOTT VASCULAR INTERNATIONAL BVBA**
**AND**
**ABBOTT CARDIO VASCULAR SYSTEMS INC.**
**AND**
**ABBOTT VASCULAR DEVICES HOLLAND B.V.**
**AND**
**ABBOTT LABORATORIES INCORPORATED**

**DEFENDANTS**

**JUDGMENT of Mr. Justice Brian J. McGovern delivered on the 10th day of March, 2011**

1. In this action, the plaintiff alleges that the defendants have infringed European Patent (IE) No. 181 902 ("the Patent"). The defendants deny infringement and counterclaim for revocation of the patent on three bases: obviousness, lack of novelty and added matter.

2. This is one of a series of actions taken in Europe in relation to this Patent. To date, proceedings have been heard in Germany, the Netherlands and the United Kingdom as well as before the European Patent Office. There have also been proceedings in the United States between the parties in respect of the same products at issue in these proceedings.

3. The products at issue in this case are manufactured in Galway and are sold by the defendants. They are coronary stents known as *Vision, Multi-link 8, Xience* and *Xience Prime*.

4. Stents are cylindrical-shaped devices, usually made of metal, that are inserted into the coronary arteries, typically after balloon angioplasty. An expanded coronary stent provides support to keep the blood vessel open.

5. In 1977, balloon angioplasty was first used. This procedure involved inserting a balloon tipped catheter into an artery (usually the femoral artery or brachial artery and guiding it to the narrowed, diseased coronary artery). The balloon is then inflated to dilate the artery before being removed. This procedure has three main potential drawbacks, namely:

(i) immediate abrupt closure;

(ii) early recoil; and

(iii)late recurrence of stenosis (re-stenosis).

6. These potential problems could be overcome by the use of stents, inserted into the coronary arteries and designed to provide sufficient support to keep the blood vessel open. There are two types of stents, namely, balloon expandable stents and self-expanding stents. A balloon expandable stent is crimped onto a balloon catheter and inserted into a femoral or brachial artery *via* a guiding catheter or wire. The stent and balloon are manoeuvred into position *via* the vasculature, and once in place, the balloon is expanded. This causes the stent itself to expand. The balloon is then removed leaving the stent in place. The self-expanding stent is inserted in a similar fashion. The stent has a sheath over it to prevent expansion until it is in the desired location.

7. In considering the issues that arise in this case, it is important to bear in mind the priority date of the Patent which is July 1994. There is little or no disagreement between the parties as to the evolution of stent design and the desirable characteristics for a stent as at the priority date. In July 1994, there were two types of stents available for use, namely, those made of wire and those made from metal tubes, which had slots and various patterns cut into them. The wire stents, because of their nature, were very flexible, but it was found that when they were delivered to the desired location, they did not provide sufficient scaffolding strength to keep the lumen open when they expanded. The stents made from cylindrical tubes had excellent scaffolding properties but were insufficiently flexible. This posed a serious problem with deliverability to the lesion which required treatment. In 1994, stents were predominantly used in emergency bail-out procedures in case of abrupt closure of coronary arteries. Therefore, the ability to reach the site of placement quickly was very important. If the stent could not be delivered in time, an emergency by-pass operation was needed.

8. Stent thrombosis was also a significant problem in 1994. It was widely believed that metal within the artery was thrombogenic and that stents containing multiple crossed wires increased the risk of thrombosis. This danger decreased in 1995, with the introduction of anti-platelet drugs.

9. Another significant issue concerned the radial strength of the stent, that is, the ability of the stent to support the vessel wall and not suffer too much recoil which might hasten re-stenosis. A balance had to be struck between providing enough material to provide radial strength but not so much as to increase the perceived risk of thrombosis. While these matters were the most important, given the use of stents in bail-out situations, there were other considerations in the minds of parties involved in the design and/or use of stents in 1994. These may be summarised as follows:

(a) **Scaffolding.** The stent ought to provide sufficient scaffolding so that parts of the artery wall do not prolapse between the gaps in the stent.

(b) **Conformability.** The stent should take the shape of the vessel upon expansion. In 1994, a degree of straightening was deemed acceptable.

(c) **Foreshortening.** It was known that when stents expanded many of them shortened longitudinally. While a small

amount of foreshortening was acceptable, it was undesirable to have significant foreshortening because the stent might not cover the entire lesion.

(d) **Maintenance of side branch artery opening upon expansion.** The stent struts should not be so close together that they would obstruct any side branch arteries.

(e) **Crimping onto the balloons.** The stent would be pre-crimped onto the balloon and should be securely held there until it reached the site where it was to be deployed.

(f) **Radiopacity.** It was important that the stent could be visualised properly once inserted so that the cardiologist could see if the whole lesion was covered and exactly where to try to implant a second stent if required.

10. These were the issues known to biomedical engineers and cardiologists who were involved in the design and/or use of stents in July 1994.

11. In assessing what comprised the common general knowledge of a person skilled in the art at the priority date, it is necessary to examine the stents available on the market at that date. A skilled person would have been aware of those stents. At the time, there were five stents available. These were:

(a) **Strecker.** The Strecker stent was a balloon expandable tantalum woven wire stent. Its main drawback was that it did not crimp satisfactorily on to the balloon and it also had a lot of metal protruding into the lumen which was thought to increase the risk of thrombosis.

(b) **Wallstent.** The Wallstent was a stainless steel self-expanding wire mesh stent. It suffered from unacceptable foreshortening upon deployment. It also created a risk of thrombosis. As it was self-expanding it caused continuous stress on the walls of the vessel. It also had rigid sharp ends which flared open, causing trauma to the artery wall. In addition, the thickness of metal was doubled at its many wire crossings.

(c) **Wiktor.** The Wiktor stent was introduced in 1992 and was a balloon expandable tantalum wire stent. Like the Wallstent it suffered from poor crimping on to the balloon although to a lesser extent. It also had moderate to poor radial strength and provided poor scaffolding.

(d) **Gianturco-Roubin I (GRI).** The GRI was a stainless steel balloon expandable serpentine wire stent. It had a clam shell design which lacked radial strength. There was also a lot of space in between the rings and coils which created a problem with tissue prolapse. Another problem with this stent was that it suffered from high re-stenosis and thrombosis rates.

(e) **Palmaz-Schatz.** This stent was available from 1992 and was a stainless steel balloon expandable stent made up of articulated slotted tubes. It was the most successful stent up to 1994, but had several problems. In the first place, it was only flexible at its articulation points, which made navigation around curved vessels difficult. It also did not conform particularly well to the vessel walls. A further problem was the risk that side branch arteries could be "jailed" or blocked off because the cells making up the stent were small. There was also a risk of prolapse opposite the connector because of the large gap between slotted tube sections. It had good radial strength and minimal recoil.

**The Skilled Team**

12. A patent specification is addressed to a person "*skilled in the art".* In the context of this case, where the proceedings concern alleged infringement of a patent for a coronary stent, two types of person would have an input and interest in the design of the stent, namely, a biomedical engineer and a cardiologist. It is accepted by the parties that as a matter of law, the skilled person does not have to be an individual and can be a team. In the context of this claim, the team would be a biomedical engineer and an interventional cardiologist, although the plaintiff argues that the Patent is primarily addressed to an engineer, as he will be the designer of the stent. But it seems to me that he can only design a successful stent, having regard to the input from a cardiologist who has to deliver the stent to the lesion in a blood vessel, and can fully inform the engineer as to the technical and medical difficulties to be overcome.

13. The following witnesses gave evidence in this case:-

Dr. Jacob Richter, the founder of the plaintiff company. He has a Ph.D. in Medical Science and has engineering expertise in the area of Medical Devices and their application.

Professor Nicolaus Reifart, an interventional cardiologist, whose experience includes the research and design of cardiac stents.

Professor Alan Snyder, a Professor of Surgery and Bioengineering, with a degree in Engineering Science and Bioengineering, with extensive experience in the design of cardiovascular devices.

On behalf of the defendant, evidence was given by Dr. Simon Davies, a consultant cardiologist, with extensive experience in the use of coronary stents, and Professor Peter McHugh, a biomedical engineer.

All of these witnesses are persons "*skilled in the art".*

**The Law**

14. Before considering the Patent, it is desirable to set out the legal principles that apply. In this case, it is necessary, not only to consider the question of infringement and the other issues arising in this case, but also, to consider what weight (if any) should be given to the decisions handed down in other jurisdictions in actions between the same parties on what are, essentially, the same issues. Happily, there is little disagreement between the parties on the law, and where differences exist, they concern how the law should be applied in this particular case, especially on the question of the effect of judgments given in other jurisdictions.

15. Ireland is a signatory to the European Patent Convention ("EPC"). The Patents Act 1992 ("the 1992 Act"), since amended, in

part, by the Patents (Amendment) Act 2006, was enacted to ratify the EPC, and was modelled on the UK Patents Act 1977.

16. In these proceedings, the principal issues are whether the Patent has been infringed and whether the Patent should be revoked. Revocation is sought on the grounds of lack of novelty, obviousness and added matter. The plaintiff has also brought a contingent application to amend the Patent.

17. In *Ranbaxy Laboratories Limited and Others v. Warner Lambert Company* [2009] 4. I.R. 584, Clarke J. addressed the principles applicable to the construction of patent claims. He approved the leading case in the UK, *Kirin Amgen v. Hoechst* [2005] R.P.C. 9, where the House of Lords (*per* Hoffman L.J.) stated that the determination of the extent of protection conferred by a patent is an examination in which there is only one compulsory question, namely, that set by Article 69 of the EPC 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?"*

Article 69(1) of the EPC states:

> *"The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims."*

18. The Protocol on the Interpretation of Article 69 of the EPC provides:

> ***"Article 1***
>
> *General Principles*
>
> *Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purposes of resolving an ambiguity found in the claim. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.*
>
> ***Article 2***
>
> *Equivalents*
>
> *For the purpose of determining the extent of the protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims."*

In the *Ranbaxy* case, Clarke J. explained how the Protocol became part of Irish law through s. 45 of the 1992 Act. Section 45 provides:

> *"45(1) The extent of the protection conferred by a patent or a patent application shall be determined by the claims; nevertheless, the description and drawings shall be used to interpret the claims.*
>
> *. . .*
>
> *(3) In the interpretation of this section, the court shall have regard to the directions contained in the Protocol on the Interpretation of Article 69 of the European Patent Convention and set out in the Second Schedule to this Act."*

19. In paragraph 3.15 of the *Ranbaxy* judgment, Clarke J. stated:

> *"[30] It should be noted from the provisions of the protocol, to which I have referred, that it was designed, at least in part, to make clear that an over literal approach to the patent and in particular the claims set out in the patent was not to be adopted. It might well be said that a literal approach had, in the past, found favour in common law countries. However, that overly literal approach had been abandoned in the common law world in advance of the adoption of the protocol. In Catnic Components Ltd v. Hill & Smith Ltd. [1982] R.P.C. 183 at pp. 242 to 243 Lord Diplock said the following:-*
>
> *'My Lords, a patent specification is a unilateral statement by the patentee, in words of his own choosing, addressed to those likely to have a practical interest in the subject matter of his invention (i.e. 'skilled in the art'), by which he informs them what he claims to be the essential features of the new product or process for which the letters patent grant him a monopoly. It is those novel features only that he claims to be essential that constitute the so-called 'pith and marrow' of the claim. A patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge. The question in each case is: whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that any variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked'.*
>
> *[31] That decision gave rise to what became known as the protocol questions. However, since Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd. [2005] R.P.C. 9, those questions have no longer had quite the same status. The question in Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd. concerned the level of generality of the patent concerned. In the course of the speech of Lord Hoffman the true question was stated to be, at para. 34:-*
>
> *'What the person skilled in the art would have understood the patentee to be using the language of the claim to mean?'*
>
> *Anything else, in Lord Hoffman's view, was only guidance directed towards attempting to answer that question.*

*[32] In Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd. [2005] R.P.C. 9 Lord Hoffman approved, subject to one modification, the summary given in Technip SA's Patent [2004] EWCA Civ 381, [2004] R.P.C. 46 at para. 41 in the following terms:-*

*'(a) The first, overarching principle, is that contained in Art. 69 itself. Sometimes I wonder whether people spend more time on the gloss to Art. 69, the Protocol, than to the Article itself, even though it is the Article which is the main governing provision.*

*(b) Article 69 says that the extent of protection is determined by the terms of the claims . It goes on to say that the description and drawings shall be used to interpret the claims. In short the claims are to be construed in context.*

*(c) It follows that the claims are to be construed purposively - the inventor's purpose being ascertained from the description and drawings.*

*(d) It further follows that the claims must not be construed as if they stood alone - the drawings and description only being used to resolve any ambiguity. The Protocol expressly eschews such a method of construction but to my mind that would be so without the Protocol. Purpose is vital to the construction of claims.*

*(e) When ascertaining the inventor's purpose, it must be remembered that he may have several purposes depending on the level of generality of his invention. Typically, for instance, an inventor may have one, generally more than one, specific embodiment as well as a generalised concept. It is the latter which matters when construing the claim, particularly the widest claim. Otherwise one is in danger of being unfair to the inventor. I put it this way in Tickner v. Honda Motor Co. Ltd. [2002]1 EWHC 8 (Patents), [2002] All E.R. (D) 178 at para. [28]: 'The whole approach goes by the sobriquet "purposive construction". You learn the inventor's purpose by understanding his technical contribution from the specification and drawings. You keep that purpose in mind when considering what the terms of the claim mean. You choose a meaning consistent with that purpose - even if that involves a meaning which, acontextually, you would not ascribe to the word or phrase. Of course in this exercise you must also be fair to the patentee - and in particular must not take too narrow a view of his purpose - it is the widest purpose consistent with his teaching which should be used for purposive construction'.*

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

*(g) It follows that if the patentee has included what is obviously a deliberate limitation in his claims, it must have a meaning. One cannot disregard obviously intentional elements. Hoffmann L.J put it this way in Société Technique de Pulverisation STEP v. Emson Europe Ltd. [1993] R.P.C. 513: '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.'*

*(h) It also follows that where a patentee has used a word or phrase which, acontextually , might have a particular meaning (narrow or wide) it does not necessarily have that meaning in context. A good example of this is Catnic Components Ltd. v. Hill & Smith Ltd. [1982] R.P.C. 183 - 'vertical' in context did not mean 'geometrically vertical', it meant 'vertical enough to do the job' (of supporting the upper horizontal plate). The so-called 'Protocol Questions' (those formulated by Hoffmann J. in Inprover Corp. v. Remington Consumer Products Ltd. [1990] F.S.R. 181 at p.189) are of particular value when considering the difference of meaning between a word or phrase out of context and that word or phrase in context. At that point the first two Protocol questions come into play. But once one focuses on the word in context, the Protocol question approach does not resolve the ultimate question--what does the word or phrase actually mean, when construed purposively? That can only be done on the language used, read in context.*

*(i) It further follows that there is no general 'doctrine of equivalents'. Any student of patent law knows that various legal systems allow for such a concept, but that none of them can agree what it is or should be. Here is not the place to set forth the myriad versions of such a doctrine. For my part I do not think that Art. 69 itself allows for such a concept - it says the extent of protection shall be determined by the terms of the claims. And so far as I can understand, the French and German versions mean the same thing. Nor can I see how the Protocol can create any such doctrine.*

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

*(k) Finally purposive construction leads one to eschew what Lord Diplock in Catnic Components Ltd. v. Hill & Smith Ltd. [1982] R.P.C. 183 called (at p. 243): 'the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge'. Pedantry and patents are incompatible. In Catnic the rejected 'meticulous verbal analysis' was the argument that because the word 'horizontal' was qualified by 'substantially' whereas 'vertical' was not, the latter must mean 'geometrical vertical'."*

20. The broad principles set out in Amgen have been expanded into a series of guidelines to assist the court in its task of construing the Patent. These are summarised by the Court of Appeal in *Virgin Atlantic v. Premium Aircraft* [2009] E.W.C.A. (Civ.) 1062, at paragraph 5:

*"(i) The first overarching principle is that contained in Article 69 of the European Patent Convention.*

*(ii) Article 69 says that the extent of protection is determined by the claims. It goes on to say that the description and drawings shall be used to interpret the claim. In short, the claims are to be construed in context;*

*(iii) It follows that the claims are to be construed purposively - the inventor's purpose being ascertained from the*

*description and drawings.*

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

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

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

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

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

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

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

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

20. The defendants complain that the plaintiff seeks to steer the court towards a consideration of the questions in this case by giving the Protocol a higher status than it merits. They point out that the Protocol questions had disappeared from the English Court of Appeal's summary of the principles on construction set out in the *Virgin Atlantic* case, and they emphasized the remarks of Lord Hoffman in the *Kirin Amgen* case where he said, at paragraph 69:

> *"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 39 and its Protocol: what will 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 . . . they simply provide a formal justification for a conclusion which has already been reached on other grounds."*

He went on to say that once the judge has construed the claims, he has answered the question of infringement and "*it could only cause confusion to try to answer the Protocol questions as well".*

21. The extent to which the court can have regard to decisions in other jurisdictions has been considered by Clarke J. in the *Ranbaxy* case. At paragraph 51, he stated:

> *". . . it is important to note that, while the broad scope of patent law has many similarities from one common law country to the next, there are, undoubtedly, some differences in the established approach in the respective jurisdictions. In particular, the underlying statutory basis does differ. Ireland and the United Kingdom have, of course, the European Patent Convention in common, and, as was pointed out by counsel for the plaintiffs, the Patents Act 1992, is in very similar terms to the equivalent United Kingdom legislation, and is clearly closely modelled on the United Kingdom Patents Act 1977. This is hardly surprising, as both the United Kingdom and Ireland are signatories to and have ratified the European Patent Convention. It is fair to state that less caution needs, therefore, to be exercised in considering the application of judgments of the courts of the United Kingdom than other common law countries. In those circumstances, it seems to me, that while it would not be appropriate to ignore the jurisprudence of other common law countries, it is the decisions of the United Kingdom courts that require most attention. The broad approach to the construction of patents is, of course, at least similar. Unless there is a material statutory difference or an established variation in the applicable jurisprudence, it does seem that the non-United Kingdom common law authorities are also persuasive in this context. However, for the reasons I have set out, caution should be applied and it should not be assumed that all relevant factors are necessarily the same."*

The learned judge distinguished between a case in a foreign jurisdiction where the same legal principles arose, where the foreign judgment would have the status of persuasive authority and a case where foreign litigation touches upon the same actual matters, rather than the same legal principles. At paragraphs 54-56, he stated:

> *"[54]The principle of the comity of courts requires that the courts in one jurisdiction should not lightly depart from a decision on the same issue made by a court of competent jurisdiction in another country which had to deal with that issue as part of litigation properly under its consideration. Thus, for example, where the courts in one jurisdiction have interpreted a contract in an particular way and where the same contract comes to be interpreted, in a separate dispute between the same or similar parties, in the courts of another jurisdiction, then the comity of courts requires that the interpretation of the contract in the second proceedings should not lightly depart from the interpretation given to the same contract in the first proceedings.*
>
> *[55] This latter principle, it seems to me, ought also apply, though obviously to a more limited extent, where the issue, while not identical, is very similar. For those reasons it seems to me to be appropriate, subject to the caveats relating to differences in statutory law, jurisprudence, the patents themselves and the evidence which I*

*have already identified, to pay appropriate regard to the international decisions in the related cases.*

*[56] However, it is also important not to lose sight of the fact that the international decisions in this case (and in particular the decisions taken by the courts of the United Kingdom which derive from an almost identical statutory regime and analogous jurisprudence) have also the status, as to their principles, of persuasive authority. If the decision of the United Kingdom Court of Appeal in the proceedings between these parties had been between wholly separate parties then, nonetheless, the comments of Jacob L. J. on 'business common sense' would be a persuasive authority in this jurisdiction. It would, of course, be open to any party to suggest that this court should not be 'persuaded' because the case was wrongly decided. Such a course of action is always open to any party. However, that decision, like any decision of the Court of Appeal in the United Kingdom in this field, is likely to be regarded as persuasive by our courts in the absence of a good reason for not so doing. For the reasons which I have already analysed, I am satisfied that the decision of the United Kingdom Court of Appeal in the proceedings between these parties . . . is persuasive as to the principles to be applied and I propose following it."*

The defendants argue that the same situation arises in this case and that the court should, therefore, give particular weight to the decision of Arnold J. in the United Kingdom proceedings between, essentially, the same parties on the same issues. The Plaintiff argues that the UK decision is wrongly decided and informed the court that leave is being sought to appeal.

**The Patent**

22. The Patent in suit has a priority date of July 1994, and is given the description *"a flexible, expandable stent".* The Patent is derived from the Patent Cooperation Treaty (PCT), WO96/03092. The Patent discloses stents that are comprised of two intertwined *"meander patterns".* The Patent describes a meander pattern as *"a periodic pattern about a center line".* Figures 1 and 2 of the Patent show a preferred embodiment of the invention. Figure 2 has been coloured to highlight the meander patterns (the first meander is blue, the second red):

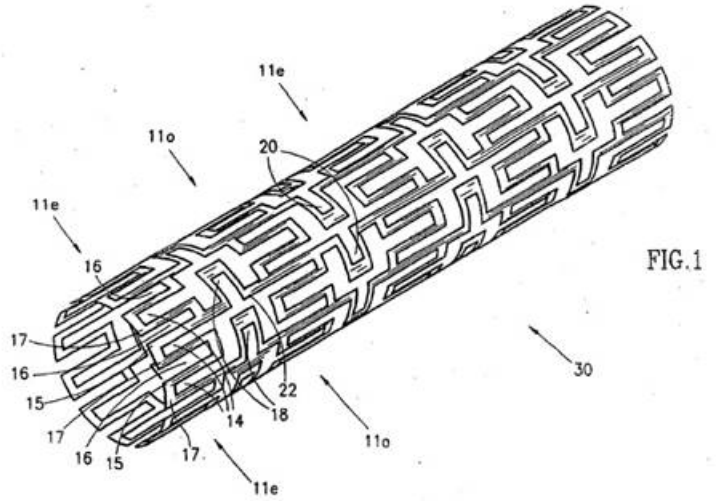


FIG.1

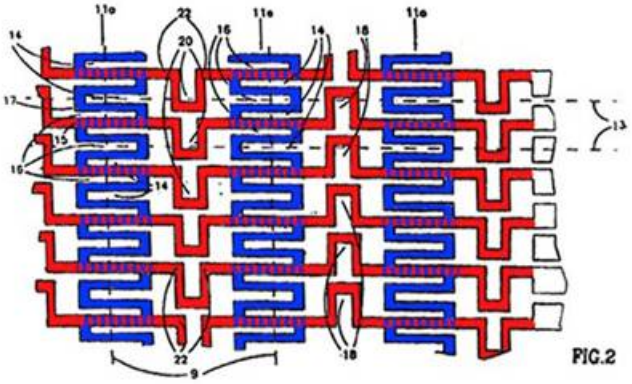


FIG.2

23. The Patent describes in summary, various embodiments of the overall inventive concept in paragraphs [0009] to [0012]. Thereafter, with reference to the figures, paragraphs [0013] to [0032] describe two specific embodiments in more detail. The use of the intertwined meander patterns provides, as the Patent explains, for a stent which has two advantages:-

(a) First, it is flexible and therefore can be easily passed through the blood vessels in order to be deployed. The way in which the meander patterns contribute to the flexibility of the stent can be observed in Figure 3. The loops of both the horizontal (or longitudinal) and vertical (or circumferential) meander patterns open or compress upon bending of the stent to provide flexibility.

Fig. 3

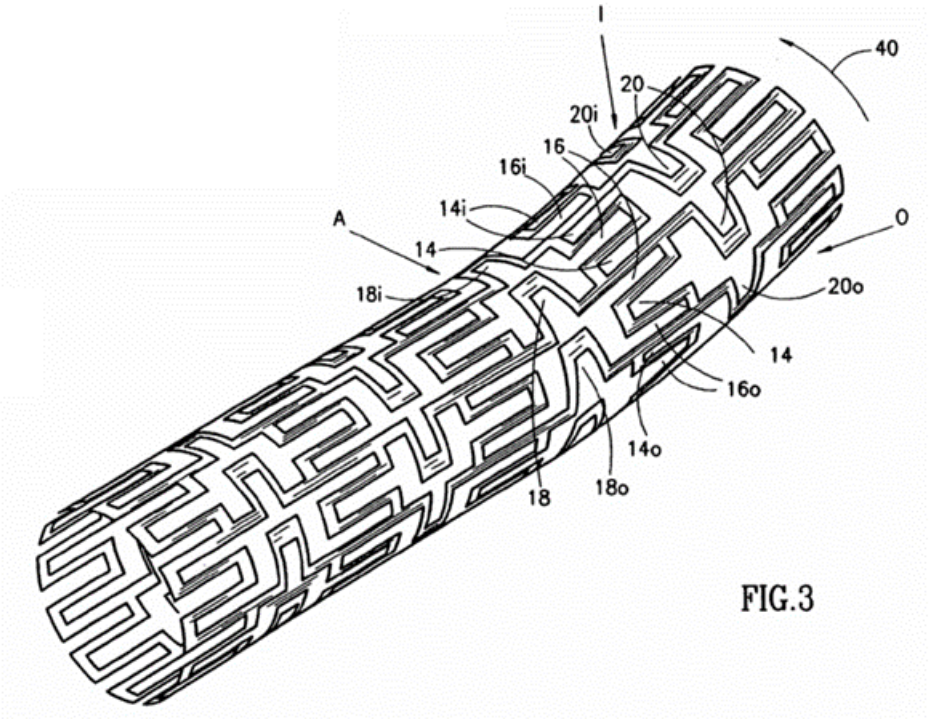



FIG.3

(b) Second, the stent minimally shrinks in the longitudinal direction during expansion. In the event that the expansion of the stent causes the vertical meander patterns to shorten, this shortening can be compensated for by the widening of the loops of the horizontal meander patterns.

The object of the invention is stated in paragraph [0007] under the heading *'Summary of the Present Invention'.* It reads:

> *"It is, therefore, an object of the present invention to provide a flexible stent which minimally shrinks, in the longitudinal direction, during expansion."*

24. The plaintiff claims that what is novel and inventive about the stent design disclosed in the Patent is the presence of longitudinally opening loops in the second (or horizontal) meander patterns, which are marked 18 and 20 in Fig. 2. These loops provide additional flexibility to the stent and also the ability to compensate for foreshortening of the stent, which might otherwise occur when the stent is expanded. The parties agree that the outcome of the infringement issue turns on the proper construction of the claims. No one has suggested that the words of the claim, and in particular, the use of the term "*meander patterns*" comprise terms of art.

25. [0008] and [0009] read as follows:-

> ***"[0008]*** *. . . the stent in the present invention is formed of a tube having a patterned shape which has first and second meander patterns having axes extending in first and second directions wherein the second meander patterns are intertwined with the first meander patterns. The first and second directions can be orthogonal to each other.*
>
> ***[0009]*** *In accordance with one embodiment of the present invention, the first meander patterns are formed into even and odd first meander patterns. The even and odd meander patterns can be 180o out of phase with each other and the odd patterns can occur between every two even patterns. The second meander patterns can also be formed of even and odd patterns."*

The wording of paragraph [0008] is interesting because it refers to the meander patterns *". . . having axes extending in first and second directions . . ."* but does not refer to a centre line or indicate that they have to be about a centre line. When one looks at the detailed description of preferred embodiments, paragraph [0015] states, *inter alia:*

> *"The term 'meander pattern' is taken herein to describe a periodic pattern about a center line and 'orthogonal meander patterns' are patterns whose center lines are orthogonal to each other."*

[0016] states:

> *"In the stent of Figs. 1-4, the two meander patterns are labelled 11 and 12 and they are most easily seen in Fig. 2. Meander pattern 11 is a vertical sinusoid, having a vertical center line 9. Meander pattern 11 has two loops, 14 and 16 per period, where loops 14 open to the right, while loops 16 open to the left. Loops 14 and 16 share common members, 15 and 17, where member 15 connects from one loop, 14, to its following loop, 16, and member 15 connects from one loop, 16, to its following loop, 14."*

In fact, Fig. 2 does not show a meander pattern labelled 12, and even a casual observation of Fig. 2 establishes that what was described as *". . . a vertical center line 9"* is not, in fact, in the centre of the sinusoidal pattern. Neither does the meander pattern which one can infer is number 12 (although not now shown) show the horizontal centre line 13 in what is, in fact, the centre of the meander pattern. This gave rise to an issue in the case as to the significance of *"center line".*

26. [0022] states that:

> *". . . both meander patterns 11 and 12 are involved in the bending. Although not shown, it will be appreciated that the stent in Figs. 1-4 can bend in any direction and in more than one direction at any time."*

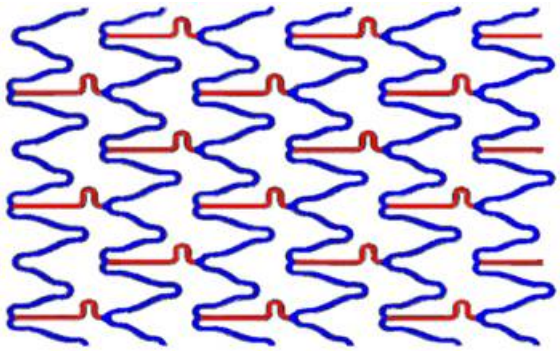
**The Claims in the Patent**
27. Claim 1 states:

> *"1. A flexible expandable stent formed of an elongated cylindrical unitary tube (30), having in a non-expanded form and in its expanded form a patterned shape, the patterned shape comprising first meander patterns (11) extending in the first direction, and second meander patterns (12) extending in a second direction, different from the first direction, wherein the first and second meander patterns comprise loops and are intertwined such that loops (14, 16) of each of the first meander patterns (11) are disposed between each of the neighbouring second meander patterns (12), and that one single loop (18, 20) of each of the second meander patterns (12) is disposed between each of the neighbouring meander patterns (11), and wherein the first and second meanders [sic] patterns (11, 12) define a plurality of enclosed spaces (42a, 42b; 44a, 44b).*
>
> *2. The stent according to claim 1, wherein the stent is formed from flat metal.*
>
> *3. The stent according to claim 1 or 2, wherein the meander patterns (11, 12) comprise a periodic pattern about a centre line in their corresponding direction.*
>
> *4. The stent according to claim one, wherein two loops (14, 16) of each of the first meander patterns (11) are disposed between each of the second meander patterns (12) . . .*
>
> *8. the stent according to any one of the preceding claims, wherein the first and second meander patterns (11) comprise odd and even meander patterns [11o, 11e] 180o out of phase. . ."*

28. It is worth noticing some differences in disclosure of the Patent between the PCT Application and the Patent in issue. The Application and the Patent have the same drawings. A crucial difference is that the scope of the broadest claim of the Patent is not limited to out-of-phase stents, whereas in the Application, the disclosure is so limited. The defendants argue that this makes sense because it is only out-of-phase stents that may experience any significant degree of longitudinal shrinkage, which is the only stated problem that the Patent seeks to overcome. The defendants point to a material change in the description in paragraph [0009] where the preferred embodiments are now described to have even and odd first meander patterns that *"can be 180o out-of-phase with each other".* The court is invited to conclude that the purpose of the change was to widen the Patent to catch actual stent products which came to the knowledge of the plaintiff only after the Application such as the defendants' stents, which had an in-phase design and so did not need to minimise shrinkage.

**The Defendants' stents alleged to infringe**
29. The plaintiff alleges infringement by the defendants small and medium "MultiLink Vision, *MultiLink 8, Xience* and *Xience Prime"* stents ("Abbott's stents"). While there are a number of stents in issue, they are sufficiently similar that the same issues arise in respect of each of them. The details of the alleged infringing stents are not in dispute, nor is it disputed that the acts alleged to constitute infringement are taking place. Infringement will only occur if the alleged infringement has all the features of the claim construed in accordance with the Protocol (which may or may not involve the application of the Protocol questions).

30. The general design of Abbott's stents is shown below.

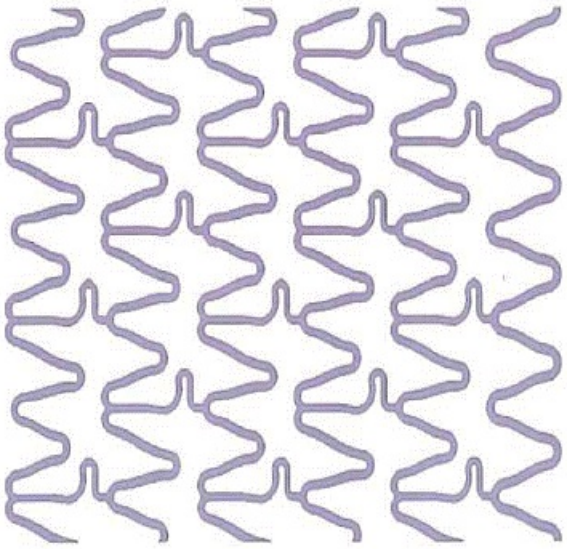


31. They consist of a series of vertical rings (blue) connected by horizontal (red) struts which contain loops to improve flexibility. In contrast to the connecting struts in the Patent which proceed in a straight line across the stent, in the Abbott stent, the connecting struts are staggered. In the vertical direction, although the loops look symmetrical, some loops are, in fact, shorter than others.

32. There are eight Abbott stent designs that are in issue: small and medium Vision; small and medium *MultiLink 8;* small and medium *Xience* and small and medium *Xience Prime*. The *Xience* and *Xience Prime* stents are of the same design and structure as the bare metal (uncoated) *Vision* and *MultiLink 8* stents, respectively, the only difference being that they are coated with material containing the anti-proliferative drug, *Everolimus.* Therefore, it is only necessary to consider four different Abbott stent designs, and of these four, the only significant differences for the purpose of this case are found in a comparison between the small and medium configurations for each of the *Vision* and *MultiLink8* stent.

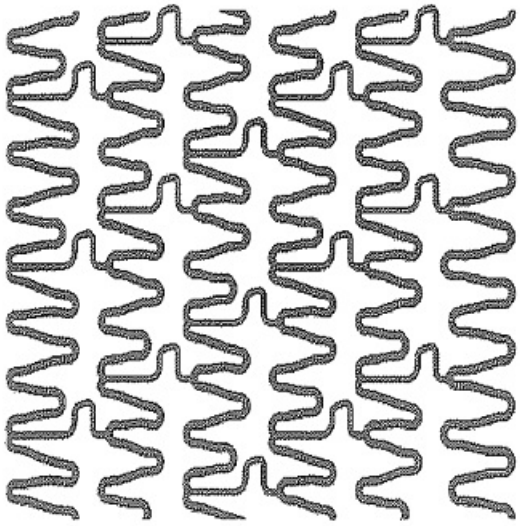
33. The small stents have six crests *per* circumferential ring and three longitudinal connectors in a staggered configuration between each ring. The defendants maintain that this staggered configuration follows the teaching of Lau in an earlier patent. The longitudinal connectors are offset from each other so that every second connector is in-line longitudinally and there is no "backbone" of connectors, as in the Medinol Patent embodiments.

*Small Multi-Link 8 configuration*



34. The medium stents have an additional three crests *per* circumferential ring. They still only have three longitudinal connectors in a staggered arrangement between each ring. Thus, the longitudinal connectors are offset from each other so that every third connector is in line longitudinally, with no "backbone" of connectors, as in the Medinol Patent embodiments.

*Medium Multi-Link 8 configuration*



35. The plaintiff alleges infringement of claims 1, 2, 3, 6, 9, 10, 11 and 12 of Patent 902. This is disputed by the defendants. The parties disagree as to how the Abbott stents should be described. The defendants claim that the plaintiff's attempt to describe them in terms of two intertwined meander patterns is totally artificial. The defendants contend that the Abbott stents contain undulating rings connected by individual, offset longitudinal links.

36. Dr. Richter, who is the founder of the plaintiff company, and its chief technical officer, stated that the plaintiff developed a prototype of the NIR stent using the designs of the 902 Patent. The designer started with Figures 7 and 8 of the Patent in suit, and he says that with minor modifications, they arrived at the design of the NIR stent. The only change made to the design in the Patent was that the loops of the second meander patterns (indicated in red below) were altered so that in the NIR stent, they point in one direction.

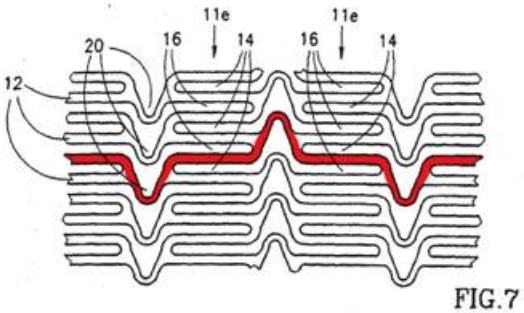
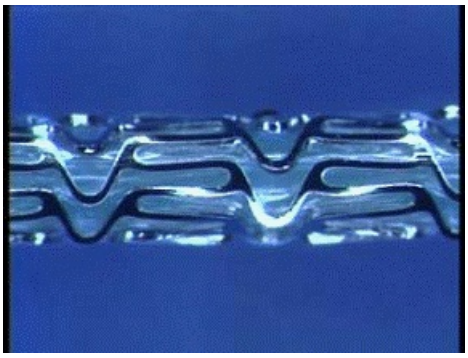



FIG.7



37. He says that this was done to make the manufacture of the stents easier. He agreed with the suggestion of counsel that instead of having the single loop in the horizontal path, alternately pointing up and down to give a precisely symmetrical pattern, it was changed so that all the loops faced downwards. This change was effected around the time of the filing of the Patent. The witness said that these changes had nothing to do with symmetry or asymmetry and that symmetry had nothing to do with stent performance.

38. Professor Reifart said that in July 1994, the field of coronary stenting was developing fast. He agreed it was possible to make a very flexible stent, either with or without a curve in the connector. He was of the view that the problem of foreshortening with the Palmaz Schatz stent was overestimated. In cross-examination, he accepted that cardiologists were not aware of any shortcomings with the Lau design and he said, *"The Multi-Link stent is an embodiment of the Lau publication".* Although he suggested that paragraph [0004] of the Patent referred to problems of longitudinal shrinking of stents on expansion, he agreed that this was not stressed heavily. In 1994, the question of symmetry was not a concern, and when asked whether it had any effect on the functioning of the stent, he said that regularity or symmetry probably makes it easier to predict what happened in the vessel, but he felt that symmetry was not an issue.

39. Professor Snyder said that a meander pattern is a path defined by the structural elements of the stent that wanders to and fro on either side of a centre line. It was a pattern that repeats. In reading the Patent, he could not understand the inventors to be making a statement that symmetry was required. He also failed to come up with any reason why symmetry would provide any functional advantage. In his view, it would not be obvious at all, or even reasonable, for someone following Lau's instructions to insert loops. The undulating rings that make up the stent need to be very close together in order to fully support the blood vessel. That would leave one without an identifiable space in which to put an added loop. Professor Snyder said that the purpose of the straight struts is to stabilise the rings and he did not see how one could be motivated to insert a strut that could actually change in length, because this would provide less stabilisation to the rings. In his view, symmetry did not have any impact on whether a stent opened evenly or unevenly. The inventive concept in the Patent in suit is the inclusion of a loop between the adjacent first meander patterns. Under cross-examination, he said that the Patent in suit discloses a flexible stent that does not foreshorten appreciably, and he agreed that one of the important or useful things that are taught by the Medinol Patent, is that avoidance of foreshortening occurs by using an out-of-phase arrangement and this is central to the teaching of Medinol.

40. In his second report, Professor Snyder says:

> *"The disagreement between me and Professor McHugh is whether the phrase 'odd and even' relating to meander patterns means that the meander patterns must be out-of-phase, or whether they can be in-phase. In summary, I believe that Professor McHugh and I agree that odd and even is not restricted to mean out-of-phase in relation to meander patterns, but differ, in that he believes odd and even is restricted to out-of-phase in relation to the first meander pattern . . . I see no basis in 902 for equating odd and even to out-of-phase in relation to either meander pattern."*

He agreed that this was different to his evidence in the Dutch court, where he equated the two, and that when reading the Patent, the reader observes the distinction between the first meander patterns being stated to be 180o out-of-phase with each other, and that there is no such statement in relation to the second meander pattern.

41. He agreed that the degree of foreshortening, if any, which occurs on expansion, depends on both meander patterns:

> *"The stent in the present invention is formed of a tube having a patent shape which has first and second meander patterns, having its axes extending in the first and second directions, wherein the second meander patterns are intertwined with the first meander patterns." [0008]*

He also agreed that this was the essence of the invention, together with the imposition of loops. He said, *"I think the principle of the invention is the intertwining of the meander patterns with loops in between"*. He accepted there was nothing in the teaching to suggest an in-phase arrangement, and that one would understand that loops 18 and 20 would provide compensation in any design that would otherwise foreshorten. It was put to Professor Snyder that the claim requires that there be multiple loops of each of the

first meander patterns between each of the neighbouring second meander patterns and he agreed. He also agreed that a second requirement of the claim is that there be one single loop of each of the second meander patterns disposed between each of the neighbouring first meander patterns, and he suggested that the invention would work fine with single loops or multiple loops. In answer to a question put by me, he accepted that it was obvious at the time to a person skilled in the art that loops were something that would assist in the expansion of a stent, but he did not think it would have been obvious that loops might come into play to prevent shrinkage. Professor Snyder was pressed by counsel to agree that at the priority date, it would have occurred to people skilled in the art, that if they wanted to make a stent more flexible, one way to do it was to put in loops. It seemed to me that the witness did not engage with this particular topic, other than saying that he understood that the Fischels stent did that, but when pressed on the point, he appeared to have trouble in answering the question in the abstract.

42. Professor Davies, a consultant at the Royal Brompton Hospital, London, adopted his statement of evidence in which he said that in 1994, the problem of foreshortening was well known to interventional cardiologists. He said:

> *"The cardiologists needed to make mental allowance or adjustment for any expected shortening of the stent during deployment."*

In his evidence, he discussed the deployment of stents and the desirability of having a flexible stent. It is clear from his evidence that flexibility was the main issue so that the stent could be delivered to a lesion in a blood vessel which might have an irregular path. Apart from flexibility aid delivery of the stent, the other issues that were important for cardiologists at the priority date were thrombosis and the radial strength of the stent required to keep the blood vessel open. He also included minimal foreshortening in the list of desirable characteristics of a stent, and said that in 1994, the problem of foreshortening was well known to interventional cardiologists and he cited some examples in his second statement of evidence.

43. Professor McHugh said that an engineer, in 1994, would appreciate the importance of symmetry in an engineering component. He said that the function of loops 18 and 20 and the use of the term *"meander pattern"* were novel features of the specification. He said there was nothing in the description of how loop 18 aids flexibility which is dependent upon the phase of the vertical path, and he agreed that the only mechanism for adding length to the horizontal path to compensate for shrinkage of the vertical path is loop 18. Although he accepted that he did not know whether anybody paid attention to a need for symmetry at the priority date, he postulated that it might have been seen as an important aspect of stent design based on what he believed would be the natural inclination of a medical device engineer based on his training and experience.

44. Professor McHugh was asked if there was any teaching in the specification of the Patent in suit that in any way hints that symmetry was required, apart from the use of the words *". . . about a center line . . ."* in paragraph [0015], and he replied that one other hint in the language of the Patent was the use of the term *'sinusoid'*, as appears in the expression *". . . the meander pattern is a vertical sinusoid having a vertical line 9 . . ."* [0016]. His view was that when one looks at the patterns, the first and second meander patterns are clearly symmetric, and although the centrelines were shown in the wrong place in the drawings, the word *'center line'* was used and had a real additional meaning. The pattern he saw was based on an engineering understanding of what a centreline is, along the line of glide-reflective symmetry. Professor McHugh accepted that the connector works in exactly the same way, whether the rings are symmetric or asymmetric, in the sense, that by opening or closing, they will aid flexibility, and this would have been obvious in 1994. He also agreed that it would have been obvious at the priority date that whether the loops pointed up or down would not matter. His initial thoughts upon reading the Lau patent would have been to put a loop in the connectors, but he admitted that he was already aware of the NIR stent before he gave this evidence.

**Alleged Infringement**

45. The Patent in suit must be construed from the perspective of a person skilled in the art to whom the Patent is addressed. The addressee, in this case, is a team consisting of a biomedical engineer and an interventional cardiologist. The question is what would a person skilled in the art have understood the patentee to have used the language of the claim to mean?

46. I am satisfied that I should use a purposive construction so as to avoid *". . . the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge"* (Diplock L.J. in *Catnic Components Ltd. v. Hill and Smith Ltd.* [1982] R.P.C. 183 at 242-243. The court has to identify the notional *"person skilled in the art"* and then identify the relevant common general knowledge of that person. The court should then look at the inventive concept of the claim in question, and if it cannot readily be identified, it should be construed. In his judgment in the *Re Glaxo Group Limited case* [2009] IEHC 277, Charleton J., at paragraph 27, referred to the *"problem and solution approach"* adopted by the European Patent Office which involves three main stages:-

> *"1.Determining the closest prior art;*
>
> *2.Establishing the technical problem to be solved;*
>
> *3. Starting from the closest prior art and the technical problem, then considering whether or not the claimed invention would have been obvious to the skilled person."*

47. It is important also to have regard to the Patent Act 1992. Section 45 provides, *inter alia:*

> *"45(1) The extent of the protection conferred by a patent or a patent application shall be determined by the claims; nevertheless, the description and drawings shall be used to interpret the claims . . .*
>
> *(3) In the interpretation of this section, the court shall have regard to the directions contained in the Protocol on the Interpretation of Article 69 of the European Patent Convention and set out in the Second Schedule to this Act."*

48. The starting position, therefore, is to look at the claims, and the drawings which shall be used to interpret them, and to do so through the eyes of a person skilled in the art to whom the patent is addressed. In the Patent in suit, paragraphs [0007] to [0012] set out a summary of the invention. It is stated that the object of the invention is to provide a flexible stent which minimally shrinks in the longitudinal direction during expansion. It is stated that this object is achieved according to the invention by a stent as defined in Claim 1. I have already quoted from Claim 1 in paragraph 27 of the judgment. What is clear from Claim 1 is that the stent in its expanded form has a patterned shape:

> *". . . comprising first meander patterns (11) extending in a first direction and second meander patterns (12) extending in a second direction, different from the first direction . . ."*

These words are clear and unambiguous and provide that there shall be first meander patterns and second meander patterns, each extending in different directions. I have no doubt that this would be clear to a person skilled in the art. In Claim 3, it is stated that:

> *"The meander patterns (11, 12) comprise a periodic pattern about a center line in their corresponding direction."*

Claim 4 provides that:

> *"Two loops (14, 16) of each of the first meander patterns (11) are disposed between each of the neighbouring second meander patterns (12)."*

49. A detailed description of the preferred embodiments is contained in paragraphs [0014] to [0032]. In paragraph [0015], the following appears:

> *"The term 'meander pattern' is taken herein to describe a periodic pattern about a center line . . ."*

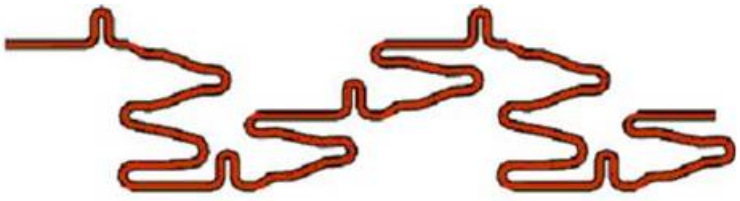
In paragraph [0016], there is a reference to Figure 2 and it is stated that the meander pattern (11) seen there:

> *". . . is a vertical sinusoid having a vertical center line 9."*

Paragraph [0017] states that:

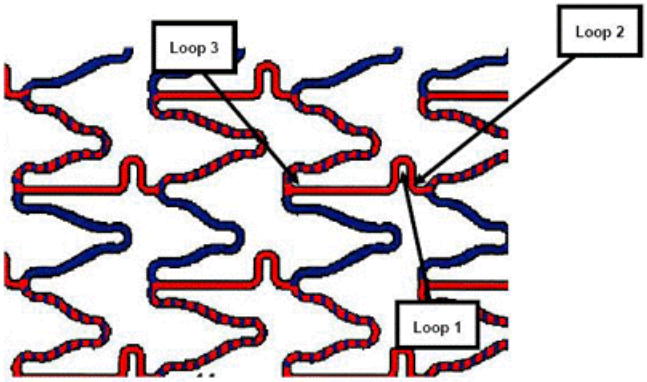
> *"Meander pattern 12 is an horizontal pattern having an horizontal center line 13 . . ."*

50. The general design of Abbott's stents is shown in paragraph 30 above. As I have already indicated, all the defendants' stents, which are alleged to infringe the Patent in suit, are sufficiently similar that a diagrammatic representation of one of them will suffice when it comes to illustrating differences between the Abbott stents and the Patent in suit. The alleged second meander pattern on the Medium Vision Stent appears as follows:



51. The defendants claim non-infringement because the undulating rings of the Abbott stents are not first meander patterns; they are not periodic patterns about a centreline. The Abbott stents intentionally contain a combination of long and short crests. If one adopts the terminology of the Patent in suit and applies it to the Abbott stents so as to look for meander patterns, it is clear that what might be referred to as a *"second meander pattern"* in the Abbott stents is not discernible at all when measured against the claims for the Patent in suit. It does not have a line of symmetry and does not run or extend *". . . in a second direction, different from the first direction . . ."* (Claim 1).

52. Furthermore, if one considers the issue of loops, one sees that the claims of the Patent in suit require that there be one single loop (18, 20) of each of the second meander patterns (12) disposed between each of the neighbouring first meander patterns (11). The defendants argue that the Abbott stents do not infringe because they contain some loops that are formed in part by the second meander pattern and in part by metal that is in both patterns, which appear as loops marked 2 and 3 in the diagram below. Loop 1 is completely within what is described as the *"second meander pattern"* by the plaintiff.




**Conclusion on Infringement**

53. The teaching of the Patent in suit is that "meander pattern" means a periodic pattern about a centreline and suggests to a person skilled in the art that the pattern is symmetrical. Using the description and drawings to interpret the claims, it is clear that the meander patterns are symmetrical and that the first meander pattern extends in a vertical direction and the second meander pattern extends in a horizontal direction, different from the first direction. While it is true that the centreline is incorrectly positioned in the drawings, this does not affect the issue. What is immediately obvious about the Abbott stents, which are alleged to infringe, is that the patterns contained therein are not periodic about a centreline. They are not symmetrical and were intentionally asymmetric, containing a combination of long and short crests in order to create a pocket in the ring for the "U-shaped" portion of the link. What the plaintiff suggests is a second meander pattern in the stents alleged to infringe are not meander patterns according to the teaching of the Patent in suit. Furthermore, to a skilled person, what is alleged by the plaintiff to be a second meander pattern in the Abbott stents is not a second meander pattern at all, and does not extend in a second direction that differs from the direction of the alleged first meander pattern. It runs, for the most part, in the same direction as the alleged first meander pattern, since substantial sections of the alleged "second meander pattern" also form part of the alleged "first meander pattern".

54. A similar conclusion has already been reached in the proceedings between the parties in the Netherlands, Germany and the United

Kingdom. These three countries, like Ireland, are all signatories to the European Patent Convention. In the case of the UK and Ireland, they also have a similar legislative regime applying to patents and the issues arising in the other courts were between the same, or almost identical, parties, and involve the same issues.

55. Before leaving the question of symmetry, I should make a few observations concerning the evidence. The preponderance of evidence was to the effect that in the Patent in suit, the connector works in exactly the same way, whether the rings are symmetric or asymmetric, and Professor McHugh accepted that it would have been obvious at the priority date that whether the loops were in-phase or out-of-phase would not matter, but it would have appeared to a skilled person that the patentee was ascribing some significance to symmetry because of the use of the words *". . . about a center line"* in paragraph [0015] and the use of the word "sinusoid" appearing in the expression *". . . the meander pattern is a vertical sinusoid having a vertical line 9 . . ."* [0016]. It would be wrong, therefore, to ignore the preferred embodiments described in the Patent. But even if one was to accept the plaintiff's argument that the issue of symmetry was of little or no importance, the attacked embodiments have no meander pattern as understood in the Patent in suit, and clearly have no second meander pattern.

56. At the hearing of this action, some time was spent on the issue of loops. The Patent discloses to a person skilled in the art that:

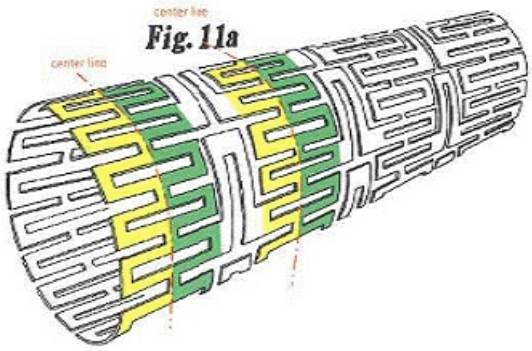
> *". . . one single loop (18, 20) of each of the second meander patterns (12) is disposed between each of the neighbouring first meander patterns (11) . . ."* **[Claim 1]**

When one looks at the Abbott stents, there is no single loop of each of the second meander patterns (12) disposed between each of the neighbouring first meander patterns (11). In the first place, there is no "second meander pattern". The plaintiff argued that Loop 3 is part of a loop of the first meander pattern and not a loop of the second meander pattern because it does not widen longitudinally upon expansion. In the United Kingdom proceedings, Arnold J. stated that this seemed to him to amount to an argument that the word 'loop' should be interpreted differently, depending on whether one is considering the first meander pattern or the second meander pattern, an assertion which he did not accept. I would agree with him. Loop 3 appears to be disposed between neighbouring first meander patterns, but if one looks at the representation of the alleged second meander pattern of the Abbott stent contained in paragraph 50 above, it seems clear that it is a loop within that pattern. I agree with the view of Arnold J. that if loop 2 was a more marginal case, it was, nevertheless, both a loop of the "second meander pattern" and also disposed between neighbouring first meander patterns. For that reason, I would agree with Arnold J. and also with the German court which said that the attacked embodiments use the technical teaching of the Patent in suit neither literally nor by equivalent means, as there is no single loop (18, 20) of each of the second meander patterns (12) disposed between each of the neighbouring first patterns (11).

57. The Abbott stents do not infringe the Patent in suit.

58. Finally, there are a number of subsidiary issues which arise for consideration. The first is obviousness over Lau. Professor McHugh gave evidence that supported a conclusion that the Patent in suit is obvious over Lau. But he conceded, in cross-examination, that he was aware of the NIR stent and the issue of the loop when he considered the issue. As the issue of obviousness over Lau and anticipation is raised by the defendants in their counterclaim, they assume the burden of proof on this issue. Anticipation by Lau turns on the single loop argument. The defendants contend that loop 3 of the Abbott stents (as illustrated in the diagram in paragraph 52 above), is a loop fulfilling the requirements of the claim because Lau's equivalent of loop 3 is its only loop of the second meander pattern between adjacent first meander patterns, and so represents the single loop required by Claim 1 of the Patent. I find the evidence on this issue inconclusive and somewhat coloured by hindsight. I therefore make no finding on this issue.

59. The other remaining issue is whether Burmeister anticipates. The plaintiff argues that there are closed loops or slots in the Burmeister patent which are not "meander patterns" according to the Patent in suit. Secondly, it does not disclose a flexible stent. On the latter point I am satisfied that the Burmeister patent discloses a flexible stent. It seems clear to me, however, that a person skilled in the art would look at Burmeister and see that the closed loops would be capable of expanding.




60. The plaintiff argues that if you take Burmeister at Figure *11a* and draw a centre line through the closed loops so as to consider the pattern on each side of the centre line as a meander pattern, there is no loop in between. That is undoubtedly correct. But there is a loop disposed between each of the closed loops. The defendants argue that, to the skilled reader, the stent disclosed in Burmeister's Figure *11a* would, inevitably, have fallen within Claim 1 of the Patent in suit. I think that the loop, in what might be considered the horizontal meander pattern in Burmeister Fig. *11a* fulfils the same function as loops 18 and 20 in Fig. 1 of the Patent in suit and the other loops open in a similar manner to the vertical meander pattern in the Patent in suit even if the loops are slots or "closed".

61. In *General Tyre and Rubber Co. v. Firestone Tyre and Rubber Co. Ltd.* [1972] R.P.C. 457, at 483-484, the Court of Appeal stated:

> *"To determine whether a patentee's claim has been anticipated by an earlier publication, it is necessary to compare the earlier publication with the patentee's claim . . . if the earlier publication . . . discloses the same device as the device which the patentee by his claim . . . asserts that he has invented, the patentee's claim has been anticipated, but not otherwise . . .*
>
> *When the prior inventor's publication and the patentee's claim have respectively been construed by the court in the light of all properly admissible evidence as to technical matters, the meaning of words and the expressions*

*used in the art and so forth, the question whether a patentee's claim is new . . . falls to be decided as a question of fact. If the prior inventor's publication contains a clear description of, or clear instructions to do or make, something that would infringe the patentee's claim if carried out after the grant of the patentee's patent, the patentee's claim will have been shown to lack the necessary novelty . . . The prior inventor, however, and the patentee may have approached the same device from different starting points and may, for this reason, or it may be for other reasons, have so described devices that it cannot be immediately discerned from a reading of the language which they have respectively used that they have discovered in truth the same device; but if carrying out the directions contained in the prior inventor's publication will inevitably result in something being made or done which, if the patentee's claim were valid, would constitute an infringement of the patentee's claim, this circumstance demonstrates that the patentee's claim has in fact been anticipated.*

*If, on the other hand, the prior publication contains a direction which is capable of being carried out in a manner which would infringe the patentee's claim, but would be at least as likely to be carried out in a way which would not do so, the patentee's claim will not have been anticipated, although it may fail on the ground of obviousness. To anticipate the patentee's claim, the prior publication must contain clear and unmistakable directions to do what the patentee claims to have invented . . . a signpost, however clear, upon the road to the patentee's invention, will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee."*

That passage was considered by the House of Lords in *Synthon v. SmithKline Beecham* [2006] 1 All. E.R. 685, at 694, when Lord Hoffmann said:

*"If I may summarise the effect of these two well known statements, the matter relied upon as prior art must disclose subject matter which, if performed, would necessarily result in an infringement of the patent. That may be because the prior art discloses the same invention. In that case, there will be no question that performance of the earlier invention would infringe and usually it will be apparent to someone who is aware of both the prior art and the patent that it will do so. But patent infringement does not require that one should be aware that one is infringing . . . it follows that, whether or not it would be apparent to anyone at the time, whenever subject matter described in the prior disclosure is capable of being performed and is such that, if performed, it must result in the patent being infringed, the disclosure condition is satisfied. The flag has been planted, even though the author or maker of the prior art was not aware that he was doing so."*

62. The determination of the question whether Burmeister anticipates depends, to some extent, on whether the enclosed slots shown at Burmeister Figure *11a* comprise loops. A person skilled in the art would consider how the Burmeister stent expands and would be in no doubt that the slots operate in a similar manner to the Patent in suit, in that they open upon expansion in the same way as facilitated by the Patent in suit. However, Medinol and Abbott are in agreement that the second meander pattern in Burmeister Figure *11a* embodiment is asymmetric. If symmetry is required for a meander pattern, Burmeister does not satisfy the definition. Given the 'meander pattern' has been construed as Abbott contend, I conclude that the Burmeister prior art does not anticipate Claim 1 of the 902 patent.