Neutral Citation Number: [2010] EWHC 2865 (Pat)

Case No: HC09C01401

IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 12 November 2010

Before :

THE HON MR JUSTICE ARNOLD

- -

Between :

ABBOTT LABORATORIES LIMITED	**Claimant**
- and -	
MEDINOL LIMITED	**Defendant**

- -
- -

Simon Thorley QC, Richard Meade QC and **Charlotte May** (instructed by **Taylor Wessing LLP**) for the **Claimant**
Antony Watson QC and **Thomas Hinchliffe** (instructed by **Hogan Lovells LLP**) for the **Defendant**

Hearing dates: 13-15, 18-20, 22, 25 October 2010

- -

Approved Judgment

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

.....

THE HON MR JUSTICE ARNOLD

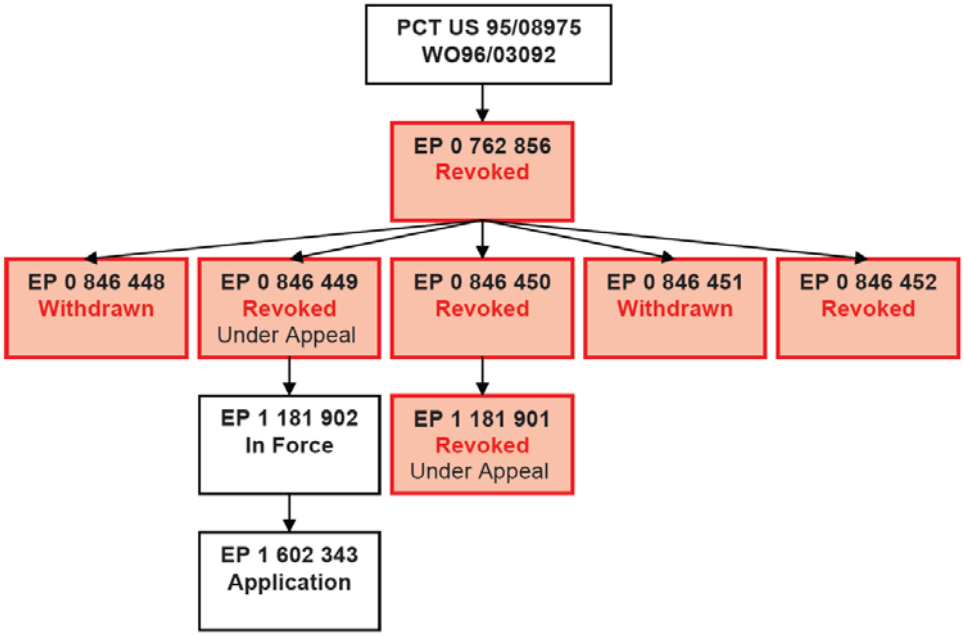
MR. JUSTICE ARNOLD :

Contents

Introduction

1. In these proceedings the Claimant ("Abbott") seeks declarations of non-infringement, and orders for revocation, of three patents for coronary stents owned by the Defendant ("Medinol"), namely European Patents (UK) Nos. 0 846 449 ("449"), 1 181 901 ("901") and 1 181 902 ("902") (collectively, "the Patents"). The Patents are related, stemming from the common European Patent Application, and later Patent, No. 0 762 856 ("856"). This in turn was based on International Patent Application No. WO/9603092 ("the Application").

2. 449 is a divisional from 856, and 902 is a divisional from 449. 901 is a divisional from a fourth European Patent Application, No. 0 846 450 ("450"), which itself was a divisional from 856. 856, 449, 450 and 901 have all been revoked by the Opposition Division of the European Patent Office. The decisions to revoke 449 and 901, dated 14 May 2008 and 11 March 2008 respectively, are under appeal by Medinol. Two further applications which are divisionals from 856 have been withdrawn by Medinol, while a further application which is a divisional from 902, No. 1 602 343, is still pending. This situation can be depicted diagrammatically as follows:



3. Medinol originally counterclaimed for infringement only in respect of 902, although it denied that Abbott was entitled to a declaration of non-infringement of 449 and 901. It appears that the reason for this was that Abbott failed to oppose any of the Patents in the European Patent Office. By the time Medinol served its counterclaim, opposition proceedings against 902 had been concluded and it was too late for Abbott to try to intervene. By contrast, the appeals in respect of 449 and 901 were still pending and thus a claim for infringement by Medinol would have given Abbott standing to intervene in those proceedings. On the first day of trial, however, Medinol sought and obtained permission to amend its counterclaim to allege infringement of 901. Furthermore, counsel for Medinol stated that Medinol's position in respect of 449 was that "if valid, it is infringed". Thus the upshot is that Medinol now contends that all three Patents have been infringed by Abbott, although it is only claiming relief in respect of 901 and 902.

4. The allegations of infringement concern the small and medium versions of each of Abbott's Vision, Multi-Link 8, Xience and Xience Prime Stents ("the Abbott Stents"). Both the District Court of the Hague in a decision dated 23 December 2009 and the Regional Court of Düsseldorf in a decision dated 30 March 2010 have held that 902 is not infringed by the Abbott Stents, albeit for different reasons. I was informed that a parallel claim is due to be tried in Ireland in January 2011.

5. Abbott contends that the Patents are invalid on the grounds of lack of novelty over European Patent Application No 0 540 290 ("Lau") and International Patent Application No. WO 95/31945 ("Burmeister"), obviousness over Lau, added matter and insufficiency. The earliest claimed priority date for all three Patents is 28 July 1994. There is no issue as to priority in these proceedings. In response to the allegation of obviousness, Medinol relies on the commercial success of stents which it says were made in accordance with the claimed inventions. In response to the allegation of added matter, Medinol has a conditional application to amend.

6. Lau is an application by Advanced Cardiovascular Systems, Inc ("ACS"), a predecessor of Abbott. The Abbott Stents are developments of the first Multi-Link

stent marketed by ACS in accordance with Lau. It is an important plank of Abbott's case in these proceedings that the Abbott Stents are based upon the teaching of Lau and not that of the Patents. Consequently, Abbott contends that the Patents cannot be both infringed by the Abbott Stents and valid in the light of Lau. Medinol disputes both these contentions.

Technical background

7. The heart receives its blood supply through the coronary arteries. These are curved in three dimensions, and in some people can become quite tortuous, particularly as a result of age and disease. The coronary arteries may become hardened, diseased and narrowed, or even blocked, by material such as cholesterol and calcium, which is known as atherosclerotic plaque. This can reduce or prevent blood (together with the oxygen and nutrients it carries) reaching the heart muscle. The blockage of an artery is called stenosis. It can lead to the death of heart muscle, myocardial infarction (heart attack) and death.

8. With less severe instances of atherosclerotic plaque, drugs, such as anti-platelet drugs, beta blockers or now statins, can be used to minimise the build up of further plaque. More severe cases are dealt with by coronary bypass surgery or percutaneous transluminal coronary angioplasty ("PTCA" or "balloon angioplasty") or the insertion of one or more stents.

9. Balloon angioplasty was first carried out in 1977. It involves inserting a balloon-tipped catheter into an artery in the groin and guiding it to the diseased coronary artery. The balloon is then inflated to dilate the artery, before being removed. There are three main potential drawbacks of balloon angioplasty: (i) immediate abrupt closure of the artery e.g. due to tearing of the artery wall, (ii) elastic recoil (i.e. contraction of the blood vessel) and (iii) later recurrence of stenosis (called restenosis).

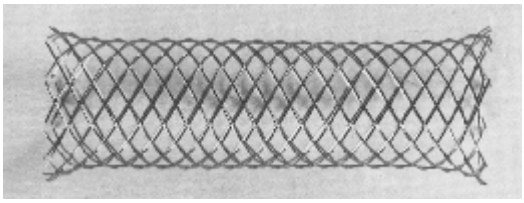
10. The first stent was inserted in 1986. Stents are cylindrical devices, usually made of metal, that are inserted into coronary arteries typically after balloon angioplasty. The basic idea behind stents is that a stent is delivered to the site of the blockage and then expanded, whereupon the stent acts as scaffolding to keep the artery open. Stents are typically delivered mounted on the end of a catheter that runs along a guide wire. The steps of inserting the stent and guiding it into position are monitored on a screen by the person conducting the operation using x-rays.

11. There are two main methods of expanding the stent. The first is to use a balloon. In this method the stent is delivered to the desired site crimped around a balloon. Once it is in position, the balloon is filled, usually with saline solution at high pressure. The pressure expands the stent, the material of which undergoes plastic deformation. Subsequently, the balloon is deflated and withdrawn with the catheter and guide wire, leaving the expanded stent in place. The second method is to use a self-expanding stent. In this method the stent is made from a material which undergoes elastic deformation. It has a sheath over it to prevent expansion until it is in the desired location.

12. Stents represented a significant advance over balloon angioplasty, in particular since they reduced the frequency of restenosis. To begin with, stents were inserted as a

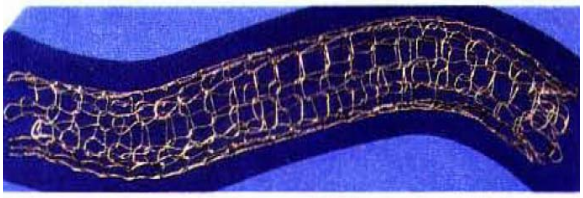
"bail-out" procedure when there was abrupt closure of the artery after balloon angioplasty, or the threat of it. Then they began to be used when balloon angioplasty gave sub-optimal results. By the end of July 1994, stents were increasingly being used on an elective basis. I shall return to this point below.

13. Since 1986 the design of stents has progressively developed. The first stent to be inserted was the Wallstent, a self-expanding stent made of stainless steel wire mesh which looked like this:

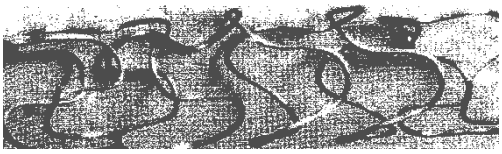


14. The Wallstent was flexible before expansion and had good radial strength after expansion. Its main deficiency was that it tended to shorten a lot on opening, with the result that when a cardiologist implanting it positioned the distal end (the one furthest away), it was unpredictable where the proximal (near) end would be after expansion and therefore how much of the vessel would be supported. Other problems were that the double thickness of metal at the wire crossing was thought to increase the risk of thrombosis and it had sharp flared ends which caused trauma to the artery wall.

15. Another early stent was the Strecker, a balloon-expandable tantalum wire stent. The Strecker stent suffered from poor crimping onto the balloon and also had a lot of metal protruding into the lumen, which was thought to increase the risk of thrombosis. It looked like this:



16. The Wiktor stent was introduced in 1992 and was a balloon-expandable tantalum wire stent. Like the Strecker (although to a lesser extent), it suffered from poor crimping onto the balloon. It also suffered from moderate to poor radial strength and provided poor scaffolding (i.e. uniform support for the vessel wall, so as to prevent prolapse). It looked like this:



17. The Gianturco Roubin I ("GRI") was a stainless steel balloon-expandable serpentine wire stent with a clam shell design. It lacked radial strength, provided poor scaffolding and suffered from high restenosis and thrombosis rates. It looked like this:

18. An important development was the Palmaz-Schatz (PS-153) stent, which was clinically available from 1992. This was a stainless steel balloon-expandable stent made up of articulated slotted tubes. The Palmaz-Schatz had good radial strength and minimal recoil. It was very successful, but nevertheless had several problems. First, it was only flexible at its articulation points. This made navigation around tortuous arteries difficult. Secondly, it did not conform particularly well to the vessel walls. Thirdly, there was a risk that side branch arteries could be obstructed because the cells making up the stent were small. Finally, there was a risk of prolapse opposite the connector because of the large gap between slotted tube sections. The Palmaz-Schatz looked like this:

The Application

19. The Application is entitled "A flexible expandable stent". The invention disclosed in the Application is summarised in the abstract as follows:

> "There is disclosed a stent (30) for implanting in the body. The stent (30) is formed of a tube having a patterned shape which has first and second meander patterns (11, 12) having axes extending in first and second directions. The first meander patterns can be formed into even and odd first meander patterns. The even and odd first meander patterns are 180 degrees out of phase with each other, and the odd patterns occur between every two even patterns. The second meander patterns are intertwined with the first meander patterns. The first and second directions can be orthogonal to each other. The second meander patterns can also be formed of even and odd patterns."

20. The Application begins by defining the field of the invention as relating generally to stents for implanting in a living body. Under the heading "Background of the invention" the Application first explains in general terms what a stent is and how it is delivered and expanded. At page 1 lines 21-29 the Application states:

> "Exemplary patents in the field of stents formed of wire are: [seven US patents]. Stents formed of cut stock metal are described in: [five US patents]."

21. The Application then discusses two of the second list of patents in more detail at page 1 line 30 – page 2 line 10:

> "The stents described in U.S. 5,102,417 to Palmaz and Schatz [actually just Palmaz] have expandable tubular grafts connected together with a flexible connector. The grafts are formed of a plurality of slots disposed parallel to the longitudinal axis of the tube. The flexible connectors are helical connectors. Since the tubular grafts are relatively rigid, the flexible connectors are needed so that the stents can bend when being fed through a curved blood vessel. When the stents of U.S. 5,102,417 expand, the grafts expand radially and, consequently, shrink longitudinally. However, at the same time, the helical connectors twist. The twisting motion is most probably harmful to the blood vessel.
>
> U.S. 5,195,984 to Schatz describes a similar stent but with one straight connector, parallel to the longitudinal axis of the tubular grafts, between tubular grafts. The straight member removes the twisting motion; however, it is not a very strong connector."

22. The next section of the Application at page 2 line 12 – page 3 line is headed "Summary of the present invention" and it is necessary to quote this in full. The first paragraph states:

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

This is the only statement in the Application of the object of the invention.

23. This section continues (emphases added):

> "The stent of 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.
>
> 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 first meander patterns are 180° 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.

> Additionally, in accordance with *a preferred embodiment* of the present invention, the second meander patterns have two loops per period and the even and odd first meander patterns are connected on first and second sides, respectively, of each loop of the second meander patterns.
>
> Alternatively or in addition, the second meander patterns are formed of even and odd second meander patterns. In *this embodiment*, the even and odd first meander patterns have loops and the even and odd second meander patterns are connected to the even and odd first meander patterns so as to leave one full loop between each pair of even and odd second meander patterns.
>
> Moreover, in accordance with a *preferred embodiment* of the present invention, the first and second meander patterns are formed from flat metal. Alternatively, they can be cut from wire. Further, they can be imbedded or covered with any body-compatible material."

The phrases I have italicised are relevant to the issue between the parties as to the disclosure of the Application, and I shall discuss them in that context.

24. The Application then introduces the drawings. Figs. 1-4, 5A and 5B are said to be illustrations of a "first preferred embodiment" of the invention. Of these Figs. 1 and 2 illustrate the stent in its straight, unexpanded state. Fig. 1 shows the whole stent in perspective and Fig. 2 shows part of the pattern in plan view (i.e. flat). Fig. 3 shows the stent in a bent position and Fig. 4 shows it in its expanded state. Figs. 5A and 5B are schematic diagrams indicating the manner in which the meander patterns of the stent change on expansion. I reproduce Figs. 1, 2 and 4 below.

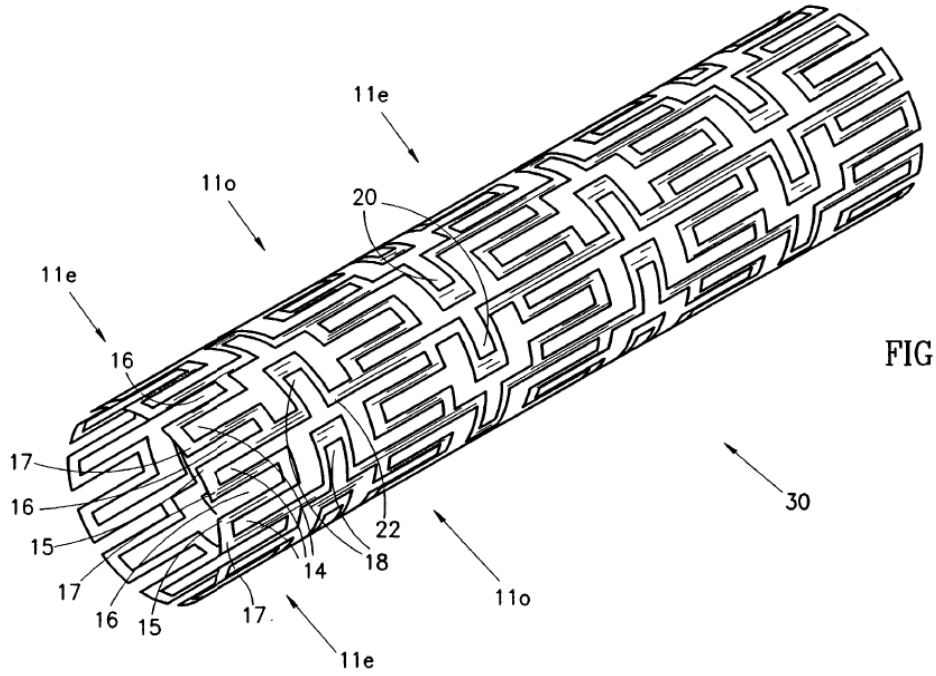

11e
11o
20
11e
16
17
16
15
17
16
15
17
14
18
22
11o
30
11e

FIG.1

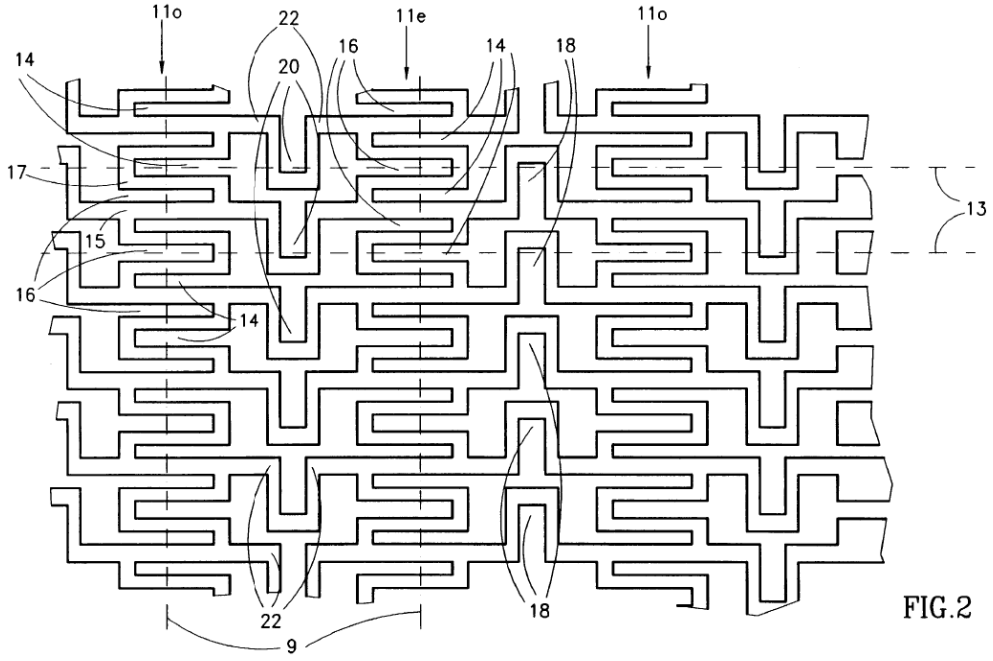

11o
22
11e
16
14
18
11o
20
14
17
15
16
14
13
22
18
9

FIG.2

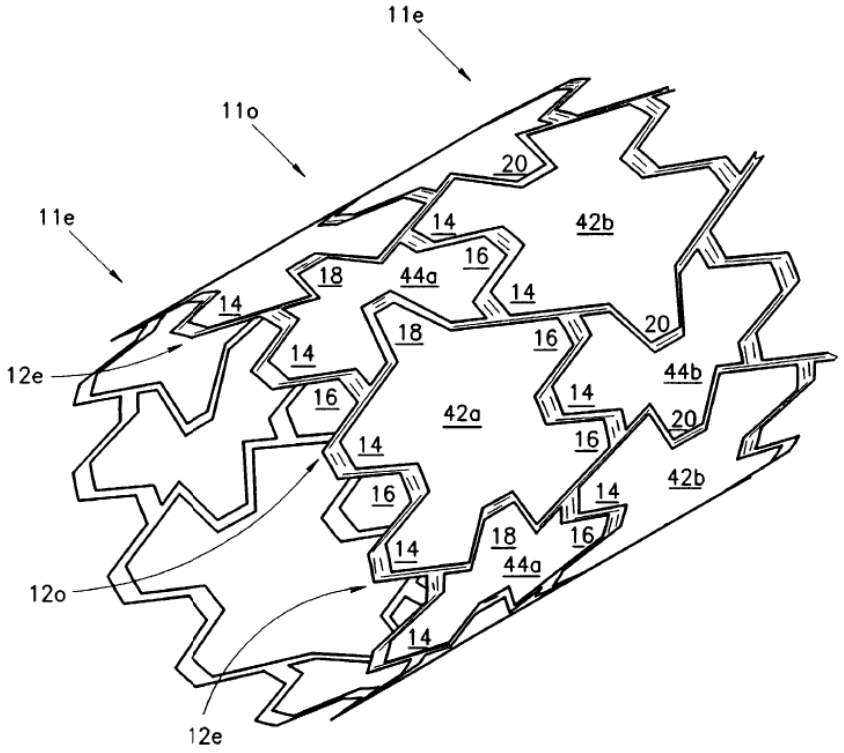


FIG.4

25. Fig. 6 is said to be an illustration of a "second embodiment". Figs. 7 and 8 are said to be said illustrations of a "third embodiment" in unexpanded and expanded states respectively. I reproduce Fig. 7 below.

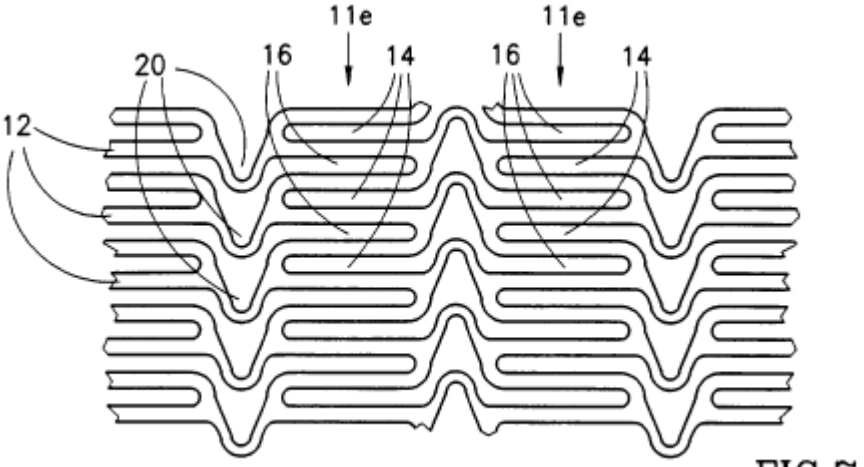


FIG.7

26. The first embodiment is described at page 4 line 5 to page 7 line 30. Two important definitions are set out at page 4 lines 15-19:

> "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."

27. The meander patterns of the first embodiment are described at page 4 line 20 – page 5 line 16 as follows (note that, contrary to what is stated in the text, reference numeral 12 has been omitted from the drawings):

> "In the stent of Figs. 1 - 4, the two meander patterns are labeled 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 wherein 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.
>
> Meander pattern 12 is an horizontal pattern having an horizontal center line 13. Meander pattern 12 also has loops, labeled 18 and 20, but between loops of a period is an extended straight section labeled 22. Loops 18 open downwards and loops 20 open upwards. Vertical meander pattern 11 is provided in odd and even (o and e) versions which are 180° out of phase with each other. Thus, each left opening loop 16 of meander pattern 11o faces a right opening loop 14 of meander pattern 11e and a right opening loop 14 of meander pattern 11o faces a left opening loop 16 of meander pattern 11e.
>
> Horizontal meander pattern 12 is also provided in odd and even forms. The straight sections 22 of horizontal meander pattern 12e intersect with every third common member 17 of vertical meander pattern 11e. The straight sections 22 of horizontal meander pattern 12o intersect with every third common member 15 of vertical meander pattern 11e. beginning with the common member 15 two after an intersected common member 17. The result is a full loop 14 between meander patterns 12e and 12o and a full loop 16 between meander patterns 12o and 12e."

28. The Application then states at page 5 lines 17-23:

> "Returning to Fig. 1, the pattern of Fig. 2 is formed into a tube 30 of an easily deformable material, such as a metal. Due to the two meander patterns, the stent of Fig. 1, when attached over a catheter balloon, is flexible and can therefore be easily dragged through curved blood vessels. An example of the way in which the stent of Fig. 1 bends is illustrated in Fig. 3."

Fig. 3 shows the unexpanded stent of Fig. 1 bent slightly about two-thirds the way along. The Application goes on to explain that, during bending, loops 14 and 16 in the vertical meander pattern 11 and loops 18 and 20 in the horizontal meander pattern 12 located on the inside of the bend contract, while those located on the outside of the bend expand. It emphasises that both meander patterns 11 and 12 are involved in the bending.

29. The Application then states at page 6 lines 8-22:

> "Fig. 4 illustrates the stent of Fig. 1 in its expanded form. When the stent expands, both meander patterns 11 and 12 expand (i.e. all loops 14 - 20 open up). As can be seen, the expanded stent has two types of enclosed spaces, a large space 42 between meander patterns 12o and 12e and a small space 44 between meander patterns 12e and 12o. As can also be seen, each large space 42 has two loops 14 on its left side and two loops 16 on its right side. The large spaces between vertical meander patterns 11e and 11o, which are labeled 42a, have loops 18 at their tops and bottoms while the large spaces between vertical meander patterns 11o and 11e, which are labeled 42b, have loops 20 at their tops and bottoms. Similarly for small spaces 44a and 44b."

30. At page 6 line 23-25 the Application states:

> "It is noted that, due to the orthogonal meander patterns 11 and 12, the stent of Fig. 1 does not significantly shrink during expansion."

The Application goes on to explain, by reference to Figs. 5A and 5B, that, as the stent expands, the vertical meander pattern 11 expands by widening its loops 14 and 16 and the horizontal meander pattern 12 expands by widening its loops 18 and 20. As the loops widen, each pattern grows in one direction and shrinks in the other. As the Application says at page 7 lines 6-20:

> "Thus, the vertical growth of the vertical meander pattern 11 compensates, at least partially, for the vertical shrinkage of the horizontal meander pattern 12, and vice versa. It is noted that the end portions of any stent are only partially compensated and therefore, may shrink, somewhat.
>
> It will be appreciated that the two orthogonal meander patterns 11 and 12 and the compensation they provide to each other provides flexibility to the unexpanded stent of Fig. 1. However, when the stent is expanded, the changes in each of loops 14 and 16 provide rigidity to the resultant stent and thus, enable the stent to maintain a blood vessel at a desired inner diameter."

31. At page 7 lines 21-30 the Application states:

> "The stent of the present invention can be manufactured from flat metal which is etched into the pattern of Fig. 2. The etched metal is then bent to form the tube 30. Alternatively, the pattern of Fig. 2 can be manufactured from welded or twisted wire.
>
> It will be appreciated that the stent of the present invention can be made from metal and/or wire. Additionally, it can be plated

> with a protective material, embedded with a medicine, and/or covered with a material which can fill in the spaces 42 and 44."

32. The Application then states at page 7 lines 31-34:

> "It will be appreciated that the present invention encompasses all stents manufactured with a pattern formed of two meander patterns, orthogonal or otherwise."

It goes on to introduce "another exemplary pattern" shown in Fig. 6 and a "more rounded version" shown in Figs. 7 and 8. At page 8 lines 2 to 10 it says:

> "The pattern of Figs. 6 and 7 is similar to that shown in Fig. 2 except that it has more horizontal meander patterns 12 and they are of one kind, rather than being even and odd as in Fig. 2.
>
> As can be seen in both Figs. 6 and 7, there are two types of vertical meander patterns 11e and 11o which are 180° out of phase with each other. The horizontal meander patterns 12 connect with every line 15 of vertical meander pattern 11e."

The Patents

33. Although the specification of each of the Patents is very similar to that of the Application, there are certain differences. In addition, there are differences between the claims of the respective Patents, particularly so between claim 1 of 901 and the claims of 449 and 902.

449

34. Under the heading "Background of the invention", the specification includes acknowledgements of three additional items of prior art at [0006]-[0008]. Under the heading "Summary of the present invention" the specification omits the passages from the Application quoted in paragraph [11] above. Instead, the specification states at [0010]:

> "This object is achieved according to the invention by a stent as defined in claim 1. Advantageous embodiments of the invention are defined in dependent claims 2 to 9."

At the beginning of [0013] the specification includes the words "According to a preferred embodiment" which do not appear in the Application.

35. Broken down into integers, claim 1 is as follows:

> "[1] A stent formed of a flat metal tube (30)
>
> [2] having in a non-expanded form and in an expanded form a patterned shape,
>
> [3] the 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,

[4] wherein the first and second meander patterns comprise loops

[5] and are intertwined such that

[a] loops (14, 16) of each of the first meander patterns (11) is disposed between all neighboring second meander patterns (12) and that

[b] one loop (18, 20) of each of the second meander patterns (12) is disposed between all neighboring first meander patterns (11)."

901

36. Under the heading "Summary of the present invention" the specification includes a new paragraph [0007] between the passages in the Application quoted in paragraphs [10] and [11] above as follows:

> "A stent of the present invention comprises a mesh of adjacent, connected cells, each cell comprising an even number of fixed length, alternating, first and second loops, connected together in a closed cell, each loop having at least two portions with an area of inflection there between, said first and second loops defining first and second angles whose bisecting lines are at angles one to another."

In the following paragraph, the specification states that the stent of the present invention "may be" formed from a tube etc, rather than "is" as in the Application.

37. Broken down into integers, claim 1 is as follows:

"[1] A stent comprising a mesh of adjacent, connected cells (42a, 42b, 44a, 44b),

[2] each cell comprising: an even number of fixed length, alternating, first (14, 16) and second loops (18, 20), connected together in a closed cell (42a, 42b, 44a, 44b),

[3] each loop (14, 16, 18, 20) having at least two portions with an area of inflection there between,

[4] said first (14, 16) and second loops (18, 20) defining first and second angles whose bisecting lines are at angles one to another;

[5] wherein the first loops (14, 16) are arranged to widen circumferentially

> [6] and characterised in that the second loops (18, 20) are arranged to widen longitudinally upon expansion of the stent."

38. There are no dependent claims.

902

39. Under the heading "Background of the invention", the description of the prior Schatz patent in the specification at [0005] and [0006] contains certain differences from that in the Application. Under the heading "Summary of the present invention" the specification includes the following passage at [0007] which was not present in the Application:

> "This object is achieved according to the invention by a stent as defined in claim 1. Advantageous embodiments of the invention are defined in dependent claims 2 to 13."

In [0009] the specification states that the even and odd first and second meander patterns "can be" 180^{o} out of phase, rather than "are" as in the Application.

40. Broken down into integers, claim 1 is as follows

> "[1] A flexible, expandable stent formed of an elongated cylindrical unitary tube (30)
>
> [2] having in a non-expanded form and in its expanded form a patterned shape,
>
> [3] the patterned shape comprising first meander patterns (11) extending in a first direction
>
> [4] and second meander patterns (12) extending in a second direction, different from the first direction,
>
> [5] wherein the first and second meander patterns comprise loops
>
> [6] and are intertwined such that
>
> [a] loops (14, 16) of each of the first meander patterns (11) are disposed between each of the neighbouring second meander patterns (12) and that
>
> [b] one single loop (18, 20) of each of the second meander patterns (12) is disposed between each of the neighbouring first meander patterns (11),
>
> [7] and wherein the first and second meanders patterns (11, 12) define a plurality of enclosed spaces (42a, 42b; 44a, 44b)."

41. Claim 2 adds the requirement "wherein the stent is formed from flat metal".

42. Claim 12 adds the requirement "wherein the first meander patterns (11) are expandable in the circumferential direction and the second meander patterns (12) are expendable in the longitudinal direction of the tubular stent". It is common ground that "expendable" is clearly a typographical error and should read "expandable".

The skilled team

43. A patent specification is addressed to those likely to have a practical interest in the subject matter of the invention, and such persons are those with practical knowledge and experience of the kind of work in which the invention is intended to be used. The addressee comes to a reading of the specification with the common general knowledge of persons skilled in the relevant art, and he or she reads it knowing that its purpose is to describe and demarcate an invention. He or she is unimaginative and has no inventive capacity. In some cases the patent is addressed to a team of persons with different skills.

44. It is common ground that the Patents are addressed to a team consisting of an interventional cardiologist and a medical device engineer. The interventional cardiologist would have experience in balloon angioplasty and stenting. He would be familiar with the properties of the different stents on the market, the factors affecting the use of stents and the desired behaviour of stents. The medical device engineer would not necessarily have experience in designing stents, which was a relatively new field in July 1994. Indeed, Medinol's engineering expert Professor Snyder said that it was his impression that it would have been very difficult to find an engineer with extensive background in stents: one would be more likely to find an engineer with training in the relevant areas in order to be able to understand the function of stents. This is supported by the evidence of Medinol's witness Dr Richter as to the qualifications of the inventors of the Patents.

45. It is also common ground that the cardiologist would be responsible for specifying the functional requirements of a stent, while the task of actually designing the stent would then be performed by the engineer. Furthermore, the emphasis of the Patents is on the engineering side. Thus the Patents discuss manufacturing techniques, but do not contain any clinical data.

The witnesses

46. Abbott's cardiology expert was Dr Simon Davies. Dr Davies has been a consultant interventional cardiologist at the Royal Brompton Hospital since March 1994. He first placed a stent in 1991. In 1994 his first choice of stent was the Palmaz-Schatz. He has extensive experience in the medical application of stents, having performed some 2,500 coronary angioplasty procedures employing an average of 2.5 stents per procedure.

47. Medinol's cardiology expert was Professor Nicolaus Reifart. Professor Reifart is chief of the Department of Cardiology of Main-Taunus Hospital in Bad Soden and a professor of the University of Frankfurt. He founded the interventional cardiology department at the Red Cross Hospital and Heart Centre in Frankfurt in 1985, where he worked until 1997. He first inserted a stent in 1990. By July 1994 he had performed around 2,000 stent insertions, and he had experience with each of the five main types of stent on the market described above. He has now inserted around 10,000 stents.

48. Both cardiologists were knowledgeable, careful and fair witnesses. The differences between them were minor.

49. Abbott's engineering expert was Professor Peter McHugh. Professor McHugh is Professor of Biomedical Engineering and Head of Department of Mechanical and Biomedical Engineering at the National University of Ireland, Galway. He has been a lecturer in the Department since 1991, being promoted to senior lecturer in 1997, Personal Professor in 2004 and to his present position in 2007. He first worked with medical devices in 1991, on the design of angioplasty catheters in 1996 and has worked on stents since 1998. He has not actually participated in the design of stents, but he has considerable experience in analysing the behaviour of stents. He has collaborated with interventional cardiologists on several occasions since 1999.

50. Professor McHugh accepted that he had minimal knowledge about stents in July 1994. Counsel for Medinol submitted that it followed that he was not in a position to give evidence about common general knowledge or obviousness. I do not accept this, since as I have already explained the engineer on the skilled team might well not have previous experience of stent design. In my judgment Professor McHugh was able to give evidence as to the common general knowledge and approach of a suitably qualified engineer to participate in the skilled team. Moreover, his evidence was transparently fair and balanced.

51. Abbott's engineering expert was Professor Alan Snyder. At the time of writing his reports Professor Snyder was Professor of Surgery and Bioengineering at the College of Medicine of the Pennsylvania State University. He has since been appointed to a role at Lehigh University. As at 1994 his medical research interests focused on prosthetic heart valves and blood pumps. Since then, his work has continued to focus on the development of blood pumps. Save for two short projects of peripheral relevance, he has not worked on stents otherwise than as a reviewer of research proposals and as an expert witness.

52. Counsel for Abbott rightly did not suggest that that Professor Snyder was not able to give evidence as to the common general knowledge and approach of the engineer on the skilled team in July 1994. He did suggest that Professor Snyder was less knowledgeable about stents now than Professor McHugh, which I accept. More importantly, counsel for Abbott pointed out that since about 2000 Professor Snyder has acted as an expert witness in a number of cases about stents, including at least six cases for Medinol in the US and Europe, some of which involved meander patterns. The problems for an expert witness of retaining objectivity after significant and prolonged participation in litigation are well known. Counsel for Abbott submitted that, understandably in these circumstances, Professor Snyder had failed to be objective in his evidence. I regret to say that I agree with this. He repeatedly failed to give direct answers to questions and instead attempted to argue Medinol's case. This extended to repudiating what he had previously said in an expert report in the Dutch proceedings when he perceived that it would cause difficulties for Medinol's case here. As a result, I consider that his evidence must be viewed with caution.

53. In addition to the expert witnesses, I heard from three witnesses of fact. Abbott called Gary Johnson and Gary Schneiderman. Mr Johnson has worked for Abbott and its predecessors since 1987. He is currently Vice President of Research and Development for Abbott Vascular. He gave evidence as to the design history leading to the Abbott

Stents, the market in metal stents and on the issue of commercial success. Dr Schneiderman has worked as an engineer in the medical and biomedical engineering fields for over thirty years. He has worked in Abbott Vascular, a division of Abbott, and its predecessor companies since 1986. He qualified as a lawyer in 2004 and is Division Counsel at Abbott Vascular responsible for patent litigation. He verified the accuracy of Abbott's product description. Medinol called Jacob Richter. Dr Richter is a founder of Medinol, its Chairman and Chief Technical Officer. He gave evidence on the alleged commercial success of Medinol's stents. I have no difficulty in accepting the evidence of each of these witnesses.

Common general knowledge

54. I reviewed the law as to common general knowledge in *KCI Licensing Inc v Smith & Nephew plc* [2010] EWHC 1487 (Pat), [2010] FSR 31 at [105]-[115].

55. In the present case there was not much dispute as to the relevant common general knowledge by the end of the trial. I find that the following matters were common general knowledge.

The common general knowledge of the interventional cardiologist

56. The cardiologist would be knowledgeable about the physiology of the heart, and in particular the coronary arteries; the causes of heart disease, and in particular atherosclerosis; and methods of treating atherosclerosis, and in particular balloon angioplasty and stents.

57. There was some disagreement as to the extent to which stents were being used, in particular on an elective basis, as at late July 1994. In my judgment the evidence establishes that by that date major coronary centres (such as Professor Reifart's) were already regularly using stents in elective procedures, and it was hoped that such use would spread more widely. It is fair to say that the elective use of stents really took off after the publication of two major trials, known as BENESTENT and STRESS, in August 1994. Nevertheless, the use of stents was increasing rapidly during 1994, and thus the market was growing fast.

58. The cardiologist would be aware of the major stents which had been marketed by that date, in particular the five designs I have described under the heading "Technical background", and their respective strengths and weaknesses. As at July 1994 none of the available stents was regarded as very satisfactory. On the contrary, there was a demand for improved stent designs.

59. The cardiologist would be aware of, and would inform the engineer of, the desired characteristics of stents. These included the following:

    i) *Flexibility* (also referred to as "deliverability"). It is desirable for the unexpanded stent to be as flexible as possible in the longitudinal direction so that it can navigate tortuous pathways in the arteries while being delivered to the desired location.

    ii) *Radial strength*. The expanded stent must have sufficient radial strength to keep the vessel open and minimise any elastic recoil.

iii) *Scaffolding*. The expanded stent must provide sufficient coverage of the vessel wall to avoid prolapse of the wall in the gaps between the struts or wires.

iv) *Conformability*. The expanded stent must conform reasonably closely to the shape of the artery once in the desired location.

v) *Minimising shrinkage* (also referred to as "foreshortening"). The unexpanded stent must not shrink unacceptably when expanded. If the shrinkage was not excessive (up to 5%) and was predictable, it was not seen as an issue; but a greater degree of shrinkage was a problem, particularly if it was unpredictable.

vi) *Avoidance of thrombosis*. In July 1994 it was generally thought that metal in an artery was thrombogenic, and accordingly that minimising the amount of metal in the stent would reduce the risk of thrombosis. This was not a major concern, however.

vii) *Secure crimping*. The unexpanded stent must be capable of being crimped securely to the balloon so that it is safely delivered to the desired location and does not fall off on the way.

viii) *Radiopacity*. The stent must be visible by x-ray radiography.

60. These desirable properties involved conflicting considerations. Accordingly, designing a stent involved a trade-off between different factors.

The common general knowledge of the medical device engineer

61. The engineer would be knowledgeable about the behaviour of materials, in particular metal, including elastic and plastic deformation; about structural mechanics; about geometry; and about the conventions of technical drawing.

62. The engineer would know that increasing the length of a beam gives it more flexibility (for example, as in a diving board). He would also know that a structure could be made flexible by providing corrugations (for example, as in a bendy drinking straw).

63. The engineer would be familiar with the concept of phase relationship, and in particular would know that sine waves and other sinusoids may be "in-phase" (successive peaks are aligned with peaks and successive troughs with troughs) or "out-of-phase" (in the paradigm case, successive peaks are aligned with troughs and vice versa).

<u>The disclosure of the Application</u>

64. A central issue in the case concerns the disclosure of the Application. This is primarily relevant to the issue of added matter, but since the textual differences between the Application and the Patents are not extensive, it also has a bearing on some of the issues of construction of the claims of the Patents. It is therefore convenient to deal with it here.

The abstract

65. Before turning to the Application itself, there is an issue of law as to the status of the abstract. Medinol seeks to rely upon this in support of its case as to the disclosure of the Application, and hence its case on added matter, whereas Abbott contends that the abstract cannot be relied on for that purpose.

66. In the EPO, Article 78(1)(e) of the European Patent Convention requires a European patent application to include an abstract. Article 85 provides, however, that:

> "The abstract shall serve the purpose of technical information only; it may not be taken into account for any other purpose, in particular for interpreting the scope of the protection sought or applying Article 54, paragraph 3."

In addition to the purposes specifically mentioned in Article 85, the Boards of Appeal have held that a patentee cannot rely upon the contents of the abstract in his application for the purposes of overcoming an objection under Article 123(2) (added matter): see T246/86 *BULL/Identification system* [1989] EPOR 344 and T606/06 (23 April 2008, unreported).

67. In the United Kingdom, section 14(2)(c) of the Patents Act 1977 also requires a patent application to include an abstract. Section 14(7) provides:

> "The purpose of the abstract is to give technical information and on publication it shall not form part of the state of the art by virtue of section 2(3) above…"

Despite the resemblance of section 14(7) to Article 85, it is not one of the provisions declared by section 130(7) to be framed so as to have the same effect as the corresponding provisions of the EPC. In *ARMCO Inc's Application* (O/84/85) the Comptroller's hearing officer accepted the applicant's argument that, since an abstract formed part of the application by virtue of section 14(2)(c), matter contained in the abstract could be considered for the purposes of an objection under section 76(2) (added matter). There is no reference in the decision to the corresponding provisions of the EPC, nor (obviously) to the later decisions of the EPO Boards of Appeal.

68. Counsel for Abbott submitted that, for reasons which are now well known, it is undesirable for domestic provisions corresponding to those in the EPC to be interpreted in a different manner than that adopted by the Boards of Appeal, and therefore section 14(7) should be interpreted in the same manner as Article 85. I accept that submission. The fact that section 14(7) is not one of the provisions listed in section 130(7) does not prevent it from being interpreted in the same way as Article 85. Nor do I see that it matters that section 14(7) omits the word "only": like Article 85, section 14(7) identifies the purpose of the abstract as being to provide technical information, and it is implicit that that is its only purpose.

69. Counsel for Abbott also submitted that the purpose of the abstract is to provide a précis of the application. As a matter of logic, it follows that, if the abstract means the same thing as the application, it adds nothing; and, if does not mean the same thing, it must be inaccurate. He relied in support of this on the reasoning of the Board of

Appeal in Case T1080/99 *TEKTRONIX/Touch control* [2003] EPOR 25 at [4.6]. I agree with this analysis.

70. For these reasons I shall ignore the abstract when considering the disclosure of the Application.

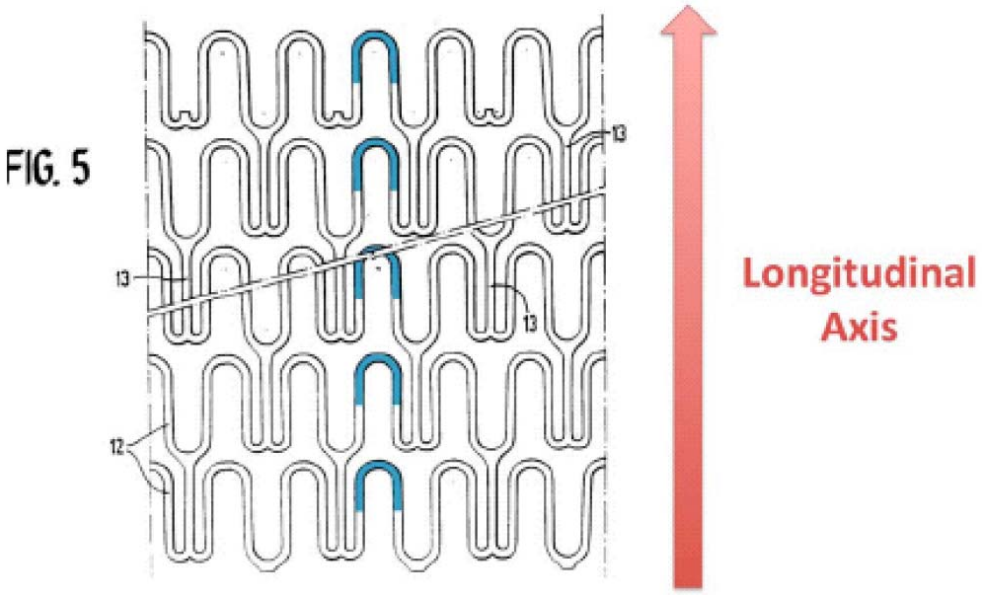
The principal issue

71. In a nutshell the principal issue as to the disclosure of the Application is whether, as Abbott contends, the invention disclosed in the Application is limited to "out-of-phase" stent designs, and in particular is directed to minimising longitudinal shrinkage in such stents upon deployment; or whether, as Medinol contends, the invention disclosed in the Application extends to any stent having two intertwined meander patterns, including an "in-phase" stent design.

In-phase and out-of-phase stent designs

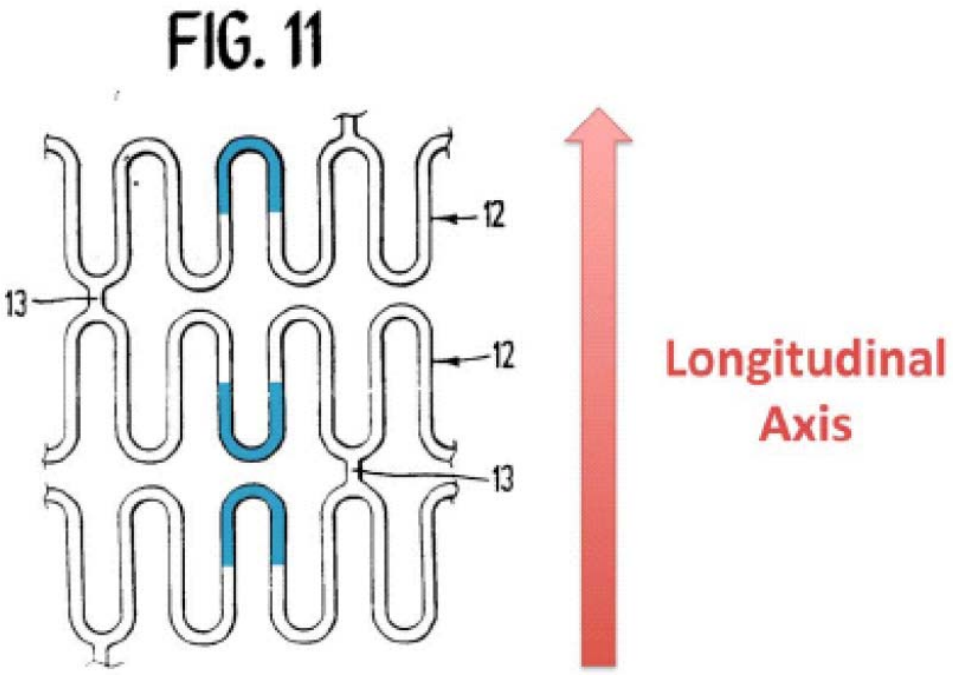
72. Before addressing this, it is necessary to explain about in-phase and out-of-phase stent designs. It is convenient to do so by reference to marked-up versions of two figures from Lau, although it should be kept firmly in mind that it is not suggested that the designs depicted in Lau were common general knowledge. (I shall describe the disclosure of Lau more fully below.)

73. Fig. 5 of Lau depicts an in-phase design (note that the longitudinal axis runs vertically whereas in the figures in the Patents it runs horizontally):



74. In this diagram successive wave-like elements (referred to by Abbott as circumferential "rings") are in-phase in the sense described above i.e. the peaks in each successive ring (some of which have been coloured blue for ease of reference) are aligned. There are connectors (referred to by Abbott as longitudinal "links") running from trough to trough every so often. (It should be noted that Abbott describes the links as "peak-to-valley", but I regard that description as confusing.)

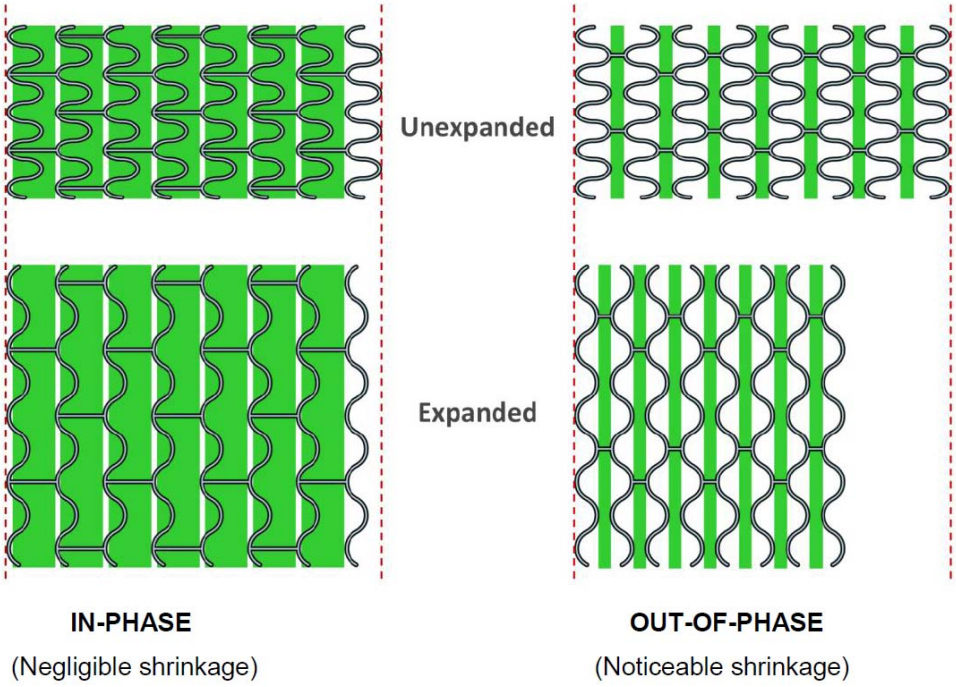
75. Fig. 11 of Lau depicts an out-of-phase design:



76. In this diagram the rings are out-of-phase in the sense described above i.e. successive peaks are aligned with troughs and vice versa. There are links running from peak to trough every so often. (Again, Abbott describes the links as "peak-to-peak" which I regard as confusing.)

77. Before proceeding further, it is important to note that it is common ground that in-phase and out-of-phase stent designs did not form part of the skilled team's common general knowledge in the sense of being established or recognised types of design. Thus the skilled team would not approach the Application knowing that these different types of design existed. Abbott contends, however, that the engineer on the skilled team would be able to recognise designs such as those depicted above as being in-phase and out-of-phase respectively. Medinol disputes this, but it accepts that the engineer would when reading the Application understand what it meant by "180^{o} out of phase" and hence what would constitute an in-phase design. I do not think it matters which side is right on the point of dispute; but if it does, I consider that the evidence supports Abbott's position.

78. For present purposes, the key difference between an in-phase design and an out-of-phase design is that, all other things being equal, an out-of-phase design which is connected peak to trough (as described above) will shrink noticeably while an in-phase design which is connected peak to peak (as described above) will exhibit no appreciable shrinkage. This is illustrated in the following diagrams:



79. It is common ground that, just as the existence of in-phase and out-of-phase designs was not common general knowledge, nor was their relative propensity to shrink. Abbott contends, however, that the engineer on the skilled team would, when reading the Application, be able to understand (a) why an out-of-phase design will exhibit shrinkage unless steps are taken to prevent it or compensate for it and (b) why such steps would not generally be necessary in the case of an in-phase design. In my judgment the evidence supports this contention.

80. Medinol established that it is possible to come up with an in-phase design connected in such a way that it will exhibit shrinkage when expanded. Indeed, such a design is disclosed in Fig. 9a of Burmeister. It does not follow, however, that the skilled readers of the Application would have such an arrangement in mind. In my judgment they would not. Indeed, it is evident that even Professor Snyder did not think of such an arrangement at the time of preparing his second report in the Dutch proceedings, instead proceeding on the basis that an in-phase design inherently avoided shrinkage.

81. Medinol also established that it is possible to come up with an out-of-phase design which does not shrink without resorting to the solution proposed by the Application. Again, it does not follow that the skilled readers of the Application would have such an arrangement in mind. Again, in my judgment they would not.

The Application

82. The interpretation of the Application is a matter for the court once instructed by the experts. I have, however, taken Professor McHugh and Professor Snyder's evidence into account in reaching my conclusions. The evidence of Professor McHugh was of greater assistance in this regard, and not merely for the general reasons I have given above. Whereas Professor McHugh was specifically asked to give his opinion as to the disclosure of the Application before reading the Patents, Professor Snyder had no recollection of having been asked to do this and it is improbable that he did.

83. There are a number of passages in the Application which are particularly relevant to the principal issue. The first is the discussion of the Palmaz and Schatz patents (quoted in paragraph 21 above). It can be seen from this passage that the Application identifies three problems with the stents disclosed in these patents, namely (i) the slotted tubes shrink longitudinally upon radial expansion, (ii) the flexible helical connectors between the slotted tubes disclosed in Palmaz twist and (iii) the straight connector between the slotted tubes disclosed in Schatz lacks strength. Medinol rightly points out that the Application does not say that the reason why the Palmaz-Schatz slotted tubes shrink is because they are out-of-phase designs. Abbott nevertheless contends, and I agree, that, having read the entire Application, the skilled team would deduce that the reason why the slotted tubes shrink longitudinally is because the slotted tubes are equivalent to out-of-phase rings connected directly peak to peak (see Figs. 1A and 1B of the Palmaz patent). In addition, Abbott contends, and I agree, that this passage does not suggest that lack of flexibility *per se* is a problem with the prior art.

84. The next passage is the statement of the object of the invention (quoted in paragraph 22 above). Medinol contends that this identifies two distinct objectives which are separately addressed in the description that follows, namely (i) flexibility and (ii) minimal shrinkage. Abbott contends that it identifies a single objective, namely to provide a stent which is both flexible and undergoes minimal longitudinal shrinkage (these already being achievable separately). I prefer Abbott's reading, which is not merely more consistent with the language of this passage, but also more consistent with the preceding discussion of the prior art and more consistent with the description which follows.

85. The third significant passage is the remainder of the summary of the invention (quoted in paragraph 23 above). Medinol contends that this passage demonstrates that the invention disclosed is not limited to the specific embodiments, in particular those introduced by the words I have italicised in the quotation. That much I accept. Medinol also contends, however, that it follows that at its broadest the invention disclosed in the Application is a stent with two meander patterns extending in different directions, a reading which Medinol says is supported by the sentence at column 7 lines 31-34 (quoted in paragraph 32 above). Although taken literally and out of context that is what these passages appear to say, I am unable to accept that the skilled team reading them in the context of the whole Application would understand them in that way. Such a reading would fail to differentiate the stents of the invention from the prior art. Furthermore, there is nothing in the Application to explain how the object of the invention can be achieved merely by using any two meander patterns. Most importantly, there is nothing in these passages which actually discloses a stent in which the first meander patterns are in-phase, even though the breadth of the language would encompass such an arrangement.

86. The fourth and fifth passages of importance are the description of the bending of the stent by reference to Fig. 3 at page 5 line 22 – page 6 line 7 (partly quoted in paragraph 28 above) and the description of the expansion of the stent by references to Figs. 4, 5A and 5B at page 6 line 8 to page 7 line 20 (partly quoted in paragraphs 29 and 30 above). Medinol makes two points about these passages.

87. First, Medinol says that they disclose how the invention achieves flexibility separately from how it achieves minimal shrinkage and thus that the former can be achieved

whether or not the latter is. I accept that bending and expansion are separately described, but I do not accept that the skilled team would understand the invention enabled flexibility to be achieved without avoiding foreshortening. The entire thrust of the Application is that the invention achieves both flexibility and minimal shrinkage. Furthermore, the Application states in terms that the two meander patterns (and not just one of them) both achieve flexibility (see in particular page 5 lines 19-22 quoted in paragraph 28 above and page 7 lines 13-16 quoted in paragraph 30 above) and avoid shrinkage (see in particular page 6 lines 23-25 and page 7 lines 5-12 quoted in paragraph 30 above). Indeed, the sentence at page 7 lines 13-16 explicitly links the two aspects by referring to the "compensation" provided by the two patterns as providing flexibility, the same language as the Application has previously used in discussing how shrinkage is minimised.

88. Secondly, Medinol says that the teaching of these passages as to how the loops in the second meander pattern provide flexibility and avoid shrinkage does not depend on the first meander patterns being out-of-phase. It is true that they do not state this in terms. In my judgment, however, the skilled team reading these passages would note that the first meander patterns are both described and shown as being out-of-phase, would understand why that would give rise to a problem of shrinkage if it was not compensated for and would appreciate that the widening of the loops in the second meander pattern does compensate for the longitudinal shrinkage of the first meander pattern on expansion as well as providing flexibility on bending. There is nothing in these passages to suggest to the skilled team that the first meander patterns may be in-phase instead, and the skilled team would not expect a design in which the first meander patterns were in-phase to suffer from the problem of shrinkage and hence to require compensating by widening of the loops in the second meander pattern. By contrast, the skilled team would appreciate that, although the second meander patterns shown in the drawings are in-phase, it does not make any difference to the invention whether the second meander patterns are in-phase or out-of-phase. Either way, the widening of the loops in the second meander patterns will compensate for longitudinal shrinkage of the first meander patterns. The skilled team would also appreciate that the same contrast had been drawn by the Application previously, albeit in describing "one embodiment", when stating that the first meander patterns "are even and odd [and] 180^{o} out of phase" whereas the second meander patterns "can be … even and odd".

89. For these reasons, I conclude that the core inventive concept disclosed in the Application is a stent with intertwined first and second meander patterns in which the widening of loops in the second meander patterns both provides flexibility in bending of the stent and minimises shrinkage by compensating for the contraction of the out-of-phase first meander patterns when the stent is expanded. In my judgment the Application does not disclose a design of stent in which the first meander patterns are in-phase.

90. I have thus far deliberately avoided reference to the claims of the Application. It should be noted, however, that the claims do not disclose a stent in which the first meander patterns are in-phase. Claim 1 is expressly limited to a stent with even and odd first meander patterns which are 180^{o} out-of-phase. Claim 6 is independent of claim 1 and does not explicitly include this limitation, but it is limited to "said even

and odd first meander patterns", which can only be a reference back to the first meander patterns of claim 1.

Construction: the law

91. The task for the court when construing a patent claim is to determine what the person skilled in the art would have understood the patentee to have been using the language of the claim to mean: see *Kirin Amgen Inc v Hoechst Marion Roussel Ltd* [2004] UKHL 46, [2005] RPC 9 at [30]-[35]. In that case the list of principles to be found in the judgment of Jacob LJ in *Technip France SA's Patent* [2004] EWCA Civ 381, [2004] RPC 46 at [41] was approved subject to one point. More recently, in *Virgin Atlantic Airways Ltd v Premium Aircraft Interiors UK Ltd* [2009] EWCA Civ 1062, [2010] RPC 8 the Court of Appeal held that the skilled reader is to be taken to know the purpose of (i) including reference numerals in patent claims, (ii) dividing claims into pre-characterising and characterising portions and (iii) filing of divisional applications, and to bring that knowledge to bear when he considers the scope of the claim.

Construction of 449 and 902

92. It is convenient to consider the construction of the claims of 449 and 902 together since the issues are largely, although not entirely, the same. 901 raises quite different issues and must be considered separately.

Flexible

93. It is common ground that "flexible" in claim 1 of 902 is a relative term and that there are degrees of flexibility. Counsel for Medinol submitted that a stent ceased to be flexible at the point where the skilled team would regard it as incapable of being delivered through the arteries to the desired location. I did not understand counsel for Abbott to dissent from this. Counsel for Medinol also submitted that a stent consisting of rigid slotted tubes joined by a flexible connector, as in Palmaz-Schatz, was not flexible. Counsel for Abbott disputed this. I agree with Abbott that it is clear from the Patents that (i) flexibility is a property of the stent as a whole and not merely part(s) of it and (ii) the patentee regards the Palmaz-Schatz stent taken as a whole as being flexible (albeit not necessarily as flexible as was desired).

Unitary

94. Abbott did not in the end dispute Medinol's contention that "unitary" in claim 1 of 902 means that the stent is made up of a single tube, rather than a plurality of tubes as in Palmaz-Schatz.

Meander pattern

95. One of the most important issues on construction is as to the meaning of the expression "meander pattern" in claim 1 of 449 and claim 1 of 902. It is common ground that this expression is defined in the Patents as meaning "a periodic pattern about a center line". It is also common ground that a "periodic pattern" is one that repeats at regular intervals. The dispute is as to what is meant by "about a center line". (For consistency with the Patents, I shall use the American spelling of "center"

throughout.) Abbott contends that "center line" means a line of symmetry, in particular a line of either reflection or glide reflection symmetry. (Glide reflection symmetry is symmetry involving reflection and translation, such as is exhibited by a sine wave or other sinusoid.) Medinol contended through Professor Snyder's evidence, in its skeleton argument and in its written closing submissions that "the 'center line' establishes the direction along which the meander pattern as a whole traverses the stent". In his oral closing submissions, however, counsel for Medinol when pressed as to the difficulties with this construction advanced an alternative construction, namely that "center line" means a line which runs approximately through the centre of the pattern, that is to say, a line which has approximately equal parts of the pattern on either side of it.

96. Professor McHugh's evidence, which was supported by the *McGraw-Hill Dictionary of Scientific and Technical Terms* and various other publications, was that the expression "center line" is a technical term used by engineers, particularly in the context of technical drawing, to denote a line of symmetry, which may be a line of either reflection or glide reflection symmetry (or indeed other forms of symmetry). I did not understand Professor Snyder really to dispute this, although he avoided answering the question directly. Medinol points out, however, that the Patents are silent about symmetry. I shall return to this point below.

97. It was also Professor McHugh's evidence, again supported by a number of publications, that a common convention employed by technical draftsmen is to denote the center line (i.e. line of symmetry) of an object by means of a line consisting of alternating dashes and dots. Furthermore, he pointed out that, if Fig. 2 is inspected carefully, it can be seen that the center lines drawn on it use this convention (although some of the dots appear to have been lost in copying). Again, I did not understand Professor Synder to dispute these points. Medinol contends that Fig. 2 is a schematic drawing. I am unimpressed by this point, however, since the evidence shows use of this convention in schematic drawings and not merely manufacturing blueprints.

98. As Professor McHugh acknowledged, on the other hand, the vertical center lines in Fig. 2 are not drawn precisely along the lines of symmetry of the vertical meander patterns and the horizontal center lines 13 are some way off the lines of symmetry of the horizontal meander patterns. He attributed to this to sloppy draftsmanship, an explanation which is at least consistent with the omission of reference numeral 12 from the figure. As is common ground, all of the stents shown in the drawings of the Patents do in fact have meander patterns which are periodic about a line of (glide reflection) symmetry. Medinol contends, however, that the positioning of the center lines in Fig. 2 shows that the expression "center line" is not being used in its technical drafting sense.

99. If the expression "center line" is not being used in its technical sense, then one would expect it to have been used in its ordinary English sense. According to the *Shorter Oxford English Dictionary*, "centre line" means "a real or imaginary line through the centre of something". Medinol's primary construction involves "center line" being understood in a quite different way to this. Abbott contends that Medinol's interpretation amounts to ignoring the word "center", or at least depriving it of any real meaning. Medinol's alternative construction is closer to the ordinary meaning of the words. On the other hand, counsel for Medinol accepted that, if "center line" is

interpreted in accordance with Medinol's alternative construction, then the horizontal centre lines 13 in Fig. 2 have been drawn inaccurately.

100. Turning to the text of the specifications, Medinol relies on the fact that [0008] of '902 refers to the first and second meander patterns "having axes extending in first and second directions". Medinol contends that this shows that what matters is that the meander patterns should have axes denoting their directions. In effect, therefore, Medinol's primary construction is that "center line" means axis, using the word axis in the sense of axis of direction (as in Cartesian coordinates). There are four problems with this argument, however. First, the draftsman used the expression "center line" in his definition of "meander pattern", and not the word axis, let alone axis of direction. Secondly, if "center line" is interpreted as meaning axis of direction, it follows that, as counsel for Medinol accepted, any line parallel to those drawn in Fig. 2 would serve as an axis of direction. This deprives both the word "center" and the word "about" in the definition of meaning. Thirdly, if "meander pattern" is interpreted to mean "a periodic pattern having an axis defining the direction of the pattern", then the words "having axes extending in first and second directions" in this passage are largely redundant. By contrast, if "axis" is understood to mean axis of symmetry, which is consistent with Abbott's interpretation of "center line", then they are not. Fourthly, this passage does not appear in 449.

101. Abbott relies on the fact that, in the description of the first embodiment, the specifications state (at [0014] of 449 and [0016] of 902) that "meander pattern 11 is a vertical sinusoid having a vertical centre line 9" and (at [0015] of 449 and [0017] of 902) that "meander pattern 12 is an horizontal pattern having an horizontal center line 13". Abbott points out that, as noted above, a sinusoid has glide reflection symmetry. On the other hand, meander pattern 12 is not described or drawn as a sinusoid (although it could be described as sinusoid with intermittent straight sections). More significantly, Abbott points out that in these passages the draftsman uses the words "vertical" and "horizontal" to denote the orientation of the meander patterns. The references to their center lines must be intended to add something more, but on Medinol's primary construction it does not.

102. The key question which remains is what technical purpose the skilled readers would understand the definition of "meander pattern", and in particular the requirement that it be "about a center line", to serve. Medinol contends that the skilled team would understand that the purpose was merely to define the direction of the meander pattern, and hence ensure that the first and second meander patterns have different directions. The problem with this is that it does not require the pattern to have a center line at all, still less a pattern which is periodic about a center line. Abbott contends that the skilled team would understand that the purpose was that the meander patterns should be symmetrical, and that the reason for this was to assist in achieving uniformity of expansion of the stent. This receives some support from the fact that prior art stents mostly had regular patterns, although not all of these were symmetrical. Medinol points out that, not only are the specifications silent about symmetry, but also the evidence demonstrates that having symmetrical meander patterns does not guarantee uniform expansion and that uniform expansion can be achieved without symmetry. As Professor McHugh said, however, symmetry is a good starting point for achieving uniformity. Furthermore, it seems to me that the explanation in the specifications of the way in which the longitudinal expansion of the second meander pattern

compensates for the longitudinal shrinkage of the first meander pattern would suggest to skilled readers that symmetrical patterns are desirable, even if not essential.

103. The Dutch court essentially accepted Abbott's interpretation of the term "meander pattern" for reasons which it expressed as follows:

> "4.2 ... Upon studying the figures of EP 902, in particular figure 2, it will be clear to the person skilled in the art that the meander patterns according to the patent are symmetrical such that the same patterns can be found on both sides of the centre line; the first pattern extends in a first (vertical) direction and the second pattern extends in a horizontal direction different from the first direction. In view of the clear description of the term in the description, which is in line with the geographical term 'to meander', this is not changed by the fact that the position of the centre line 13 of the second meander pattern is drawn incorrectly - probably as a result of sloppiness in drafting the drawing of figure 2 …
>
> 4.6 As explained above, the person skilled in the art will take the term 'meander patterns' to mean periodical patterns extending symmetrically around a center line, (at least) in the sense that the same patterns can be found on both sides of the center line, which is the case in the meander patterns according to the patent. … The argument that the phrase 'periodic pattern about a center line' should be taken to mean a general direction in which the meander pattern extends, as argued by Medinol in the footsteps of its expert, Dr Synder, is dismissed as too broad an interpretation. As Abbott correctly pointed out, the words 'about a center line' are not synonymous with, or equivalent to, 'in a general direction', which is the terminology one would have expected if the patent holder had meant to say this. The interpretation advocated by Medinol strips the words 'center' and 'about' of virtually all meaning and therefore cannot be accepted as correct. In any event, that would be at odds with the requisite legal certainty for third parties."

104. For what it is worth, I note that in *Medinol Ltd v Guidant Corp* 417 F. Supp. 2d 280 Judge Shira Scheindlin sitting in the US District Court of the Southern District of New York when considering a claim for infringement of Medinol's US Patents Nos. 5,843,120, 6,443,982 and 6,461,381 also rejected Medinol's interpretation of "meander pattern" in favour of one which required symmetry.

105. The German court disagreed with the Dutch court's conclusion on this point for reasons which it expressed at [II.1] as follows (substituting the word "center" for the word "middle" used in the translation provided to me):

> "What is to be understood by the term 'meander pattern' according to the technical teaching of the patent in suit is disclosed to the person skilled in the art in section [0025] [*sic*: this appears to be a typographical error, the intended reference

> being to [0015]]. This shows that the term 'meander pattern' refers to a periodic pattern around a center line. This, however does not necessarily mean that this pattern also has to be arranged symmetrically around [a] center line. A pattern can also be periodic and be intersected by a (notional) center line, without having to 'run' (exactly) symmetrical along this line. There is no indication in the patent description that it is of essential significance for the technical function of the stent according to the invention that an (exact) symmetry is maintained.
>
> Such a symmetry may in fact be present along a notional center line in the figures illustrated in the patent specification (in particular Figure 2). This, however, does not in itself justify a limitation of the scope of patent in suit to this embodiment, as was undertaken by the Dutch court in its judgment… The interpretation that it is not essential for the patent in suit to show symmetry along a center line is moreover also confirmed by the fact that in the embodiment shown in Figure 2 the line described explicitly as being a horizontal center line (13) in paragraph [0027] is precisely not a line along which such a (exact) symmetry can be detected.
>
> There is furthermore also no indication that a symmetrical arrangement of the meander pattern is necessarily required for a solution of the task of the patent in suit of providing a flexible stent that contracts minimally during expansion in a longitudinal direction. The appraisal expert commissioned by the Defendants in fact also admits in his private expert opinion that the task of the patent in suit can also be solved not only with a symmetric, but also with an asymmetric arrangement of the pattern, even if the latter is possibly more difficult…"

106. Although it is clear from this that the German court rejected a requirement of symmetry, it is not clear to me precisely how the German court did interpret the words "about a center line". It appears, however, that its interpretation was similar to Medinol's alternative construction.

107. I have no hesitation in rejecting Medinol's primary construction. As discussed above, this suffers from a number of difficulties. In my view the real choice is between Abbott's construction and Medinol's alternative construction. I have already outlined the main points in favour of Abbott's construction. I agree with the German court that the strongest point against Abbott's construction is that the skilled team would appreciate, if it thought about it, that the invention would work in essentially the same manner if the meander patterns were asymmetric. This is clearest in the case of the second meander pattern, where the pattern will perform its function equally well if all the loops point in one direction rather than in alternate directions. If one asks whether the skilled readers would nevertheless conclude from reading the Patents that symmetry was required, however, I consider that the answer is yes. The two key reasons for this are that, first, the patentee has taken the trouble to define the term "meander pattern" and has done so using a term with a clear technical meaning, and

secondly, symmetry has an apparent technical advantage. The remainder of the Application is supportive of that understanding except for the misplacement of the lines 13 in Fig. 2 and that appears to be due to sloppy drawing. Furthermore, a significant problem with Medinol's alternative construction is that it is uncertain: if it is sufficient that the pattern is approximately equally distributed about the centre line, how do the skilled readers know whether they are within the claim or not? Accordingly, I prefer Abbott's construction.

Loop

108. The next issue concerns the meaning of the term "loop" in claim 1 of each of the Patents. The specifications do not contain any definition of this term. Abbott contends that "loop" means nothing more than a portion of the pattern or mesh that has the shape of a loop. Abbott accepts, however, that it is clear from the Patents that "loop" is not restricted to a loop in accordance with the primary definition of "loop" in the *Shorter Oxford English Dictionary* ("A portion of a string, rope, thread etc., doubled or crossing itself so as to form an aperture, commonly fastened at the point of crossing or juncture"). Rather, the Patents use the term "loop" to embrace a path that is open-ended. The question which arises is how to distinguish a "loop" from a mere curve. Abbott suggests that, in context, a "loop" is a curve that is more acute than 90^{o}. The basis for this suggestion is Fig. 8 of the Patent, a coloured version of which I reproduce below.

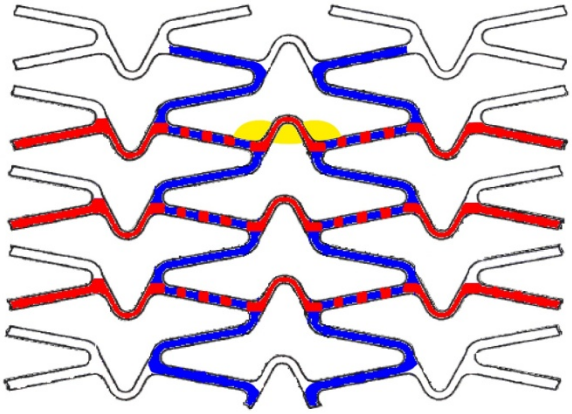


FIG. 8

109. In this version the first (vertical) meander pattern is coloured blue, the second (horizontal) meander pattern is coloured red and members common to both patterns are striped. Three areas are coloured yellow. It is common ground that the red curve which borders the middle yellow area is a loop. It is also common ground that the curves which border the left and right yellow areas cannot be loops. This is because the specifications teach the reader that there is a single loop of the second meander pattern between adjacent first meander patterns. Abbott says that what differentiates the loop from the adjacent curves is the acuteness of the angle, and that, although not spelt out by the specifications, a rational cut-off point is 90^{o}.

110. Medinol argues that this analysis cannot be correct since it depends on the angle between the ring and the link (to use Abbott's terminology) at the point of connection, and that the patentee cannot have intended to exclude minor variants of Fig. 8 in

which the link joins the ring at an angle more acute than 90^{o}. In my view this point has force.

111. For its part, Medinol contends that "loop" should be interpreted functionally, namely as denoting "a portion of a meander pattern or cell that is folded up for the purpose of providing for a change in the length of the meander pattern or cell in response to forces encountered by the stent". In support of this interpretation, Medinol points to the functions of the loops in the meander patterns described in the specifications. I have discussed these when considering the disclosure of the Application.

112. Abbott argues that this interpretation reads more into the claims than is justified since (with the exception of integer [6] of claim 1 of 901) claim 1 of each of the Patents is expressed in geometrical rather than functional terms. I am unimpressed with this argument. Given that (i) the specifications do not contain any definition of "loop", (ii) it is clear that the patentee is using the expression in a broader sense than its primary dictionary definition and (iii) it is clear that there must be a distinction between a loop and a mere curve, it seems to me that the only way in which the skilled team can determine what counts as a "loop" is by reference to a functional criterion. I agree with Medinol that the functional criterion that emerges from the teaching of the specifications is that quoted in paragraph 111 above.

113. For these reasons, I prefer Medinol's interpretation of "loop". I do not, however, accept Medinol's further contention that "loop" does not include a closed loop i.e. a loop in accordance with the primary dictionary definition. I cannot see any reason why the skilled team would think that such a loop was excluded provided that it fulfils the functional requirement for a "loop".

Disposed between

114. Another significant issue concerns the interpretation of the words "disposed between". It is important to note at the outset that this expression is used twice in claim 1 of 449 and claim 1 of 902.

115. First, integer [5][a] of claim 1 of 449 requires that the first and second meander patterns be intertwined such that "loops (14, 16) of each of the first meander patterns (11) is [*sic*] disposed between all neighboring second meander patterns". Similarly, integer [6][a] of claim 1 of 902 requires that the first and second meander patterns be intertwined such that "loops (14, 16) of each of the first meander patterns (11) are disposed between each of the neighbouring second meander patterns". It is common ground that these integers should be interpreted in the same way.

116. Secondly, integer [5][b] of claim 1 of 449 requires that the first and second meander patterns be intertwined such that "one loop (18, 20) of each of the second meander patterns (12) is disposed between all neighboring first meander patterns". Similarly, integer [6][b] of claim 1 of 902 requires that the first and second meander patterns be intertwined such that "one single loop (18, 20) of each of the second meander patterns (12) is disposed between each of the neighbouring first meander patterns". Again, it is common ground that these integers should be interpreted in the same way.

117. The issue is what is meant by "disposed between" in the context of integer [5][b]/[6][b], but it is common ground that, since the same expression is used in integer [5][a]/[6][a], it must be construed consistently in both contexts.

118. It is convenient to begin with what the expression does not mean. At one stage I thought that Medinol was arguing that a loop was only disposed between neighbouring meander patterns if the loop shared no member with those meander patterns ("no common metal"). As counsel for Medinol accepted, however, this cannot be correct. The reason why this cannot be correct is that, as noted above, integer [5][a] of claim 1 of 449 and integer [6][a] of claim 1 of 902 both require that the loops of the first meander pattern be disposed between neighbouring second meander patterns. It is clear from the description of the specific embodiments, however, that this must involve the loops sharing members with the meander patterns. This is illustrated in the coloured version of Fig. 2 which I reproduce below.

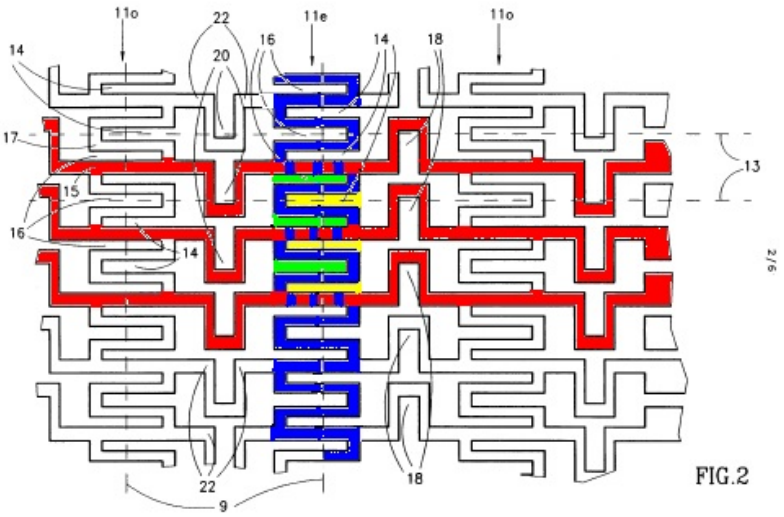


FIG.2

119. In this version a first (vertical) meander pattern is coloured blue and three second (horizontal) meander patterns are coloured red. Shared members are striped. The spaces within the loops of the first meander patterns are coloured yellow and green. It can be seen that there are only loops (plural) of the first meander pattern disposed between each of the neighbouring second meander patterns if the shared (striped) members are included as parts of the loops. This is perfectly consistent with the functional interpretation of the word "loop" which I have accepted: a loop can still perform that function even if part of the loop consists of a member shared with a different meander pattern.

120. What then does "disposed between" mean? Abbott's interpretation is simple: loops of the first meander pattern are disposed between neighbouring second meander patterns if at least part of each of the loops is located between the meander patterns even if other parts are constituted by shared members, and one loop of the second meander pattern is disposed between neighbouring first meander patterns if at least part of the loop is located between the meander patterns even if another part is constituted by a shared member.

121. Medinol's interpretation was articulated by counsel for Medinol as follows:

> "My Lord, our submission is, you have to allocate loops between the vertical or the horizontal paths and you do that allocation based on function. The function of the loop in the horizontal path is to lengthen that path. It follows that any angle made with the vertical path which does not lengthen the horizontal path is not a loop that the patent is referring to by the one loop of the horizontal path. … That means that any angles made at the junction points between the horizontal path and the vertical path do not provide the function of a horizontal loop because they do not lengthen the horizontal path."

122. Despite the efforts of counsel to explain it, I have found this submission hard to understand. It appears to me to be a submission about the meaning of the word "loop" rather than a submission about the meaning of the words "disposed between". To the extent that Medinol is contending that the criterion for what counts as a "loop" is a functional one, as I have said, I accept that contention. It seems to me, however, that Medinol is going further and contending that the criterion for what counts as a "loop" differs depending on whether the putative loop is part of the first meander pattern or the second meander pattern. This understanding appears to be confirmed by Medinol's case on infringement (as to which, see below). I do not accept this contention for the following reasons.

123. First, as counsel for Abbott submitted, the claims use the word "loop" to define the relevant portions of both meander patterns. That strongly suggests that "loop" does not bear a different meaning depending on which meander pattern one is talking about. This is particularly true in the case of claim 1 of 449 and claim 1 of 902, since integer [4] of the former and integer [5] of the latter say that "the first and second meander patterns comprise loops". It would be very surprising if the word "loops" here meant different things depending on whether one was considering the first or the second meander pattern. A similar point emerges from integer [5]/integer [6].

124. Secondly, Medinol's argument seems to me to be inconsistent with its own interpretation of the word "loop" which I have quoted in paragraph 111 above. That interpretation does not differentiate between loops of the first meander pattern and loops of the second meander pattern. Still less does it suggest that a different functional criterion should be applied to determine what counts as a "loop" of the second meander pattern to that which should be applied to determine what counts as a "loop" of the first meander pattern.

125. Thirdly, I consider that Medinol's argument is contrary to the thrust of the specifications. As I have discussed in relation to the Application, the specifications emphasise that both meander patterns can contribute to flexibility and avoidance of foreshortening. They also explain that the widening of the loops in one pattern compensates for the widening of the loops in the other pattern and vice versa, as required. Thus the specifications do not draw the sort of distinction between different types of loops that Medinol seeks to draw. Furthermore, as Medinol itself emphasises in other contexts, the specifications are explicit that the meander patterns need not be orthogonal to each other and thus need not be vertical and horizontal.

126. Fourthly, it appears to me that Medinol's focus upon the angles made at the junction points is an attempt to sidestep the problems for its case caused by the words "disposed between" and its acceptance that those words do not exclude shared

members. There is nothing in the specifications about angles at junction points, however. Indeed, Medinol itself rightly rejects Abbott's attempt to construe the word "loop" by reference to the angle made by the curve in question.

127. Accordingly, I conclude that Abbott's interpretation of "disposed between" is the correct one.

Formed from flat metal/formed of a flat metal tube

128. Claim 2 of 902 requires that the stent is "formed from flat metal", while claim 1 of 449 requires that it be "formed of a flat metal tube". In their skeleton arguments and written closing submissions both parties proceeded on the basis that these expressions should be interpreted in the same manner, but as a result of a question from me about this both sides modified their position during closing speeches. Abbott contends that both of these expressions should be interpreted as requiring that the stent be manufactured from a flat sheet of metal which is first cut into patterns and then formed into a tubular shape. On this interpretation, the word "flat" refers to the condition of the starting material. Medinol contends that they should both be interpreted as extending to a stent which is manufactured by cutting patterns into a tube of metal. On this interpretation, "flat" refers to the cross-sectional profile of the final stent. In the alternative, Medinol contends that, even if "formed from flat metal" bears the former meaning, "formed of flat metal tube" bears the latter meaning. Abbott contends that, if so, there is an added matter objection.

129. Abbott argues that its interpretation is supported by a number of passages in the body of the specifications. For this purpose I shall refer for convenience solely to 902. First, there is the passage at [0003] acknowledging prior art stents "formed of wire" and "formed of cut stock metal". It is common ground that this passage draws a contrast between these two types. Professor McHugh's evidence was that "stock metal" means unprocessed metal such as a flat sheet or tube and that stents formed of cut stock could be made by either cutting from flat metal and then rolling or cutting from tube. I did not understand Professor Synder to disagree with this. To my mind, this passage is neutral.

130. Secondly, there is the passage at [0012] which states that "the first and second meander patterns are formed from flat metal". This adds nothing to the wording of the claim, however.

131. Thirdly, and more significantly, there are passages at [0019] and [0027]. The former states that "the pattern of Fig.2 is formed into a tube". The latter states:

> "The stent of the present invention can be manufactured from flat metal which is etched into the pattern of Fig. 2. The etched metal is then bent to form the tube 30. Alternatively, the pattern of Fig. 2 can be manufactured from welded or twisted wire."

In my judgment, it is clear from this that the specification envisages the specific embodiments of the invention being manufactured from a flat metal sheet which is first cut and then rolled. It does not necessarily follow, however, that the skilled readers would conclude that the patentee intended to limit the claims to stents made in that way (or from wire).

132. Abbott argued that the skilled readers, and in particular the engineer on the team, would appreciate that there were advantages and disadvantages in manufacturing a stent in the manner described at [0027] compared to cutting from tube. For example, making the patterns from flat sheet metal allows for enhanced ability to perform quality control inspections of both sides of the pattern during manufacturing, yet it requires welding and often the presence of a weld "bump". On the other hand, etching or laser cutting the pattern in an already made solid tube makes it very difficult to inspect the inside surface of the pattern, although it eliminates the need for welding and the presence of a weld "bump". I accept this, but in my judgment it does not necessarily follow that the skilled readers would conclude the patentee intended to exclude the latter method.

133. I have to say that it seems to me that the natural meaning of "formed from flat metal", particularly in the light of [0027], is as Abbott contends. Nevertheless, I have come to the conclusion that the skilled readers would not consider that the words of claim 2 of 902 were intended to be limited to that method of construction. The words are capable of being interpreted in the broader sense contended for by Medinol; the skilled team would realise that the method of manufacture made no difference to the invention and that there are pros and cons with both methods; and there is nothing in the specification to suggest that the patentee intended strict compliance with this requirement, if narrowly read.

134. As for claim 1 of 449, I consider that this plainly covers both methods of manufacture. The word "of" points away from the words being directed to a specific method of manufacture, and the juxtaposition of the words "flat" and "tube" indicates that the former describes the cross-sectional profile of the tube rather than the material from which it is made.

Expandable

135. Claim 12 of 902 requires that the first meander patterns are "expandable in the circumferential direction" and the second meander patterns are "expandable in the longitudinal direction". The issue here is what is meant by "expandable", particularly in the case of the second meander patterns. Medinol contends that "expandable" simply means capable of expanding in the specified direction in normal use of the stent, and thus it is immaterial whether the second meander patterns actually expand in the longitudinal direction in any particular circumstances. Thus Medinol says it is sufficient if there can be longitudinal expansion of the second meander patterns upon bending the unexpanded stent. Abbott contends that "expandable in the longitudinal direction" means that the second meander patterns must expand upon (i.e. during) expansion of the stent.

136. I prefer Medinol's interpretation for the following reasons. First, it better reflects the words of the claim. Abbott's interpretation involves reading words into the claim. Secondly, Abbott's construction depends on the proposition that the only function of the second meander patterns is to expand upon expansion of the stent. The specification makes it clear, however, that this is not their only function. They also expand upon bending. Thirdly, Medinol's interpretation reflects the teaching of the specification more generally, which is that both meander patterns can expand as required to promote flexibility and minimise shrinkage.

Construction of 901

137. There are a number of difficult issues of construction of claim 1 of 901. In each case, the specification is of little or no assistance, because there is no explicit basis in the text for the relevant features of the claim. I am therefore forced to interpret the language of the claim as I best I can in the light of the general teaching of the specification.

138. Before proceeding further, it should be noted that both sides rely upon different aspects of the decision in *Virgin v Premium* in support of their respective cases. Medinol relies upon the fact that the claim incorporates reference numerals from the drawings, and thus the skilled readers will expect that the claim reads onto those features. Abbott relies upon the fact 901 is a divisional, and thus the skilled readers will appreciate that subject-matter described in the specification may be claimed in another patent.

Comprising a mesh of adjacent, connected cells

139. Integer [1] of claim 1 of 901 requires a stent "comprising a mesh of adjacent, connected cells". Medinol contends that "a mesh of adjacent, connected cells" requires a contiguous array of cells. I do not understand Abbott to dispute this. Abbott points out, however, that the claim includes the word "comprising" and that that is normally interpreted to mean "including" rather than "consisting of": see e.g. the EPO's *Guidelines for Examination* (December 2007, Part C Chapter III paragraph 4.21. Counsel for Medinol faintly suggested that in the context of claim 1 of 901 "comprising" should be interpreted as meaning "consisting of", but I see no reason to give it a more restricted interpretation than normal. It follows that claim 1 extends to a stent which includes a mesh of adjacent, connected cells but also includes other members.

Fixed length

140. Integer [2] of claim 1 of 901 requires that each cell of the mesh comprise "an even number of fixed length, alternating, first (14, 16) and second loops (18, 20) connected together in a closed cell (42a, 42b, 44a, 44b)". There are disputes as to the meaning of both "fixed length" and "alternating".

141. So far as "fixed length" is concerned, Abbott contends that the loops are of "fixed length" if their length is the same. Furthermore, Abbott says this means that the first loops must all be of the same length and the second loops must all be of the same length, but it accepts that this does not mean that the first and second loops are the same length as each other. Medinol contends that "fixed length" means that the loops do not change in length, in particular by stretching, whereas they do widen circumferentially or longitudinally as the case may be.

142. Abbott contends that the technical purpose of having fixed length loops is to achieve regularity and hence uniformity of expansion. As I have discussed in relation to the meaning of "meander pattern", I accept that the skilled team would see this as a relevant consideration. I do not see, however, that this leads to the conclusion that the words should be interpreted as Abbott suggests rather than as Medinol suggests.

143. Medinol contends that the skilled team would appreciate that the technical purpose of requiring the loops to be of fixed length was to exclude loops made of polymeric materials. I am not convinced by this, since there is nothing in the specification to suggest that this is the purpose.

144. In the absence of any explanation in the specification or any clear technical pointer, one is left with the language of the claim. It seems to me that Medinol's interpretation fits the language of the claim better than Abbott's, for two reasons. First, the claim uses the words "fixed length". It does not say "same length" or "equal length". Secondly, the words "fixed length" qualify both the first and second loops. This suggests that, in this respect, the first and second loops are the same; yet on Abbott's interpretation they differ from each other. In addition, I consider that Medinol's interpretation is somewhat more consistent with the general teaching of the specification. I also note that the EPO Opposition Division appears to have adopted this interpretation (see below).

145. It is fair to say that the specification does not explicitly instruct the readers to make the loops in the meander patterns of fixed length, let alone how to do so. I shall return to this point when considering added matter and insufficiency, but I do not see that it provides a sufficient reason to reject Medinol's interpretation as a matter of construction.

Alternating

146. As to "alternating", Abbott contends that this should be given its ordinary English meaning, namely first one and then the other in succession. Thus "alternating first and second loops" means a first loop and then a second loop in succession. Medinol contends that it is sufficient if there are alternating groups of loops.

147. In support of its interpretation, Medinol relies on the fact that the reference numerals 42a, 42b, 44a and 44b in claim 1 of 901 refer to Fig. 4. Both for this reason and because there is nothing to suggest to the contrary, the skilled readers would understand that claim 1 of 901 was intended to read onto the embodiment of Figs. 1-4. As can be seen from Fig. 4, the loops of cell 42a go (reading clockwise from the bottom of the cell) first loop 14, first loop 16, first loop 14, second loop 18, first loop 16, first loop 14, first loop 16, second loop 18. Similarly, the loops of cell 42b go first loop 14, first loop 16, first loop 14, second loop 20, first loop 16, first loop 14, first 16, second loop 20.

148. Counsel for Abbott accepted that, on Abbott's interpretation of "alternating", claim 1 did not read onto Figs. 1-4, and in particular did not read onto cells 42a and 42b. He submitted that, since 901 is a divisional, the skilled readers would understand that claim 1 might not necessarily read onto that embodiment. He also submitted that the skilled readers would conclude that the inclusion of reference numerals 42a and 42b in the claim was a mistake. (It is worth noting that he did not rely upon the fact that the claim is in two-part form, and therefore one would ordinarily expect the pre-characterising portion to be based on the closest item of prior art. In my view he was right not to do so, since there is nothing in 901 to suggest that the pre-characterising portion is based on any identifiable item of prior art.)

149. I am unable to accept this argument. It seems to me that the skilled team would take the reference numerals as a clear indication that claim 1 was intended to read onto Fig. 4, and in particular cells 42a and 42b. There is nothing in 901 to suggest to the contrary. That being so, the skilled readers would appreciate that "alternating" must be interpreted as including the sequence of loops I have described in paragraph 147 above.

150. In my judgment it follows that the skilled readers would not interpret "alternating" as confined to its strict meaning of "first one and then the other in succession". Rather, they would interpret "alternating" more loosely. In my view a 1, 1, 1, 2, 1, 1, 1, 2 pattern can be described having "alternating" 1s and 2s in a loose sense: it alternates between three 1s and one 2. On the other hand, I do not accept that the skilled team would interpret "alternating" as broadly as Medinol suggests, since Medinol's interpretation involves reading in the word "groups" which is simply not there.

Even number

151. There is no dispute between the parties as to what the words "even number" mean. There is, however, a dispute as to how the loops are to be counted. Abbott contends that the total number of first and second loops in the cell must be even, whereas Medinol contends that the total number of loops in alternating groups of loops must be even. In my judgment Abbott is correct on this point. Medinol's construction amounts to re-writing the claim.

Loops defining first and second angles whose bisecting lines are at angles one to another

152. Integer [4] of claim 1 of 901 requires that the first and second loops define first and second angles whose bisecting lines are at angles. Given the complete absence of support in either the text or the drawings, I find this feature somewhat baffling. How does a loop define an angle? What counts as "at angles"? And why does any of this matter?

153. Medinol contends that what this feature boils down to is that "the first and second loops do not point in the same direction", i.e. they have a different orientation, even if only slightly different. I did not understand counsel for Abbott to take issue with this interpretation, and I therefore accept it.

The second loops are arranged to widen longitudinally upon expansion of the stent

154. Integer [6] of claim 1 of 901, which is the characterising feature of the claim, requires that "the second loops are arranged to widen longitudinally upon expansion". Abbott contends that this means that *all* the second loops of *each* cell of the mesh must widen longitudinally *during* expansion. Medinol contends that it is sufficient if *some* loops widen *in some circumstances* either *during* or *after* expansion. Medinol accepts, however, that claim 1 of 901 does not extend to loop widening which only occurs as a result of bending an unexpanded stent. To that extent, Medinol accepts that claim 1 of 901 is narrower than claim 12 of 902.

155. In this case I prefer Abbott's interpretation. Unlike claim 12 of 902, claim 1 of 901 does not merely require that the second meander patterns are generally capable of expanding in the longitudinal direction, it requires they are "arranged to widen

longitudinally upon expansion of the stent". As I have discussed in relation to the Application, the specification describes bending and expansion of the stent separately. So far as expansion is concerned, it specifically states at [0023] that (emphasis added):

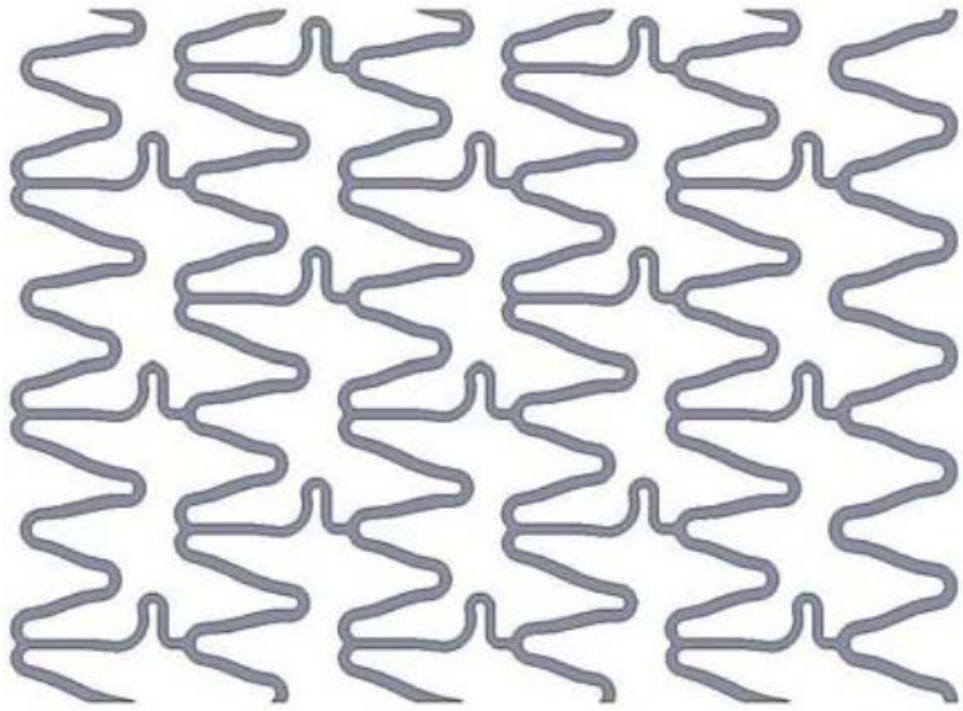
> "When the stent expands, both meander patterns 11 and 12 expand (i.e. *all* loops 14 – 20 open up.)"

It is true that this statement is made in the context of describing the first embodiment, but there is nothing in the specification to indicate that other embodiments may behave differently in this respect. On the contrary, it is clear that all the embodiments described in the specification will behave in this way. Furthermore, there is not a word in the specification about what happens after expansion of the stent. In the light of the teaching of the specification, I consider the skilled readers would conclude that the words "the second loops … widen … upon expansion of the stent" meant precisely what they said.

Infringement

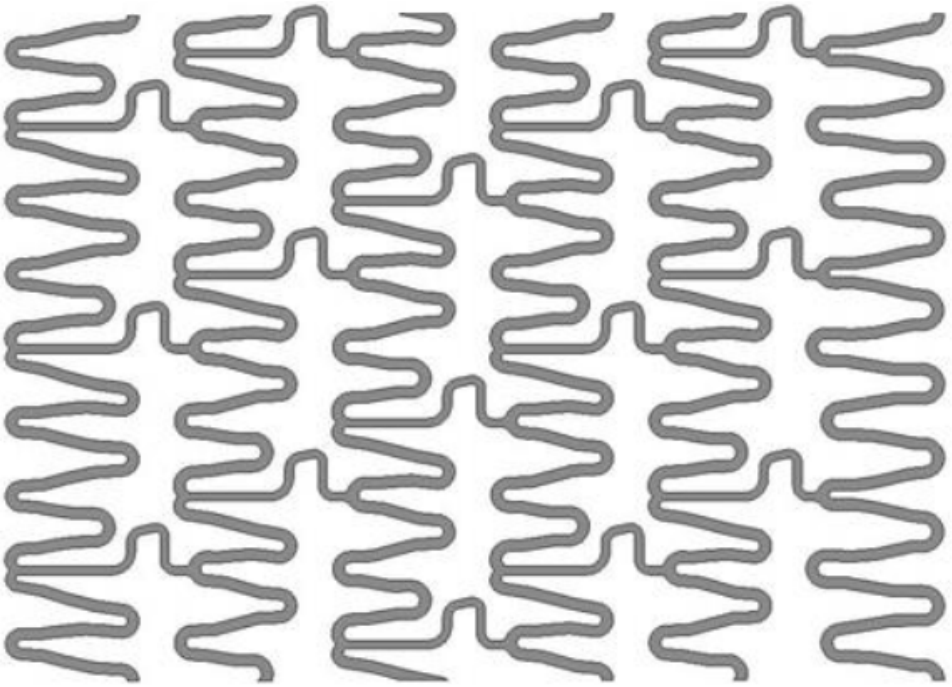
156. There are eight Abbott stent designs that are in issue: small and medium Vision; small and medium Multi-Link 8; small and medium Xience; and small and medium Xience Prime. However, the Xience and Xience Prime stents have the same design as the Vision and Multi-Link 8 stents respectively, the only difference being that they are coated with material containing the anti-proliferative drug everolimus. Furthermore, for the purposes of infringement there are no significant differences between the Vision and Multi-Link 8 stents. For present purposes, therefore, I can concentrate on the Multi-Link 8 stents.

157. In plan view the small Multi-Link 8 looks like this:



158. Abbott describes this design as having six crests per circumferential ring with three longitudinal links between each ring. The longitudinal links between successive rings are staggered, so that every other link is aligned.

159. In plan view the medium Multi-Link 8 looks like this:



160. Abbott describes this design as having nine crests per circumferential ring with three longitudinal links between each ring. The longitudinal links between successive rings are staggered, so that every third link is aligned.

161. Abbott contends that these designs are based on the teaching of Lau (as to which, see below). It is common ground, however, that there is one difference between these designs and the specific embodiments depicted in Lau, namely that the links in these designs incorporate U-shaped portions, whereas the links shown in Lau do not.

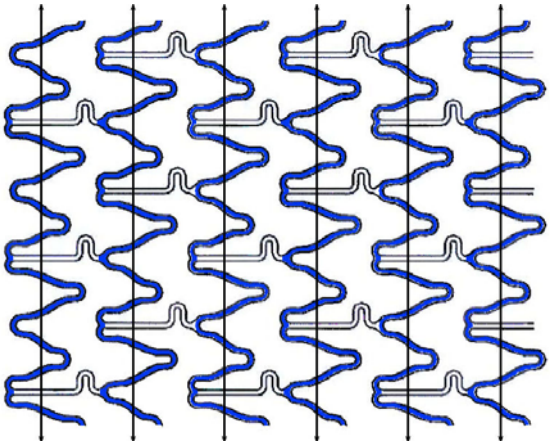
162. Abbott also contends that, since these designs are all in-phase designs with links which run from trough to trough, they would not suffer from appreciable foreshortening even without the U-shaped portions. I do not understand Medinol to dispute this. As Medinol points out, however, this is not in itself a defence to infringement, since the claims cover in-phase designs. Furthermore, Medinol contends that the U-shaped portions contribute to the flexibility of the Abbott Stents.

163. Although there are differences between the small and medium designs as I have described, they are not significant with respect to infringement, and so I shall concentrate for convenience on the small design. The issues on infringement primarily turn on the construction of the claims. There is, however, one factual issue which I must resolve.

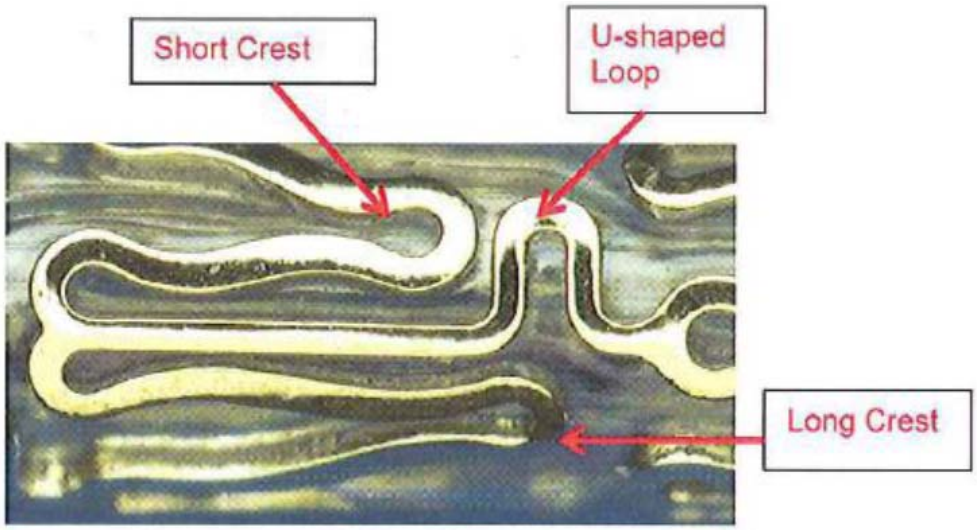
Claim 1 of 902

164. *Meander patterns*. The first issue is whether the Abbott stents have first and second meander patterns. Although the dispute is similar in relation to both, there is a difference between the two. I shall therefore consider them separately.

165. Medinol identifies the first meander patterns in the Abbott Stents as shown in blue below:

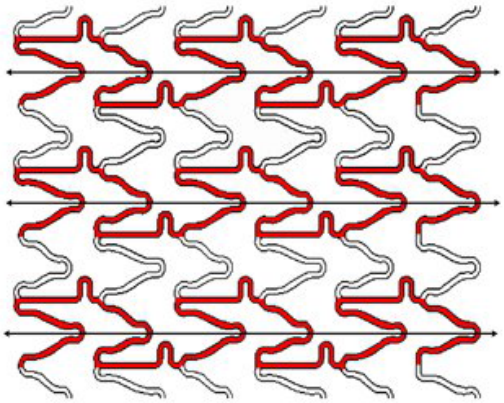


166. There is no dispute that these patterns can be identified in the Abbott Stents and that they are periodic. Medinol contends that each pattern is periodic about a center line, namely the vertical lines shown in this drawing. Abbott contends that these patterns are not periodic about a center line, since they are not symmetrical. Furthermore, Mr Johnson's evidence is that the patterns are intentionally asymmetric and for good reason. This is that the patterns contain a combination of "long" and "short" crests in order to create a "pocket" in the ring for the U-shaped portion of the link. Without that configuration, the U-shaped portion would either need to be nested within a valley (which would decrease crimpability to the balloon) or placed between the rings (which would decrease scaffolding). This asymmetry can be seen more clearly from the following photograph of an Abbott stent:

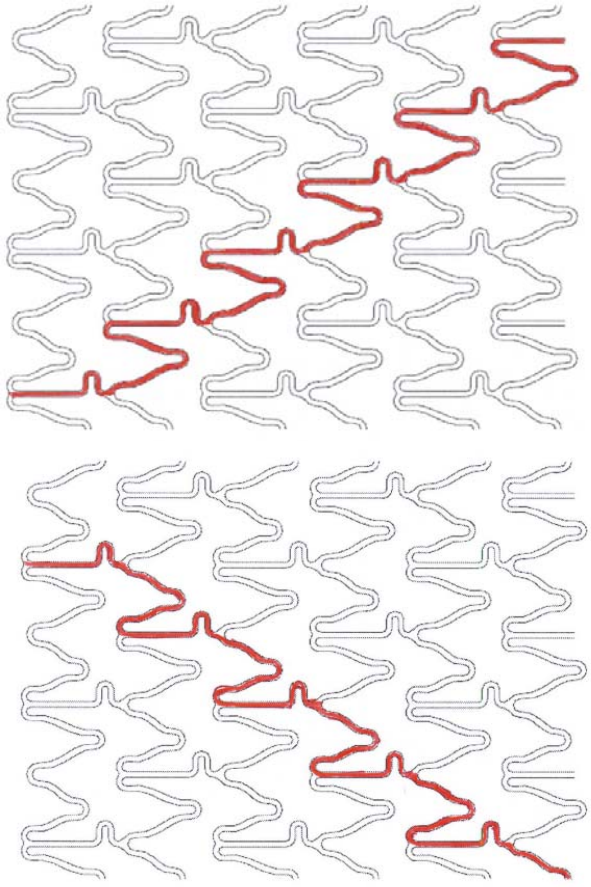


167. Given that I have accepted Abbott's construction of "meander pattern", it follows that the patterns proposed by Medinol as being the first meander patterns are not meander patterns at all since they do not fall within that definition.

168. Medinol identifies the second meander patterns in the Abbott Stents as shown in red below. Again, Medinol says that these patterns are periodic about the lines shown.



169. Abbott contends that this way of looking at the Abbott Stents is artificial and involves imposing a pattern on what is really a different design of stent. Furthermore, Abbott points out that one could equally well identify other longitudinal patterns in its stents, such as the two shown in red below:



170. Counsel for Medinol accepted that each of these patterns fell within Medinol's interpretation of "meander pattern". This is itself is not an obstacle to Medinol's infringement case, however, since claim 1 of 902 (and claim 1 of 449) requires a patterned shape "comprising" first and second meander patterns, which does not

exclude the presence of third, fourth or fifth meander patterns. Nevertheless, it does emphasise the need for careful scrutiny of Medinol's case on the second meander patterns.

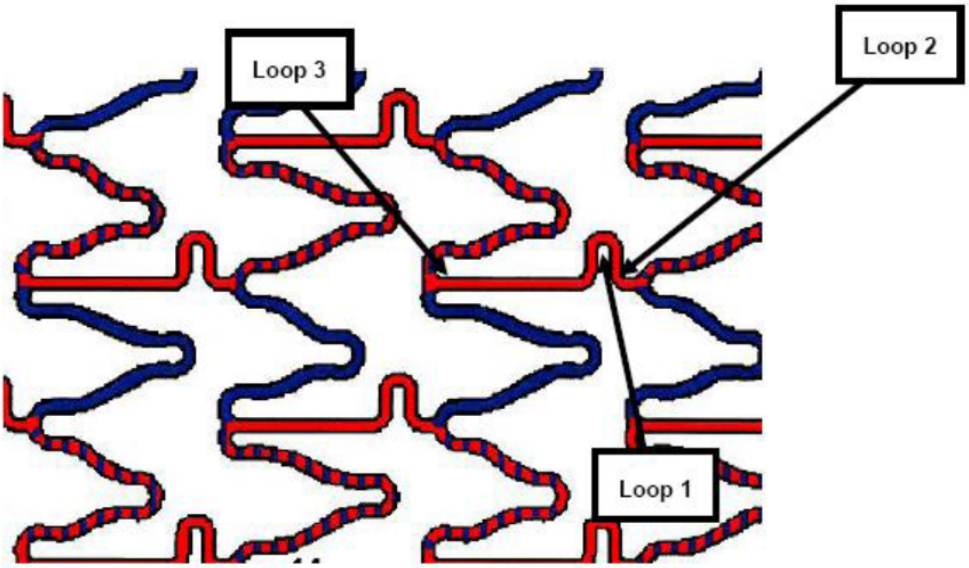
171. In this regard, I note that the Dutch court gave three reasons for concluding that the Abbott Stents did not have second meander patterns as required by claim 1 of 902. First, the patterns relied on were not meander patterns at all since they were not symmetrical. Secondly, even if the Abbott Stents had first meander patterns, they did not have second meander patterns since as a matter of reality the first meander patterns were simply joined by U-shaped links. Thirdly, even if the Abbott Stents had second meander patterns, they did not extend in a different direction to the first meander patterns since very substantial portions of both patterns were the same.

172. As set out above, the German court explicitly disagreed with the first of these reasons. Although the decision is not so explicit as to the second and third points, as I understand it, the German court did not agree with those either.

173. Given that I have accepted Abbott's construction of "meander pattern", it follows that the patterns proposed by Medinol as being the second meander patterns are not meander patterns at all since they do not fall within that definition. I therefore agree with the Dutch court as to the first reason. If I had accepted either of Medinol's constructions of "meander pattern", however, I would not agree with the Dutch court's second and third reasons. On Medinol's interpretations, one can identify second meander patterns which overall extend in different directions to the first meander patterns it relies on. On the other hand, I consider that Medinol's case as to the second meander patterns has consequences with regard to the next issue.

174. *One loop of each second meander pattern disposed between neighbouring first meander patterns.* The second issue is whether, assuming that the Abbott Stents have first and second meander patterns as alleged by Medinol, they have a single loop of each second meander pattern disposed between neighbouring first meander patterns.

175. Abbott contends that they do not, but have three such loops, as shown in the following diagram (where the first pattern is blue, the second pattern is red and shared members are striped):



176. It is common ground that, on the assumption set out above, Loop 1 is a loop of the second meander pattern and that it is disposed between neighbouring first meander patterns. Medinol disputes that Loop 2 or Loop 3 is a loop of the second meander pattern or, if they are, that they are disposed between neighbouring first meander patterns.

177. The Dutch court did not address this issue in its decision. The German court did, and held that at least Loop 3 was a loop of the second meander pattern disposed between neighbouring meander patterns. Its reasons were as follows:

> "The Plaintiff on the other hand cannot be successful with its objection that loop 3 cannot be a loop belonging to the second meander pattern because the two limbs of the relevant loops of the first meander pattern would move apart when the stents are being expanded, which would occur - according to the Plaintiff - entirely independent of the linear section of the connector (straight section), with the connector always remaining at the same position and not being involved in the behaviour of the surrounding loops in bending operations. According to the patent in suit, the goal is to create - something to which the Plaintiff also repeatedly refers - a flexible stent which contracts minimally when expanding in a longitudinal direction (…. section [0007]). It is according to the invention not significant which contribution the first and the second meander pattern make to ensuring flexibility and the minimum longitudinal contraction. The patent in suit also does not assume that the goals of the patent are to be achieved by single loops. The goal is rather to solve the task of the patent in suit by means of two meander patterns running in different directions. As it is not significant for realisation of the feature group C whether single loops run in a different direction as that of the overall orientation of the meander, it can also not be relevant for realising feature E.2 whether single loops contribute to the

> solution of the task of the invention, provided this solution is solved by the entire meander pattern to which the relevant loop belongs."

178. In my judgment, at least Loop 3 is both a loop of the second meander pattern and disposed between neighbouring first meander patterns. Loop 3 is a loop because it satisfies the functional definition of a loop which I have accepted above. As I understand it, it is common ground that Loop 3 can widen or contract on bending of the stent and will widen *circumferentially* upon expansion. Medinol argues 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. As discussed above, this seems to me 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. For the reasons given there, I do not accept that. Loop 3 is not a loop of the first meander pattern, but of the second meander pattern. Furthermore, on the interpretation of the words "disposed between" that I have accepted, Loop 3 is disposed between neighbouring first meander patterns.

179. Loop 2 is a more marginal case, but in my view this is both a loop of the second meander pattern and disposed between neighbouring first meander patterns as well.

Claim 2 of 902

180. The Abbott stents are manufactured from a tube which is cut, and not from flat sheet metal which is cut and then formed into a tube. On the construction of claim 2 which I have accepted, however, this claim would be infringed if claim 1 was.

Claim 12 of 902

181. Abbott admits that, if the Abbott Stents have first meander patterns as alleged by Medinol, then they are expandable in the circumferential direction. Abbott also admits that, if the Abbott Stents have second meander patterns as alleged by Medinol, then, when the Abbott Stents are bent while crimped on a balloon, some of the loops of the second meander pattern identified as Loop 1 above will widen in the longitudinal direction. It follows that, on the construction of claim 12 which I have accepted, this claim would be infringed if claim 1 was. There is a factual issue between the parties as to what happens to Loop 1 in other circumstances. I shall address this when dealing with claim 1 of 901.

Claim 1 of 449

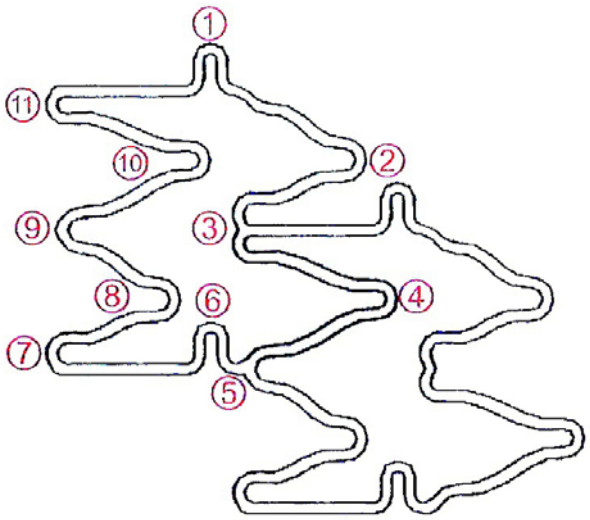
182. There is no separate issue on infringement of claim 1 of 449 beyond those considered above.

Claim 1 of 901

183. *Fixed length.* As I understand it, there is no dispute that the loops in the Abbott Stents satisfy this requirement as I have construed it.

184. *Alternating* and *even number*. It is convenient to deal with these issues together. Abbott contends that the cells in the Abbott Stents neither have alternating first and

second loops, nor an even number of them. Abbott says that the loops are as shown in the following diagram:



185. Medinol says that Loop 5 in this diagram is not a "loop" within the meaning of the claim at all, and that once this is taken out of the equation there is an even number of loops (10) which alternate five first loops, one second loop, three first loops, one second loop.

186. I agree with Abbott for the following reasons. First, I consider that Loop 5 is a loop within the claim (see paragraph 179 above). Secondly, if Loop 5 is discounted, then I consider that, for similar reasons, Loop 3 should also be discounted, which would still leave an odd number of loops. Thirdly, even if Loop 5 is discounted and Loop 3 is not, I do not accept that there would be an even number of alternating first and second loops. This is for two reasons. The first reason is that, if Loop 3 is a loop, then I regard it as a third loop and not a second loop. This in itself does not prevent infringement, due to the presence of the word "comprising" in integer [2]; but it does mean that it cannot count towards the even number of first and second loops. The second reason is that, even if Loop 3 is a second loop, I do not regard the pattern 1, 1, 1, 1, 1, 2, 1, 1, 1, 2 as one in which 1 and 2 alternate even in the loose sense I have accepted in paragraph 150 above.

187. *The second loops are arranged to widen longitudinally upon expansion of the stent.* Abbott disputes that the second loops (i.e. those numbered 1 and 6 in the diagram above) widen longitudinally upon expansion of the stent. I have set out my construction of these words already. As noted above, there is a factual issue between the parties as to how the Abbott stents behave.

188. Certain matters are either common ground or established on the evidence:

i) When a straight crimped Abbott Stent is expanded, the loops do not widen.

ii) When a crimped Abbott Stent is bent, the loops on the outside of the curved part of the stent widen while those on the inside of the curved part contract.

iii) When a straight expanded Abbott Stent is bent into a curve, the loops on the outside of the curved part of the stent widen by about 2-5% of the width of the loop and those on the inside contract.

iv) If an Abbott Stent is bent and expanded simultaneously, the loops on the outside of the curved part of the stent widen and those on the inside contract. This will occur both when the stent is straight to begin with and when the stent is moderately bent to begin with.

v) If a crimped bent Abbott Stent is expanded by a balloon in such a way that the stent is straightened (i.e. bent back), then the loops on the inside of the curved part of the stent will widen and those on the outside will contract compared to their state prior to expansion.

189. The dispute is as to what happens to the loops when a bent crimped Abbott Stent is expanded without changing the curvature of the stent. Medinol contends that in these circumstances the loops at least on the outside of the curve will widen, while Abbott disputes this. There was a great deal of evidence about this issue, much of which I regard as inconclusive or peripheral. I will therefore deal with it as briefly as possible.

190. The starting point is that, since Medinol now positively alleges infringement of 901, the burden lies on it to prove what happens to the loops in this scenario. Despite this, Medinol has not relied on any experimental evidence in support of its case. In particular, it has not relied on any finite element analysis ("FEA") of its own despite having in-house expertise in FEA. Following an order for specific disclosure which I made on 8 September 2010, it sought to rely upon an analysis of an FEA model created for Abbott, but ended up agreeing that the facts established by this did not go beyond points (i) and (iii) in paragraph 188 above. Nor has Medinol relied upon any photographs in support of its case.

191. Medinol did rely upon promotional materials issued by Abbott and evidence given by Mr Johnson as to the function of the loops in question in the Abbott Stents, namely to aid flexibility and conformability of the stents. This evidence does not establish, however, that the loops participate in expansion as distinct from bending of the stents.

192. Professor McHugh and Professor Snyder disagreed on this issue. In summary, Professor Snyder's view was that, as the diameter of the bent stent increased on expansion, the increase in curvature of the outer side of the stent would mean that the length of the outer side of the stent would increase, and that this would be provided for, at least in part, by widening of the loops. Professor McHugh's view was that, as bent stent expanded, the circumferential rings would move relative to each other (namely, further apart on the outside of the curve and closer together on the inside), and that this would enable the outer side of the stent to get longer without the loops widening. I did not understand either expert to resile from their respective positions during cross-examination. Two points struck me as particularly relevant in considering the weight to be given to their respective opinions, in addition to my general comments on their evidence above. First, Professor Snyder included some photographs in his first report which he appeared to be relying on as showing that the loops did widen. In his third report, however, he accepted that these photographs could not be relied on for this purpose. Secondly, as discussed in more detail below, Professor McHugh relied on both photographs and measurements taken from those

photographs, which he maintained supported his opinion. In particular, Professor McHugh said that no loop widening could be seen on inspection of the photographs. Thus Professor Snyder's opinion was based on nothing more than theoretical analysis, whereas Professor McHugh's opinion was based not only on theoretical analysis, but also on both inspection and measurement of photographs. For these reasons I give more weight to Professor McHugh's opinion, even though as I shall explain I do not consider that the photographic evidence itself is determinative.

193. In his second report replying to Professor Snyder's first report, Professor McHugh relied on photographs, and measurements taken from those photographs, as showing that the loops contracted rather than widened. Medinol objected that this was an experiment. As a result, Abbott agreed to serve a notice of experiments in respect of the taking of the photographs (curiously, it did not include the procedure by which the measurements were taken in the notice) and to repeat that experiment in the presence of Medinol's representatives. Medinol makes a considerable number of criticisms both of this experiment and of the measurement procedure. I do not propose to go through all these criticisms seriatim. I accept that many, although not all, of them have force. If the burden lay upon Abbott to prove that the loops did not widen in the scenario in question, and the photographs and measurements were the only evidence relied upon by Abbott, then I would not feel able to conclude that Abbott had discharged that burden. As I have pointed out, however, that is not the position. On the contrary, the burden lies upon Medinol to prove that the loops do widen in this scenario; Medinol have adduced no positive evidence to that effect other than Professor Snyder's opinion; Professor McHugh's evidence is to the contrary; and, even if the Abbott photographs and measurements cannot be relied on as positively proving that the loops do not widen, they are at least consistent with Professor McHugh's opinion. Certainly, Medinol did not conduct an experiment in reply to Abbott's experiment to show that taking photographs and measurements in a manner which was not subject to Medinol's criticisms lead to a different conclusion.

194. Counsel for Medinol argued strenuously that, even absent any other evidence, it should be inferred from points (ii)-(v) in paragraph 188 above that the loops on the outside of the stents widened when bent Abbott Stents were expanded. I am not persuaded that those matters do enable that inference to be drawn, however. Each of those scenarios involves some bending of the stent, whereas the scenario presently under consideration involves just expansion. In that respect, it is closer to scenario (i).

195. For these reasons, I conclude that Medinol has not proved that the loops do widen when the bent stent is expanded.

196. It follows that Medinol has not established that any of the loops in the Abbott Stents widen longitudinally on expansion, as distinct from bending, of the stents. In any event, even if some of the loops widen longitudinally on expansion of the stents, some do not. On the construction of integer [6] of claim 1 that I have accepted, this means that this integer is not satisfied by the Abbott Stents.

Conclusion on infringement

197. None of the Patents is infringed by the Abbott Stents.

Lau

198. Lau was published on 5 May 1993 claiming a priority date of 28 October 1991. At column 1 lines 1-36 Lau reviews the prior art. At page 1 lines 37 – 50 it states:

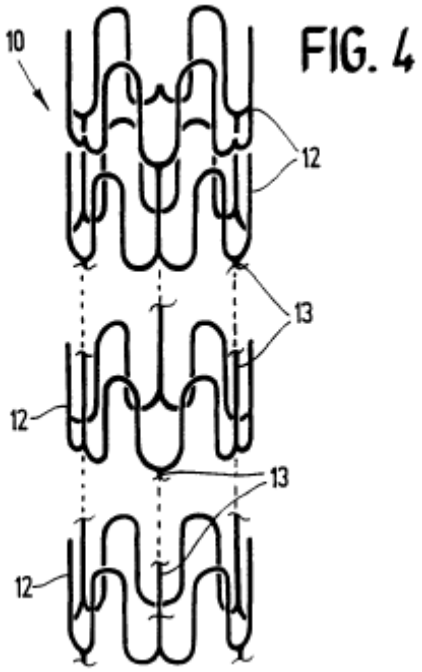
> "What has been needed and heretofore unavailable is a stent which has a high degree of flexibility so that it can be advanced through tortuous passageways and can be readily expanded and yet have the mechanical strength to hold open the body lumen into which it expanded. The present invention satisfies this need.
>
> The present invention is directed to an expandable stent which is relatively flexible along its longitudinal axis to facilitate delivery through tortuous body lumens, but which is stiff and stable enough radially in an expanded condition to maintain the patency of a body lumen such as an artery when implanted therein."

199. As Lau explains at column 1 line 51 – column 2 line 14, this objective is achieved by a stent which has "a plurality of radially expandable cylindrical elements which are relatively independent in their ability to expand and to flex relate to one another" with "interconnecting elements or struts extending between adjacent cylindrical elements [which] provide increased stability and are preferably positioned to prevent warping of the stent upon the expansion thereof". As noted above, Abbott refers to the cylindrical elements as "rings" and the interconnecting elements as "links". I shall use this shorthand while bearing in mind that these expressions are not to be found in Lau itself.

200. Lau goes on to say at column 2 lines 43-47 and column 3 lines 10-15 that:

> "Preferably, the undulating patterns of the individual cylindrical structures are in phase with each other in order to prevent the contraction of the stent along its length when it is expanded.
>
> …
>
> Preferably, all of the interconnecting elements of a stent are joined at either the peaks or the valleys of the undulating structure of the cylindrical elements which form the stent. In this manner there is no shortening of the stent upon expansion."

201. This arrangement can most clearly be seen from Figs. 4 and 5, showing a perspective view of the stent and a plan view of a flattened section of the stent respectively. I reproduce Fig. 4 below. I have already reproduced Fig. 5 in paragraph 73 above.



202. Lau goes on to say at column 3 lines 16-20 that:

> "The number and location of elements interconnecting adjacent cylindrical elements can be varied in order to develop the desired longitudinal flexibility in the stent structure both in the unexpanded as well as the expanded condition."

203. Lau returns to this point at column 5 line 56 – column 6 line 33, where it describes varying the number and position of the interconnecting elements by reference to four schematic diagrams, Figs. 7-10. Fig. 7 shows a single link between successive rings which are all aligned with one another. Fig. 8 shows staggered single links. Fig. 9 shows staggered double links. Fig. 10 shows staggered triple links. Although not illustrated, Lau states that "four or more" links may be provided between rings. At column 6 lines 18-34 Lau cautions:

> "However, as previously mentioned, all of the interconnecting elements of an individual stent should be secured to either the peaks or valleys of the undulating structural elements in order to prevent shortening of the stent during the expansion thereof."

204. Lau goes on to describe at column 6 lines 34-49 by reference to Fig. 11 an alternative stent structure in which "the cylindrical elements are in serpentine patterns but out of phase with adjacent cylindrical elements". I have reproduced Fig. 11 in paragraph 75 above.

Burmeister

205. Burmeister is an application by SciMed Life Systems, Inc which was filed on 18 May 2005 with a priority date of 19 May 2004 and was published on 30 November 1995. It is thus a novelty-only citation under section 2(3) of the 1977 Act corresponding to Article 54(3) EPC.

206. Burmeister's invention is summarised in the abstract as follows:

> "A new multiple component stent (10) which allows for initial self-expansion and subsequent deformation to a final enlarged size. In one embodiment, stent (10) comprises a first resilient element (12) and a second deformable element (14). In another embodiment, stent (30) is made of a first austenite component (32) and a second martensite component (34)."

207. As this suggests, the main thrust of Burmeister is to provide a stent that is partly self-expanding and partly balloon-expandable. To this end, the stent is constructed partly from a resilient (elastically deformable) material, in particular austenite, and partly from a plastically deformable material, in particular martensite.

208. Under the heading "Background of the invention" Burmeister says that stents are often introduced into the desired position in the body by percutaneous techniques (page 1 lines 9-10). It goes on to identify certain problems with prior balloon expandable and self-expandable stents, one of which is that the balloon expandable stents may not offer ideal performance in tortuous passages in blood vessels (page 1 lines 24-25). It then says that the stents of the invention provide the best features of both types of stent without their drawbacks (page 1 lines 31-32).

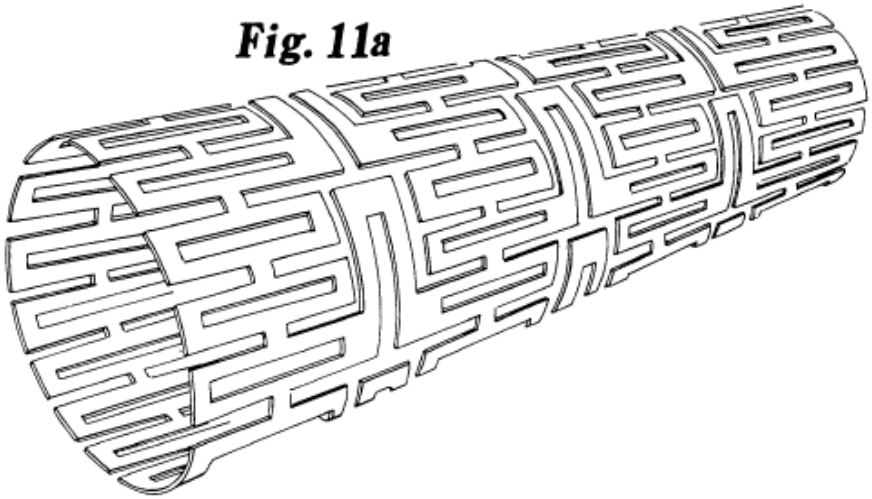
209. Under the heading "Detailed description of the invention", Burmeister states at page 4 lines 14-18:

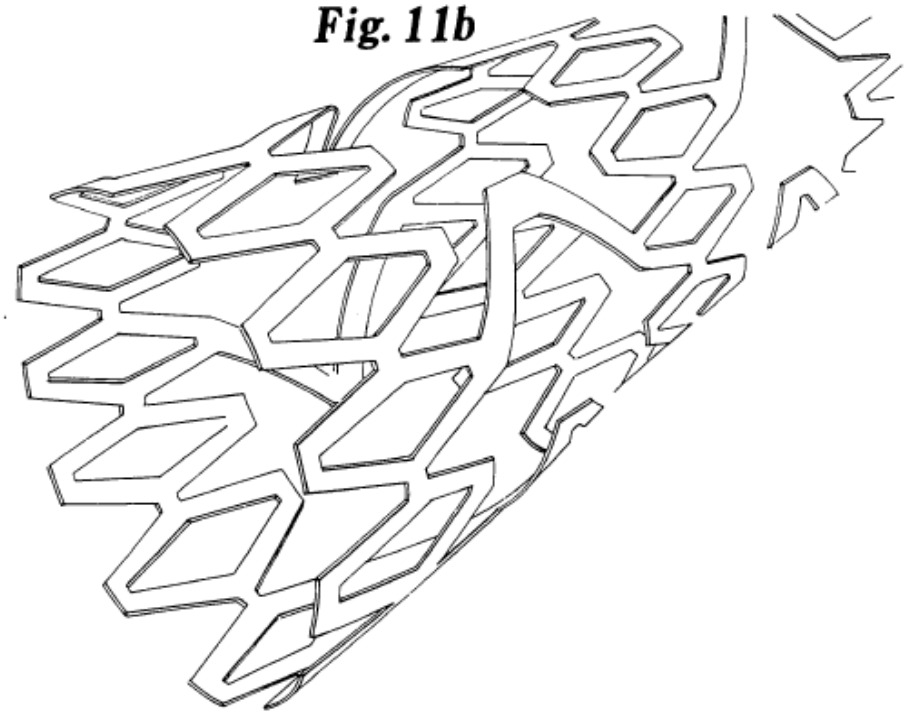
> "Given such a stent construction of two components i.e. strands 12 and 14, it can be seen that stent 10 may be readily loaded on a catheter as by placing it over an uninflated balloon on a balloon catheter and compressing it tightly around the balloon and then placing a sheath over the stent to hold it in place during the transluminal placement procedure."

210. At page 12 lines 11-16 Burmeister states:

> "Figures 8 to 11 represent examples of various expandable configurations (a = closed, b = expanded) which may be incorporated into the devices of this invention. The version shown in Figures 10a and 10b may be modified as shown in Figures 10c and 10d (closed and open, respectively) by omitting portions (indicated at 100 in figures 10c and 10d) as to render the stent flexible for articulation. This may be done to other of the structures as well to improve flexibility."

211. Abbott rely upon Figures 11a and 11b, which I reproduce below:





Novelty

212. As was explained in *Synthon BV v SmithKline Beecham plc* [2005] UKHL 59, [2006] RPC 10, in order for an item of prior art to deprive a patent claim of novelty, two requirements must be satisfied. First, the prior art must disclose subject matter which, if performed, would necessarily infringe that claim. As it was put by the Court of Appeal in *General Tire and Rubber Co v Firestone Tyre and Rubber Co Ltd* [1972] RPC 457 at 486, "[t]he prior inventor must be shown to have planted his flag at the precise destination before the patentee". Secondly, the prior art must disclose that subject matter sufficiently to enable the skilled addressee to perform it. In the present case the dispute is over the first requirement rather than the second.

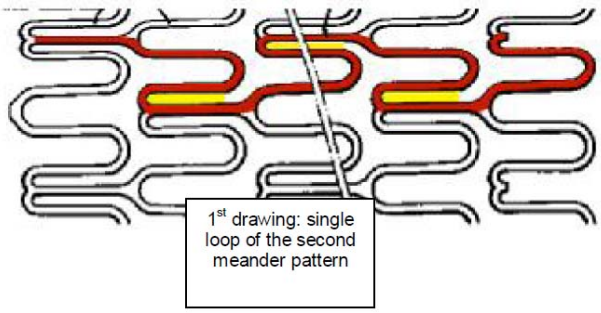
Novelty over Lau

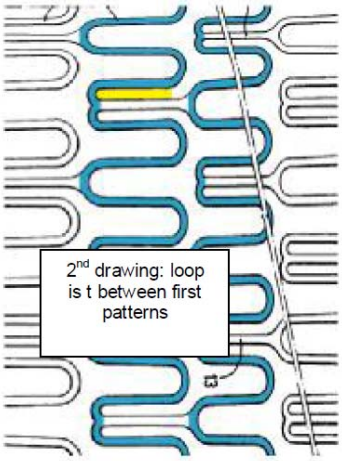
213. Abbott contends that, if the Abbott Stents infringe, 449 and 902 (but not 901) lack novelty over Lau. Since I have concluded that the Abbott Stents do not infringe, this

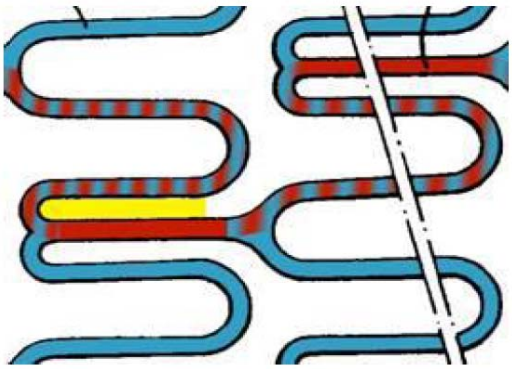
issue does not arise. I should, however, briefly deal with the position on the assumption that the claims are to be construed as Medinol contends and hence the Abbott Stents do infringe.

214. Medinol accepts that, on its construction of the claims, Lau discloses each of the features of claim 1 of 449 and claim 1 of 902 except integer [5][b]/[6][b] i.e. a single loop of the second meander patterns disposed between neighbouring first meander patterns. Abbott contends that Lau also discloses this feature.

215. Abbott's case on this point is conveniently illustrated in the following drawings based on Fig. 5 of Lau, using Medinol's interpretations of "meander pattern":







3rd drawing: loop includes "red-only" portion of the second meander pattern alone

216. The second drawing shows two neighbouring first (vertical) meander patterns coloured blue. The first drawing shows a second (horizontal) meander pattern coloured red. The third drawing shows both patterns, with blue representing material that forms part of the first pattern, red representing material that forms part of the second pattern and stripes representing material that forms part of both patterns. The part representing the single loop on Abbott's case is coloured yellow on all three drawings. Abbott contends that this is a single loop of the second meander pattern disposed between adjacent first meander patterns.

217. The loop relied on by Abbott in this context is essentially the same as Loop 3 which Abbott relies on the infringement context (see paragraph 175 above). Medinol's argument is the same in relation to both. For the reasons I have given in relation to construction and infringement, I consider that Abbott is right in relation to both Loop

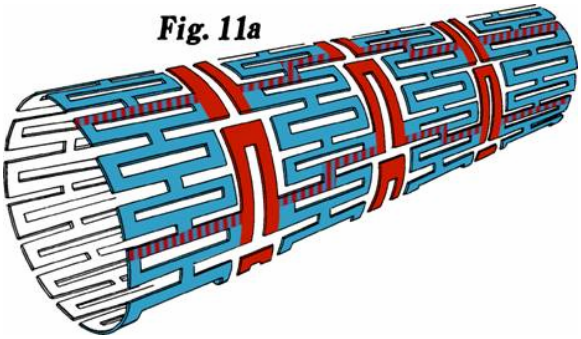
3 and the yellow loop in Lau. Thus on this basis Lau would anticipate claim 1 of 449 and claim 1 of 902. I note that this conclusion is the same as that reached by the EPO Opposition Division in its decision concerning 449. If, however, the claims were to be construed as Medinol contends, so that Loop 3 did not count, then it would follow that the yellow loop would not count either and thus Lau would not anticipate. I do not believe it is necessary for present purposes for me to consider the subsidiary claims.

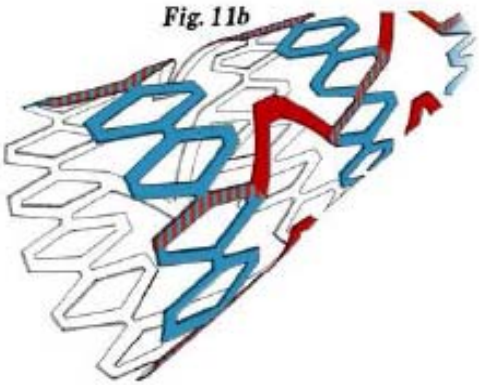
Novelty over Burmeister

218. Abbott contends that, if the Abbott Stents infringe, 449 and 902 lack novelty over Burmeister. Since I have concluded that the Abbott Stents do not infringe, this issue does not arise. I should, however, deal with the position on the assumption that "meander pattern" is to be construed as Medinol contends. As for 901, Abbott contends that this lacks novelty over Burmeister in any event.

219. *449 and 902*. In relation to claim 1 of 449 and claim 1 of 902, Medinol contends that Burmeister does not anticipate for two reasons. First, it does not disclose a flexible stent. Secondly, it does not disclose first meander patterns comprising loops.

220. Abbott's case is that the first and second meander patterns in Burmeister (on Medinol's construction of "meander pattern") may be identified as follows (as before, blue is first, red is second and striped is shared material):





(It will be appreciated that there are a number of ways in which the shared parts of the second pattern could be drawn, but this makes no difference to the essence of the argument.) If Fig. 11a is compared with Fig. 11b, it can be seen that the blue patterns have expanded circumferentially and the red patterns have expanded longitudinally.

221. *Flexible*. Medinol contends that, although a skilled team seeking to implement Fig. 11 of Burmeister might well make a flexible stent, it would not inevitably do so. In support of this contention, it relies in particular on the evidence of Professor McHugh in cross-examination, in which he accepted that, depending on the choice of materials, dimensions and thicknesses, one could get a very rigid stent. Abbott contends that, since Burmeister expressly says the stents it discloses are intended to be delivered to the desired location through tortuous arteries, in particular in the passages cited in paragraphs 208 and 209 above, the skilled team putting that teaching into effect would make the stents described, including the Fig. 11 design, sufficiently flexible for that purpose. In support of this contention, it relies upon evidence given by Professor Snyder in cross-examination.

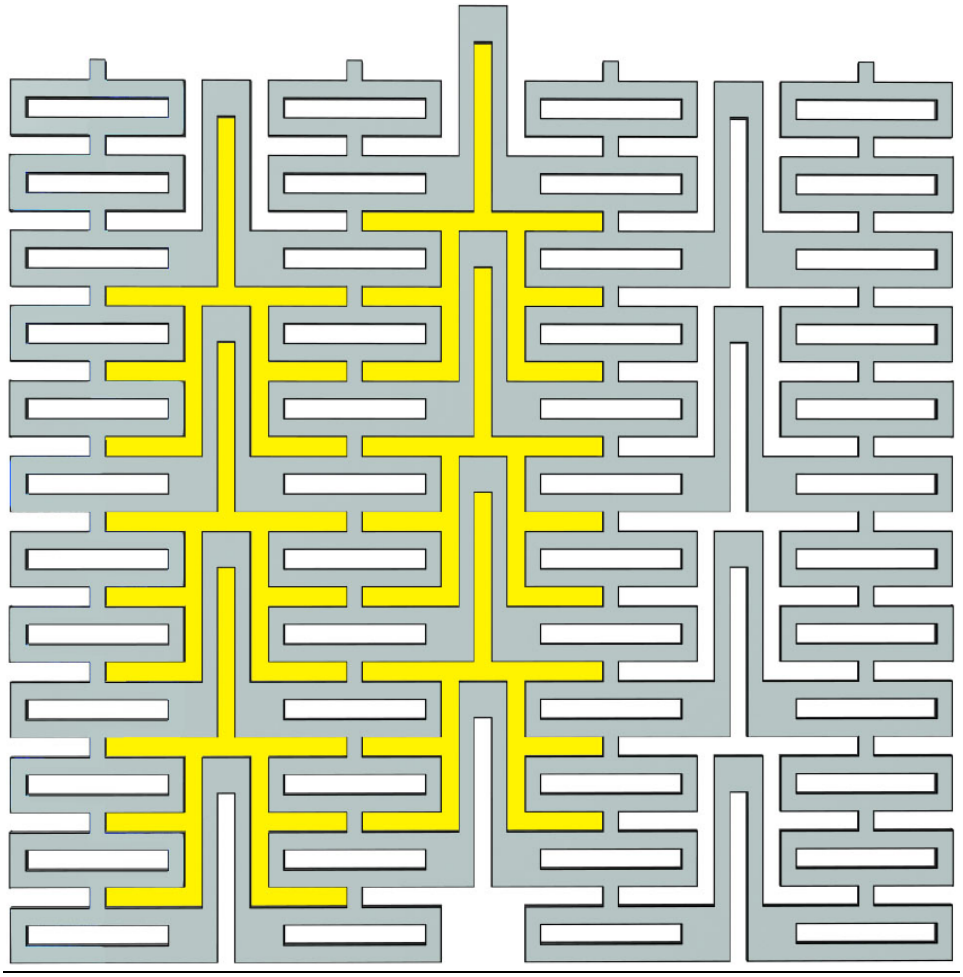
222. In my judgment, Burmeister contains teaching which, if faithfully followed by the skilled readers when making a stent of the design depicted in Fig. 11, will inevitably result in a stent which is flexible as I have construed that expression. It may be that it would only be flexible to the same extent as the Palmaz stent, in that it would only flex at the points where the links are located; but that is enough for this purpose. I am not persuaded otherwise by Professor McHugh's answers relied on by Medinol, since it seems to me that they were not premised upon applying the whole of the relevant teaching of Burmeister.

223. Furthermore, it seems to me that this conclusion is supported by the sentence at page 12 lines 15-16 (quoted in paragraph 210 above). Medinol argues that this teaches the skilled readers to modify the design of Fig. 11 in order to achieve flexibility. I disagree. In my view it teaches the skilled readers to modify the design of Fig. 11 to *improve* flexibility. This indicates that the Fig. 11 design is intended to have some flexibility without such modification.

224. *First meander patterns comprising loops*. Medinol argues that the first meander patterns which Abbott identifies in Burmeister do not comprise loops. I disagree. As Abbott argues, one can identify loops in two different ways. The first and simplest is that the slots are "loops" as I have construed that term. They satisfy the functional criterion, as demonstrated by Fig. 11b, and it is immaterial that they are closed. Secondly, even if one disregards the slots themselves on the basis that they are closed, there are identifiable loops above and below the slots. These too satisfy the functional criterion.

225. *Conclusion on 449 and 902*. I therefore conclude that, if "meander pattern" were to be construed as Medinol contends, Burmeister would anticipate claim 1 of 449 and claim 1 of 902. I note that this conclusion is the same as that reached by the EPO Opposition Division in its decision concerning 449. I do not believe it is necessary for present purposes for me to consider the subsidiary claims.

226. *901*. Medinol contends that Burmeister does not disclose cells with alternating first and second loops. So far as the slotted cells are concerned, I accept that these only comprise first loops. Abbott points out, however, that Burmeister also discloses a second type of cell between the slots, as shown coloured yellow in this diagram, which depicts the pattern of Fig. 11 in plan view:



227. Medinol does not dispute that these cells comprise an even number of fixed length alternating first and second loops on its constructions of "fixed length" and "alternating". Although I have not accepted Medinol's interpretation of "alternating", the loops are alternating on the construction I have adopted since they follow the pattern 1, 1, 1, 2, 1, 1, 1, 2. Medinol argues, however, that on this basis the stent does not comprise a mesh of adjacent connected cells. I disagree. These cells are adjacent and connected, and together they form a mesh. The presence of the slotted cells is immaterial due to the word "comprising".

228. I therefore conclude that Burmeister anticipates claim 1 of 901.

Obviousness

The law

229. A patent will be invalid for lack of inventive step if the invention claimed in it was obvious to a person skilled in the art having regard to the state of the art at the priority date. The familiar structured approach to the assessment of allegations of obviousness first articulated by the Court of Appeal in *Windsurfing International Inc v Tabur Marine (Great Britain) Ltd* [1985] RPC 59 was re-stated by Jacob LJ in *Pozzoli v BDMO SA* [2007] EWCA Civ 588, [2007] FSR 37 at [23] as follows:

"(1)(a) Identify the notional 'person skilled in the art';

(b) Identify the relevant common general knowledge of that person;

(2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;

(3) Identify what, if any, differences exist between the matter cited as forming part of the 'state of the art' and the inventive concept of the claim or the claim as construed;

(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?"

230. In both *H. Lundbeck A/S v Generics (UK) Ltd* [2008] EWCA Civ 311, [2008] RPC 19 at [24] and *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc* [2008] UKHL 49, [2008] RPC 28 at [42] Lord Hoffmann approved without qualification the following statement of principle by Kitchin J at first instance in the former case:

> "The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success."

231. In *Mölnlycke AB v Procter & Gamble Ltd* [1994] RPC 49 at 112-114 the Court of Appeal held that the primary evidence as to obviousness will be that of properly qualified experts and that secondary evidence "must be kept firmly in its place". Recently Jacob LJ, with whom Sullivan and Waller LJJ agreed, considered the topic of secondary evidence in some detail in *Schlumberger Holdings Ltd v Electromagnetic Geoservices AS* [2010] EWCA Civ 819 at [76]-[85]. He said that it would be wrong to read *Mölnlycke* as saying that secondary evidence is always of minor importance. He explained the relevance of secondary evidence as follows at [77]:

> "It generally only comes into play when one is considering the question 'if it was obvious, why was it not done before?' That question itself can have many answers showing it was nothing to do with the invention, for instance that the prior art said to make the invention obvious was only published shortly before the date of the patent, or that the practical implementation of the patent required other technical developments. But once all other reasons have been discounted and the problem is shown to have been long-standing and solved by the invention, secondary evidence can and often does, play an important role. If a useful development was, in hindsight, seemingly obvious for years and the apparently straightforward technical step from

> the prior art simply was not taken, then there is likely to have been an invention."

232. Jacob LJ went on to discuss a number of types of secondary evidence that may be relevant in this way, namely (i): failed attempts by others to find a satisfactory solution to the problem, (ii) commercial success of the patented product, (iii) the reaction of experts at the time of the invention and (iv) attempts by others to patent the same invention. In relation to commercial success, he referred at [80] to *Haberman v Jackel International Ltd* [1999] FSR 683 as "a particularly dramatic example of commercial success which turned a case of apparent technical obviousness into one of non-obviousness" and said that "Laddie J's non-exhaustive summary of the factors relevant when a patent is defended against a charge of obviousness by commercial success remains a masterpiece". That summary is as follows:

> "(a) What was the problem which the patented development addressed? Although sometimes a development may be the obvious solution to another problem, that is not frequently the case.
>
> (b) How long had that problem existed?
>
> (c) How significant was the problem seen to be? A problem which was viewed in the trade as trivial might not have generated much in the way of efforts to find a solution. So an extended period during which no solution was proposed (or proposed as a commercial proposition) would throw little light on whether, technically, it was obvious. Such an extended period of inactivity may demonstrate no more than that those in the trade did not believe that finding a solution was commercially worth the effort. The fact, if it be one, that they had miscalculated the commercial benefits to be achieved by the solution says little about its technical obviousness and it is only the latter which counts. On the other hand evidence which suggests that those in the art were aware of the problem and had been trying to find a solution will assist the patentee.
>
> (d) How widely known was the problem and how many were likely to be seeking a solution? Where the problem was widely known to many in the relevant art, the greater the prospect of it being solved quickly.
>
> (e) What prior art would have been likely to be known to all or most of those who would have been expected to be involved in finding a solution? A development may be obvious over a piece of esoteric prior art of which most in the trade would have been ignorant. If that is so, commercial success over other, less relevant, prior art will have much reduced significance.
>
> (f) What other solutions were put forward in the period leading up to the publication of the patentee's development? This overlaps with other factors. For example, it illustrates that others in the art were aware of the problem and were seeking a solution. But it is also of relevance in

that it may indicate that the patentee's development was not what would have occurred to the relevant workers. This factor must be treated with care. As has been said on more than one occasion, there may be more than one obvious route round a technical problem. The existence of alternatives does not prevent each or them from being obvious. On the other hand where the patentee's development would have been expected to be at the forefront of solutions to be found yet it was not and other, more expensive or complex or less satisfactory, solutions were employed instead, then this may suggest that the *ex post facto* assessment that the solution was at the forefront of possibilities is wrong.

(g) To what extent were there factors which would have held back the exploitation of the solution even if it was technically obvious? For example, it may be that the materials or equipment necessary to exploit the solution were only available belatedly or their cost was so high as to act as a commercial deterrent. On the other hand if the necessary materials and apparatus were readily available at reasonable cost, a lengthy period during which the solution was not proposed is a factor which is consistent with lack of obviousness.

(h) How well has the patentee's development been received? Once the product or process was put into commercial operation, to what extent was it a commercial success. In looking at this, it is legitimate to have regard not only to the success indicated by exploitation by the patentee and his licensees but also to the commercial success achieved by infringers. Furthermore, the number of infringers may reflect on some of the other factors set out above. For example, if there are a large number of infringers it may be some indication of the number of members of the trade who were likely to be looking for alternative or improved products (see (d) above).

(i) To what extent can it be shown that the whole or much of the commercial success is due to the technical merits of the development, *i.e.* because it solves the problem? Success which is largely attributable to other factors, such as the commercial power of the patentee or his license, extensive advertising focusing on features which have nothing to do with the development, branding or other technical features of the product or process, says nothing about the value of the intention."

Obviousness over Lau

233. Again, this issue only arises if Medinol is right on construction. I must therefore address it on that assumption.

234. *Step (1)(a): identify the notional person skilled in the art.* I have done this above.

235. *Step (1)(b): identify the relevant common general knowledge.* Again, I have done this above.

236. *Step (2): identify the inventive concept or construe the claim*. As I have said, I am assuming that the claims are to be construed as Medinol contends.

237. *Step (3): identify the differences*. Medinol accepts there is only one difference between the in-phase stent designs disclosed in Lau and claim 1 of each of the Patents, namely that the links between the rings do not include a single loop.

238. *Step (4): would it have been obvious?* Abbott's case is straightforward. As Medinol accepts, in July 1994 there were both commercial and technical reasons for seeking better stent designs. Abbott contends that, if the skilled team were seeking to design a flexible stent starting from Lau, it would be obvious to try to improve the flexibility of Lau and that the engineer would know from his common general knowledge that one way in which he could improve the flexibility of the stent would be to incorporate a loop into the links between the rings. As Abbott points out, the Lau in-phase designs do not need modification to compensate for foreshortening. Abbott accepts there are other possible modifications which could be made to the Lau stents, but submits that this is immaterial.

239. Abbott contends that this case is supported by secondary evidence that a number of third parties conceived of the idea of using looped longitudinal connectors at around the same time as Medinol or least before becoming aware of Medinol's patents or stents based thereon. The evidence in question consists of five third party patents and applications disclosing looped connectors (discounting a Medinol patent) and four commercial stents with such connectors. Medinol accepts that two of the patents and applications, one of which is Burmeister, were filed without knowledge of Medinol's invention; but contends that there is evidence to suggest that the others were copied from the NIR stent based on Medinol's patents, which began trials in August 1994, underwent further trials in summer 1995 and was formally announced in December 1995. Medinol also points to the fact of the patents and applications have filing dates somewhat after July 1994. Against this, Abbott points out that (i) a number of the patents and applications stem from earlier filings, (ii) so far as the commercial stents are concerned, these would have taken several years to develop and (iii) in two instances Medinol's suggestions of copying are contradicted by the chronology. My conclusion is that the evidence does suggest that a number of third parties thought of using looped longitudinal connectors either before July 1994 or at least before they became aware of Medinol's design. It is difficult to place much weight on this, however, since there is no evidence as to the qualifications of the individuals responsible for these designs, and in particular how inventive they were; and there is evidence that most of the companies thought it worth trying to patent their designs even if they did not frame claims of the kind in issue in these proceedings.

240. Medinol has a number of answers to Abbott's case. First, Medinol says that the skilled team would have no reason to think that Lau's designs needed to be made more flexible since Lau describes its stents as being flexible. I do not accept this. It is clear from the evidence of the cardiologists that in July 1994 flexibility was one of the most important requirements of a stent and that there was a demand for more flexible stents than were then available. Lau describes the stents disclosed as "relatively flexible" (column line 45). It does not suggest that they were perfectly flexible.

241. Secondly, Medinol says that, if it was obvious to improve Lau in the manner suggested, Lau would itself have disclosed this possibility. I am unimpressed by this

argument. Lau claims priority from an application nearly three years before the priority date of the Patents. The inventors were trying to improve on the prior art available then. The fact that they did not suggest incorporating a loop does not prevent it from being obvious to a skilled team trying to improve upon Lau's designs nearly three years later. Nor do I regard it as significant that in 1994 Lau and a different group of colleagues filed a series of US patent applications for a self-expanding stent without links, but with a polymeric fibre woven between the rings.

242. Thirdly, Medinol says that, if the skilled team wished to improve the flexibility of the stent, Lau itself would teach them how to do this at column 3 lines 16-27 (partly quoted in paragraph 202 above). Medinol says that, following this guidance, if the skilled team wished to increase the flexibility of the stent, it would reduce the number of links and stagger them. Abbott replies that this does not exclude other ways of improving flexibility. Abbott suggests that, if the skilled team decided to go for a large number of links to improve radial strength and scaffolding, then it would need another method to improve flexibility. Medinol ripostes that this is pure hindsight, in particular because Lau teaches that the closely spaced rings are responsible for radial strength and scaffolding (see column 5 lines 51-56). Furthermore, Medinol argues that there is not much space for a loop in the Lau designs and creating space would have consequences for other desired properties of the stent. This argument receives some support from one of Abbott's points on non-infringement (see paragraph 166 above). More generally, Medinol says that, as soon as it departed from simply implementing Lau, the skilled team would be faced with a complex design problem involving trade-offs between the various desiderata as discussed in paragraphs 59 and 60 above. For example, putting loops into the connectors would increase the amount of metal in the stent, which would have been perceived as increasing the risk of thrombosis. In my view, this argument has more force than Medinol's first two points.

243. Fourthly, Medinol relies by way of secondary evidence on the fact that Abbott's predecessors did not take the supposedly obvious step until the introduction of the Vision in June 2003, nine years after the publication of Lau. Instead, they first made a series of other changes to the original Multi-Link. I do not understand how the predecessors' delay in taking this step after they became aware of the NIR stent can demonstrate non-obviousness, however. It is likely that they will have become aware of the NIR stent not later than around the time it was commercially launched in Europe, namely in May 1996. Certainly, Mr Johnson's evidence is that he became aware of the NIR stent in either 1995 or 1996. On the other hand, Medinol also points out that Abbott has not adduced any evidence that anyone at its predecessors thought of introducing a single loop prior to becoming aware of the NIR stent. Nor is there any explanation as to why not, if indeed the step was an obvious one.

244. Fifthly, Medinol relies on commercial success of the NIR stent. Abbott disputes that this falls within the claims of the Patents, but it is common ground that this point falls away if the claims are construed as contended for by Medinol. Since Medinol sold the NIR stent through a distributorship with Boston Scientific Corporation ("BSC"), which declined voluntarily to give disclosure for this purpose, it is only able to provide limited evidence as to sales and marketing. Nevertheless, it is clear that the NIR did have some degree of commercial success, since Medinol made and sold over 2 million NIR stents to BSC, generating over US$705 million in revenue. In addition, it was copied by another manufacturer until BSC successfully sued to restrain the

infringement. As Abbott points out, however, the problem with this argument is that Mr Johnson's evidence shows that, except for one month immediately after the launch of the NIR, sales of the NIR were consistently lower than the sales of the Multi-Link stent made in accordance with Lau. Accordingly, such success as the NIR enjoyed cannot demonstrate inventiveness over Lau.

245. Furthermore, there are also at least three other difficulties with the argument. First, Lau was published less than 15 months before 28 July 1994 and the Multi-Link was not launched commercially even in Europe until 1995. Thus there was no long-felt want for an improvement over Lau, let alone the Multi-Link. Secondly, the inventions in the Patents were not directed to solving problems with the Lau design, particularly as commercialised in the Multi-Link. The Multi-Link was flexible because it was a ring and link design with staggered connectors. Although, as I have said, Lau did not purport to have come up with a perfectly flexible stent, there is no evidence that lack of flexibility was perceived to be a problem with the Multi-Link. Furthermore, since it was an in-phase design, it did not suffer from appreciable foreshortening. Thirdly, it is far from clear that such success as the NIR stent enjoyed was due to the inventions as opposed to other factors. Thus Professor Reifart said that one reason for the success of the NIR stent was that it crimped firmly to the balloon, which has nothing to do with the inventions in the Patents.

246. No doubt for these reasons, counsel for Medinol submitted in his closing submissions that the strongest point in Medinol's favour was that there had been what he described as a "bidding war" between BSC and Johnson & Johnson ("J&J") for access to the NIR. I do not accept that that is an accurate description of what happened. Medinol engaged in lengthy negotiations with J&J, but J&J walked away from the negotiations when it decided to make a hostile bid for Cordis instead. Thereafter Medinol did a deal with BSC on less favourable terms than had been under discussion with J&J. It seems to me that these negotiations do provide some evidence that the NIR stent design, the intellectual property relating to which constituted one of Medinol's main assets at that time, was perceived to be meritorious by significant players in the field, but the essential flaw in the argument is similar to that identified above. Neither J&J nor BSC had access to the Multi-Link. The fact that they were looking for a design to market in competition with the Multi-Link does not demonstrate inventiveness of that design over Lau.

247. Sixthly, Medinol relied upon some favourable contemporaneous comments on the NIR stent. I am unimpressed by the quality of this evidence, however.

248. Seventhly, Medinol relies on the decision of Kitchin J in *Abbott Laboratories Ltd v Evysio Medical Devices ULC* [2008] EWHC 800 (Ch), [2008] RPC 23 at [193]-[199] where he held that it was not obvious in 1996 to modify the Multi-Link (which he found to be common general knowledge at that date) in the light of the Application (as I have defined it above) to introduce a looped longitudinal link. I gain limited assistance from this, since the obviousness attack before Kitchin J was a different one to that which I have to consider and the evidence before me is different in a number of respects.

249. Thus far I have not referred to the evidence of the experts. Professor McHugh's opinion was that the step was an obvious one to take, while. Professor Snyder's

opinion was that it was not. I have already covered the reasons underlying those opinions in the discussion above.

250. In my view the arguments on obviousness are quite finely balanced. In the end, however, I am not persuaded that the step of introducing longitudinal loops into Lau has been shown to have been obvious. There is no pointer in that direction in Lau itself, and once the skilled team decided to modify the designs disclosed in Lau they would be faced with a multi-dimensional problem with a number of potential avenues to follow and a number of conflicting criteria to balance against each other. If the step was an obvious one, it is difficult to see why Abbott's predecessors did not think of it prior to becoming aware of the NIR stent even though there was no particular problem of either flexibility or foreshortening with the Lau designs.

Added matter

The law

251. The test for added matter was stated by Aldous J in *Bonzel v Intervention Ltd (No 3)* [1991] RPC 553 at 574 as follows:

> "The decision as to whether there was an extension of disclosure must be made on a comparison of the two documents read through the eyes of a skilled addressee. The task of the Court is threefold:
>
> (1) To ascertain through the eyes of the skilled addressee what is disclosed, both explicitly and implicitly in the application.
>
> (2) To do the same in respect of the patent [as proposed to be amended].
>
> (3) To compare the two disclosures and decide whether any subject matter relevant to the invention has been added whether by deletion or addition. The comparison is strict in the sense that subject matter will be added unless such matter is clearly and unambiguously disclosed in the application either explicitly or implicitly."

252. More recently, Jacob LJ stated the law in *Vector Corp v Glatt Air Techniques Ltd* [2007] EWCA Civ 805, [2008] RPC 10 as follows:

> "4. In *Richardson-Vicks' Patent* [1995] RPC 568 at 576 I summarised the rule in a single sentence:
>
> > 'I think the test of added matter is whether a skilled man would, upon looking at the amended specification, learn anything about the invention which he could not learn from the unamended specification.'
>
> I went on to quote Aldous J in *Bonzel*. His formulation is helpful and has stood the test of time.

5. The reason for the rule was explained by the Enlarged Board of Appeal of the EPO in G1/93 *ADVANCED SEMICONDUCTOR PRODUCTS/Limiting feature* [1995] EPOR 97 at [Reasons 9]:

> 'With regard to Article 123(2) EPC, the underlying idea is clearly that an applicant shall not be allowed to improve his position by adding subject-matter not disclosed in the application as filed, which would give him an unwarranted advantage and could be damaging to the legal security of third parties relying upon the content of the original application.'

6. Mr Richard Arnold QC provided a clear articulation as to how the legal security of third parties would be affected if this were not the rule:

> 'The applicant or patentee could gain an unwarranted advantage in two ways if subject-matter could be added: first, he could circumvent the "first-to-file" rule, namely that the first person to apply to patent an invention is entitled to the resulting patent; and secondly, he could gain a different monopoly to that which the originally filed subject-matter justified.'

7. Kitchin J has recently helpfully elaborated upon the *Bonzel* formulation in *European Central Bank v Document Security Systems* [2007] EWHC 600 (Pat), 26th March 2007:

> '[97] A number of points emerge from this formulation which have a particular bearing on the present case and merit a little elaboration. First, it requires the court to construe both the original application and specification to determine what they disclose. For this purpose the claims form part of the disclosure (s.130(3) of the Act), though clearly not everything which falls within the scope of the claims is necessarily disclosed.
>
> [98] Second, it is the court which must carry out the exercise and it must do so through the eyes of the skilled addressee. Such a person will approach the documents with the benefit of the common general knowledge.
>
> [99] Third, the two disclosures must be compared to see whether any subject matter relevant to the invention has been added. This comparison is a strict one. Subject matter will be added unless it is clearly and unambiguously disclosed in the application as filed.
>
> [100] Fourth, it is appropriate to consider what has been disclosed both expressly and implicitly. Thus the addition of a reference to that which the skilled person would take for granted does not matter: *DSM NV's Patent* [2001] RPC 25 at [195]-[202].

> On the other hand, it is to be emphasised that this is not an obviousness test. A patentee is not permitted to add matter by amendment which would have been obvious to the skilled person from the application.
>
> [101] Fifth, the issue is whether subject matter relevant to the invention has been added. In case G1/93, *Advanced Semiconductor Products*, the Enlarged Board of Appeal of the EPO stated (at paragraph [9] of its reasons) that the idea underlying Art. 123(2) is that that an applicant should not be allowed to improve his position by adding subject matter not disclosed in the application as filed, which would give him an unwarranted advantage and could be damaging to the legal security of third parties relying on the content of the original application. At paragraph [16] it explained that whether an added feature which limits the scope of protection is contrary to Art. 123(2) must be determined from all the circumstances. If it provides a technical contribution to the subject matter of the claimed invention then it would give an unwarranted advantage to the patentee. If, on the other hand, the feature merely excludes protection for part of the subject matter of the claimed invention as covered by the application as filed, the adding of such a feature cannot reasonably be considered to give any unwarranted advantage to the applicant. Nor does it adversely affect the interests of third parties.
>
> [102] Sixth, it is important to avoid hindsight. Care must be taken to consider the disclosure of the application through the eyes of a skilled person who has not seen the amended specification and consequently does not know what he is looking for. This is particularly important where the subject matter is said to be implicitly disclosed in the original specification.'

8. When amendment of a granted patent is being considered, the comparison to be made is between the *application* for the patent, as opposed to the granted patent, and the proposed amendment (see the definition of 'additional matter' in s.76(1)(b)). It follows that by and large the form of the granted patent itself does not come into the comparison. This case was to some extent overcomplicated by looking at the granted patent, particularly the granted claim 1.

9. A particular, and sometimes subtle, form of extended subject matter (what our Act calls 'additional matter') is what goes by the jargon term 'intermediate generalisation'. Pumfrey J described this in *Palmaz's European Patents* [1999] RPC 47, 71 as follows:

> 'If the specification discloses distinct sub-classes of the overall inventive concept, then it should be possible to amend down to one or other of those sub-classes, whether or not they are presented as inventively distinct in the specification before amendment. The difficulty

> comes when it is sought to take features which are only disclosed in a particular context and which are not disclosed as having any inventive significance and introduce them into the claim deprived of that context. This is a process sometimes called "intermediate generalisation".'"

253. Jacob LJ reiterated this guidance when giving the judgment of the Court of Appeal in *Napp Pharmaceutical Holdings Ltd v Ratiopharm GmbH* [2009] EWCA Civ 252, [2009] RPC 18 at [71]. In that case he went on to say in relation to one of the added matter allegations:

> "98. We can deal with this quite shortly. The added subject-matter is said to be contained in claim 6. Mr Silverleaf put it this way:
>
> > 'We say that if that claim covers water soluble spheronising agents, it must also disclose the possibility of using them or it does not actually read on to them at all; because otherwise the teaching of the document is to use water insoluble ones. We say if in fact the claim is wide enough to cover water soluble spheronising agents, there must be added matter.'
>
> 99. The trouble with that submission is that claim 6 does not mention – so cannot possibly teach – water soluble spheronising agents. It just specifies 'a spheronising agent.' The fallacy in the argument is to equate disclosure of subject matter with scope of claim, a fallacy struck down as long ago as 1991 in *AC Edwards v Acme Signs & Displays* [1992] RPC 131 (see e.g. *per* Fox LJ at p.143)."

254. As well as the domestic jurisprudence referred to above, counsel for Abbottt relied on the jurisprudence of the EPO Boards of Appeal as set out in the *Case Law of the Boards of Appeal of the European Patent Office* (6th ed, 2010) at pp. 346-355, and in particular the test stated in T331/87 *HOUDAILLE/ Removal of feature* [1991] EPOR 194 and regularly applied subsequently when considering an amendment which concerns the deletion or replacement of a feature from a claim. This is that deletion or replacement is permitted if, but only if, the skilled person would directly and unambiguously recognise that (i) the feature was not explained as essential in the disclosure, (ii) it was not, as such, indispensable for the function of the invention in the light of the technical problem it served to solve and (iii) the deletion or replacement required no real modification of other features to compensate for this change. Counsel for Medinol submitted that the decision of the Court of Appeal in *Napp* with regard to claim 6 was inconsistent with this test. I do not accept that. Although it is correct that the Court of Appeal did not apply that test, the Court did not approach the case as one of deletion or removal of a feature of a claim. In any event, there is nothing to indicate that the test was urged upon the Court of Appeal, still less that it was rejected. Nor is it possible to tell from the judgment whether application of the EPO test would have led to a different result. Counsel for Medinol also submitted, however, that if there was any difference between the approach laid down by the Court of Appeal and that applied by the EPO Boards of Appeal, then I

was bound by the former. That I accept. Accordingly, I shall apply the law as stated by the Court of Appeal.

Abbott's general point

255. Abbott has a general allegation of added matter which it advances in relation to all three Patents. In short, this is that the Application did not disclose stents with in-phase first meander patters, whereas the Patents do.

256. I accept the first limb of this allegation for the reasons given above. Subject to one point on 902 discussed below, I do not accept the second limb. Although there are certain specific small differences, as noted above, in general the disclosure of the Patents is no different to the disclosure of the Application. It is true that the claims of the Patents were broadened from the claims of the Application, but claim broadening during prosecution is permissible provided that no additional matter is disclosed thereby. Moreover, as Abbott itself points out, this is not a case where a feature of a claim was simply deleted or replaced by another feature. The claims of 449 and 902 were substantially re-written, while claim 1 of 901 is based on claim 14 of the Application with the addition of what are now integers [5] and [6]. It is also true that the claims of the Patents are broad enough to cover in-phase first meander patterns, which is why Medinol is able to claim that the Abbott Stents infringe, but it does not follow that the Patents disclose such patterns. There is nothing in either the specifications or claims of the Patents which discloses in-phase first meander patterns. In this respect, the reasoning of the Court of Appeal in *Napp* is directly applicable to the present case.

257. In addition to this general point, there are a number of specific allegations in relation to the individual Patents.

449

258. Abbott contends that the addition of [0010] adds matter because it discloses that the object of providing a flexible stent which minimally shrinks in the longitudinal direction is achieved by a stent as defined in claim 1, that is to say, a stent which may have in-phase first meander patterns. Abbott says that this discloses for the first time that the advantage of avoiding foreshortening is achieved in relation to in-phase first meander patterns. In my judgment the answer to this allegation is the same as the answer to the general point: although claim 1 covers in-phase first meander patterns, it does not disclose them. Accordingly, [0010] does not disclose anything about stents with in-phase first meander patterns.

259. A separate point concerns the words "formed of a flat metal tube". As noted above, Abbott contends that, if these words have a different meaning to "formed from flat metal", then they constitute added matter since they disclose for the first time a stent formed from a tube as distinct from a flat sheet. On the view that I have taken as to the meaning of these expressions, however, this point does not arise.

901

260. Abbott contends that there is no disclosure in the Application of fixed length first and second loops which widen longitudinally upon expansion of the stent, and that these

are disclosed for the first time by claim 1 of 901. I do not accept this. Although the fixed length loops were not disclosed in the body of the Application, they were disclosed in claim 14. Reading that claim in the context of the Application as a whole, I consider that it is implicit those loops widen longitudinally upon expansion of the stent. Accordingly, claim 1 of 901 adds nothing. Abbott argues that the difference is that the Application only discloses this in the context of an out-of-phase design, but the answer to this is the same as the answer to the general point.

261. I note in passing that Abbott does not advance a different allegation of added matter which was upheld by the EPO Opposition Division when revoking 901.

902

262. Abbott's first point in relation to 902 is the same as the first point in relation to 449 discussed above. The answer is the same.

263. Secondly, as I have noted previously, the specification of 902 states at [0009] that the first meander patterns "can be 180^{o} out of phase", whereas the Application said "are 180^{o} out of phase". This change eliminates the contrast in the Application between the way in which the first meander patterns are described and the way in which the second meander patterns are described. In my judgment, this does constitute added matter, since it discloses for the first time to the skilled readers the possibility that the first meander patterns may not be out-of-phase.

Amendment

264. Medinol's application to amend is conditional upon a finding of added matter. Since the only allegation I have upheld is that dealt with in paragraph 263 above, it is only necessary to consider the application so far as it relates to that allegation. So far as that is concerned, Medinol's application is to return the wording to its original state. In my judgment, that amendment cures the added matter and is a permissible amendment.

Insufficiency

265. The only allegation of insufficiency pursued by Abbott concerns the requirement for "fixed length" loops in 901. Counsel for Abbott relied in this respect on the reasoning of the EPO Opposition Division when it revoked 901:

> "The opponent presents an argument that the feature 'fixed length … loops' in the claim of the opposed patents does not satisfy the requirements of Article 83 EPC.
>
> It is the opinion of the opposition division that, as a result of this feature, the European patent does not disclose the invention sufficiently clear and complete for it to be carried out by a person skilled in the art.
>
> In reaching this opinion, the opposition division follows the argument of the opponent that there is no disclosure in the patentee specification as to how a stent may be manufactured

> having loops which have a fixed length and which also widen, as defined in the claim. The opposition division is assisted by the Guidelines for Examination, C-II, 4.9, which indicated that a detailed description of at least one way of carrying out the invention must be given. It is observed that the only reference to loops of fixed length in the specification is in the claim and in the statement of invention (paragraph 0006). Otherwise, the specification is concerned with widening of the loops causing expansion of the stent with no mention of the loops being of fixed length. Since none of the examples explicitly concerns stents possessing loops which widen and which are of fixed length, and this information is not clearly and unambiguously derivable from the drawings, the patent is seen to fail the test of sufficiency of disclosure of providing a detailed description of at least one way of carrying out the invention."

266. Counsel for Abbott did not, however, cite any evidence to support this objection. Indeed, although Abbott pleaded this point in its Grounds of Invalidity, I cannot see that Professor McHugh addressed it in either of his reports. By contrast, Professor Snyder did deal with it in his first report, and so far as I can see he was not cross-examined on this point. Professor Snyder's evidence was that Figs. 5A and 5B of 901 disclosed a loop which had a fixed length and widened upon expansion. More generally, he said that a loop has "reserve material" within its structure which enables it to widen without lengthening.

267. In these circumstances I conclude that the allegation of insufficiency is not made out.

Overall conclusions

268. For the reasons set out above, I conclude that:

i) 449 and 902 are valid (in the case of 902, as proposed to be amended);

ii) 901 is invalid since it lacks novelty over Burmeister;

iii) none of the Patents is infringed by the Abbott Stents.