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Case No: HC06C02439
HC06C02440
HC06C03048

IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 21 April 2008

Before :

THE HONOURABLE MR JUSTICE KITCHIN

- -

Between :

ABBOTT LABORATORIES LIMITED	**Claimant**
- and -	
EVYSIO MEDICAL DEVICES ULC	**Defendant**
(sued as Divysio Solutions ULC in HC06C02440)	

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- -

Mr Simon Thorley QC and Mr Richard Meade (instructed by **Taylor Wessing**) for the **Claimant**
Mr Henry Carr QC and Mr Andrew Lykiardopoulos (instructed by **Bristows**) for the **Defendant**

Hearing dates: 18 - 22 February, 25 – 27 February 2008

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Judgment

MrJustice Kitchin :

Introduction

1. These three related patent actions concern coronary stents which are small medical devices placed inside a coronary artery to expand the vessel at the site of a blockage. They are often classified as either "balloon expandable" or "self-expanding", which describes the mechanism by which they are enlarged. Each type is delivered to the blocked artery on a catheter. Once expanded, the catheter is withdrawn and the stent remains in place providing a metal scaffold to hold the artery open and ensure proper blood flow.

2. The actions have a rather complex history which is not relevant to any issue I have to determine. The parties are agreed that for all practical purposes I can regard the three actions as one in which the claimant, Abbott Laboratories Limited ("Abbott"), seeks declarations that certain of its coronary stents do not infringe three patents held by the

defendant, Evysio Medical Devices ULC ("Evysio"), and revocation of each of those patents. Evysio has counterclaimed for infringement.

3. Abbott is the UK subsidiary of Abbott Laboratories, the well known multi-national healthcare company. It has been involved in the production and sale of medical devices for many years. In 2006 it acquired the vascular device business of a company called Guidant. A subsidiary of Guidant was a company called Advanced Cardiovascular Systems Inc ("ACS"), which itself made a particular stent called the Multi-Link which forms the basis of one of the attacks on the patents and was the predecessor of the alleged infringements.

4. Evysio, formerly known as Divysio, is a Canadian company based in British Columbia. Its exclusive licensee is the healthcare company known as Medtronic.

5. The three patents in suit are European Patent (UK) 0 888 093 ("093"), European Patent (UK) 0 888 094 ("094") and European Patent (UK) 1 066 804 ("804"). They have virtually identical specifications and each claims priority from the same four applications, the earliest of which was filed on 5 March 1996. These four applications led to two PCT applications which were filed on 5 March 1997. There are only two applications for three patents because 804 is a divisional of 093.

6. The patents contain a very large number of claims but the parties agreed during the course of the hearing that the only claims which I have to consider in these proceedings are:

   i) claim 1 of 093;

   ii) claims 1 and 6 of 094;

   iii) claims 1 and 23 of 804, which Evysio unconditionally applies to merge into a single claim.

7. The products alleged to infringe are:

   i) The Multi-Link Vision stent which comes in two sizes, small and medium.

   ii) The Multi-Link Xience stent which is structurally the same as the Vision stent but is coated with a therapeutic substance. It does not raise any issues beyond those which arise in relation to the Vision stent.

   iii) Modified versions of the above stents in which a "dimple" on one of the curves of the rings is rather deeper than in the original Vision and Xience stents. Abbott contends that whatever might be the position in relation to the original products, this change removes the modified stents from the scope of all of the claims in issue.

8. The parties therefore agree that all I need to consider is the Vision stent, in its two sizes, and the corresponding modified stents.

9. In attacking the patents, Abbott contends that there is nothing new or inventive in any of them and submits the fact there are three of them, with no fewer than 53 claims between them, is merely symptomatic of Evysio's approach of seeking to claim

essentially the same three or four known and trivial ideas in a large number of different permutations and presentations. It also argues that some of the features of the claims in issue have no proper basis in the priority documents or the applications as filed.

10. The issues which therefore arise for determination are:

i) Whether the original and modified Vision stents infringe any of the claims asserted against them.

ii) In respect of those claims which are entitled to priority, whether they are anticipated or rendered obvious by a piece of documentary prior art called Medinol or by the Multi-Link stent sold by ACS, in either case taken together with the common general knowledge. Abbott also asserts the Multi-Link stent was itself common general knowledge, as was a commercial embodiment of the Medinol documentary prior art called the NIR stent. Abbott originally also relied upon a further piece of documentary prior art called Fischell but decided not to pursue this attack after the close of evidence and before final submissions.

iii) Whether claims 1 of 093, 6 of 094 and 1 and 23 of 804 are entitled to priority. This is of crucial importance. In relation to any claim which is not entitled to priority, Abbott relies, in addition to the prior art to which I have referred, upon the public disclosure at a meeting of cardiologists in Rotterdam in December 1996 of stents made in accordance with the preferred embodiments of each of the patents. Evysio accepts that the Rotterdam disclosure invalidates all claims which lose priority. There is no dispute that claim 1 of 094 is entitled to priority but this claim is of no great significance because Evysio accepts that if Abbott infringes then the claim is anticipated or rendered obvious by the Multi-Link.

iv) Whether 093 and 804 are invalid for added matter. Evysio amended the specifications in the course of prosecution and Abbott contends that, in doing so, Evysio presented various aspects of their stent configurations as being of technical or inventive significance.

v) Whether the patents are insufficient. Abbott asserts that one of the key integers of the claims in issue (the requirement of "flat" apices) is so unclear that the skilled person would have no idea how to implement it, not knowing what "flat" means or how to test for it.

The witnesses

11. Each side called two experts, an interventional cardiologist and an expert in bioengineering. For Evysio I heard evidence from Professor Rothman and Professor Williams and for Abbott I heard evidence from Dr. Segal and Professor Prendergast.

12. Professor Rothman is a consultant cardiologist and the Director of Cardiac Research and Development at Barts and the London NHS Trust. In 2001, he was appointed an Honorary Professor of Interventional Cardiology at Queen Mary, University of London. In the course of his career he has advised many different companies

operating in the pharmaceutical and medical devices sectors, including Abbott, Lilly, Guidant, Johnson & Johnson, Cordis, Medtronic and Boston Scientific. The products upon which he has advised include stents, catheters, balloons, guide wires, material surfaces and coatings and drug therapies used in conjunction with interventional cardiology. He has worked with cardiovascular stents since the late 1980s when he was trained in the implantation of the Palmaz-Schatz stent by Dr Schatz, one of its inventors, who visited his institution to train him. He was the first to implant a Palmaz-Schatz stent in this country and since then has worked with many different stents and has followed developments in stent design with interest. His group within Barts and the London NHS Trust is the largest interventional cardiology centre in the UK.

13. Professor Rothman was very well placed to assist me as to the state of mind of the interventional cardiologist interested in using or designing stents in 1996. It was suggested by Abbott that he lacked objectivity in seeking to paint a picture in his first report of the stent art as being in the dark ages in 1996. I reject this criticism. It was not a fair reflection of his evidence, as I shall explain. It was also submitted that Professor Rothman understated the involvement of engineers in stent design at that time and that he wrongly characterised those making stents as being part of a cottage industry. I reject this criticism too. It was quite clear that by 1996 a number of substantial manufacturing companies were working in the field including, most notably, Cook, Johnson & Johnson, Cordis, Medtronic, Arterial Vascular Engineering ("AVE"), Guidant and ACS. But they did not represent the whole picture and I accept Professor Rothman's evidence that stents were sometimes designed by much smaller enterprises. Moreover, he readily accepted in the course of cross-examination that the larger companies to which I have referred would have employed engineers. Overall, I found Professor Rothman to be a very fair and helpful witness.

14. Professor Williams is a visiting professor in the Christian Barnard Department of Cardiothoracic Surgery in Cape Town, South Africa. He has a first class honours degree in physical metallurgy, a PhD in materials science and a DSc in biomaterials science, all from the University of Birmingham. He then moved to the University of Liverpool where, in the period 1968 to 1972, he established the first laboratory in the UK dealing with biomaterials science and implantable devices. In 1991, he became a Professor and Head of the Department of Clinical Engineering at the University of Liverpool and in 2004, he was appointed Director of the UK Centre for Tissue Engineering in that department. He retired from the University of Liverpool at the end of last year and has since been appointed to his present position. He first started working with and researching the biocompatibility of cardiovascular stents in the 1980s and has followed developments in stent design ever since. Abbott rightly made no criticism of the way Professor Williams gave his evidence. He was a careful and precise witness and I found his evidence of considerable assistance.

15. Dr Segal has been an interventional cardiologist since 1987. He received his medical degree from the Tufts University of School of Medicine in 1980 and completed his internship and residency in internal medicine at Harvard University. He was awarded a three year cardiology fellowship at Stanford University and completed a post-doctoral fellowship in coronary interventions at Sequoia Hospital, California in 1987. He has implanted coronary stents in humans since 1990, at which time he was the Principal Investigator for the Gianturco-Roubin stent, which was undergoing clinical

trials. Over the course of the last 16 years he has implanted stents of various designs including the Multi-Link stent from ACS, the NIR stent from Medinol and the Palmaz-Schatz stent from Johnson & Johnson.

16. It became apparent during the course of Dr Segal's cross-examination that he has acted as an expert witness in a number of patent actions over the course of the last ten years, three or four of which were for Guidant or Abbott. He was also clearly very familiar with patents. Dr Segal was the subject of two principal criticisms by Evysio. First, he gave evidence in his report that the ACS Multi-Link was "in wide use in Europe in 1995" and that the NIR stent "was presented at the Second Thoraxcenter Course on Stenting in Rotterdam in December 1995 and was widely used throughout Europe". However, in the course of his cross-examination, he accepted that both statements were not correct and it became apparent that he really had no basis for making them. I recognise that Dr Segal was more familiar with the stent landscape in the US where the regulatory requirements were, at that time, rather stricter than in Europe with the consequence that he was, as Professor Rothman described, "in the third world" as far as stents were concerned. Further, his impression of the position in Europe at any particular moment was often based upon material obtained from documents and not from first hand involvement. Nevertheless, I formed the clear view that Dr Segal was unduly casual in preparing his first report and consequently I believe I must approach the opinions he expressed in it with a degree of caution.

17. The second criticism of Dr Segal was not one directed to him personally but rather that he approached the question of obviousness with hindsight. As I elaborate in considering the question of validity, it also became apparent during the course of his cross-examination that his opinions were formulated with knowledge of the inventions of the patents and a measure of hindsight. This is a further matter to which I must have regard when considering the weight to be attached to his evidence.

18. Professor Prendergast is Director of the Trinity Centre for Bioengineering and Dean of Graduate Studies at Trinity College, Dublin. He graduated with a degree in mechanical engineering from Trinity College in 1987 and gained his PhD in 1991. From 1993 to 1995 he was a research fellow at Nijmegan University Hospital in the Netherlands and returned to Trinity College in September 1995. At that time he saw the importance of the bioengineering stent business in Ireland and identified cardiovascular devices as a growth area and a focus for his research. Since that time he has had a close interest in stent design. I consider that Professor Prendergast gave his evidence fairly and objectively and I found it of great assistance.

The skilled addressee

19. Professor Rothman and Professor Williams for Evysio expressed the opinion in their reports that, in 1996, the individuals who were mostly responsible for stent design were interventional cardiologists who were working with and had experience of stents. Only after a stent design had been developed would the inventor take the idea and often a prototype to the device companies and seek assistance for commercialisation. Professor Rothman developed this theme by explaining that it was quite common for interventional cardiologists who came up with new stent designs to form their own companies to develop and exploit them. He suggested that large companies were typically very risk averse in the 1990s and this gave small start-up companies the opportunity to develop new designs, which were taken to larger

medical device companies at a later stage in order to benefit from their marketing capabilities. Production engineers might have been brought in as part of this process of development to advise on manufacturing techniques and issues. But the interventional cardiologist would typically have taken the lead on issues of stent design.

20. Dr Segal and Professor Prendergast for Abbott were of the view that engineers would play a rather greater part. They considered that the interventional cardiologist with an interest in stent design would work with an engineer. Indeed, any development might largely be the product of the engineer with some input from the cardiologist.

21. I have come to the conclusion in the light of all the evidence that, by 1996, developments in stent design would generally have been the result of a cooperative effort between an interventional cardiologist and an engineer. I have no doubt that the cardiologist would be the individual likely to identify the practical problems with existing stents. However the development of any improvement would have required collaboration between them. The desirable technical features of a stent require an understanding of the way in which it is deployed and the necessary mechanical characteristics to enable this to be achieved. Stents have complex geometries and competing mechanical requirements. Unless an interventional cardiologist had a good understanding of the engineering and mechanical principles involved he would need to call upon an engineer. I am confirmed in this conclusion by the fact many of the teams actually working on stents at the time included engineers. Further, the inventors of many stent design patents were engineers, often working with physicians. Moreover, as will be seen, the patents in issue describe engineering concepts such as the force needed for expansion, stress during expansion and the facilitation of plastic deformation. These are all engineering concepts and, in the course of his cross-examination, Professor Rothman frequently deferred questions relating to them to Professor Williams.

22. In conclusion, I accept Abbott's submission that the skilled addressee is a team including an interventional cardiologist and a design engineer. However, I believe the interventional cardiologist would be the member of the team primarily responsible for identifying the problems with existing stents and where the opportunities for improvement lay.

Technical background

Introduction

23. It was well known for a number of years prior to 1996 that coronary heart disease is caused by a gradual build up of cholesterol and other deposits on the walls of the arteries which supply the heart muscles with blood. Left untreated, coronary heart disease can cause severe symptoms, including chest pain, arrhythmia and ultimately a heart attack.

24. Prior to the development and use of stents, the recognised treatment for partially occluded coronary arteries was balloon angioplasty. In summary, a deflated balloon is fed into the vessel and steered to the site of the vessel narrowing. The balloon is then inflated to expand the vessel diameter and disrupt the material causing the narrowing. However, it was found that balloon angioplasty suffered from a number

of problems. The vessel might fail to expand at all or it might expand and then tear leading to an acute closure. Sometimes the expansion would appear successful but then the vessel would recoil within two or three days leading to what is known as sub-acute vessel closure. Further, for the six months or so following balloon angioplasty there was a significant risk of re-narrowing (restenosis) at the site of expansion. Approximately 30% of all patients who underwent balloon angioplasty had to have the procedure repeated within six months due to such complications.

25. In the mid 1980s, and following trials on dogs, interventional cardiologists began to consider the implantation of stents into the coronary arteries of humans as an additional mode of treatment of arterial disease. As mentioned at the outset of this judgment, a stent is essentially an implantable tubular structure which is moved to the site of the closure in an unexpanded form and then deployed to provide a cylindrical scaffolding which holds the artery open and allows the blood to flow. There are two types of stent, those which are expanded by a balloon and those which self-expand. Each is delivered to site of the closure on a catheter. Once expanded, the catheter is withdrawn and the stent remains in place.

Attitude to stents at the date of the patent

26. There was a dispute between the parties as to the attitude of interventional cardiologists to stents by 1996. I must therefore begin with a little history. One of the earliest pioneers of stents was a Dr Sigwart. In 1986, he implanted into a human a self expanding stent called the Wallstent. Subsequently, he and his colleagues reported the implantation of 24 self expanding stents in the coronary arteries of 19 patients suffering from a variety of conditions including restenosis after angioplasty, stenosis of coronary bypass grafts and acute coronary occlusion during angioplasty or sub-acute coronary occlusion shortly after angioplasty (a use often referred to as "bailout") so avoiding the need for immediate coronary artery bypass graft surgery ("CABG"). Some complications of thrombosis occurred but the results were broadly encouraging and the FDA gave approval for phase I trials in the US, which were carried out using balloon expandable Gianturco-Roubin and Palmaz-Schatz stents. The structure of all these stents is described further in the next section of this judgment.

27. In the meantime, by early 1988, self-expanding stents had been implanted in over 100 patients. They were used for a variety of conditions including acute and sub-acute vessel occlusion, restenosis and as an adjunct to primary angioplasty (known as elective use). The results of this series of operations were described as sobering. Four patients died before repeat angiography, there was complete stent occlusion in 24% of patients and a long-term restenosis rate of 14% in those stents that remained patent. The overall mortality rate at one year was over 7%. As Professor Rothman explained, this was a very poor outcome and worse than that expected from angioplasty alone. The results considerably diminished the optimism generated by the initial studies and, as a result, most interventional cardiologists were not prepared to use stents and many doubted that they had a significant future in the treatment of coronary disease.

28. Nevertheless, stents retained their supporters and further reports emerged from Dr Roubin and Dr Schatz in the late 1980s and the early 1990s with mixed, albeit slightly more favourable, results. Another of these supporters was Professor Rothman. In the

late 1980s and the early 1990s, he at the London Chest Hospital and some other cardiologists in other centres continued to use stents in bailout situations where the alternative was immediate CABG. However, stents were not routinely used electively in patients undergoing balloon angioplasty. In general cardiologists were cautious. They were conscious, not only of the problem of restenosis, but also of the risk of thrombosis. It had become increasingly apparent that stents were thrombogenic, inducing local blood clot formation. In order to reduce this risk, patients were given very powerful combinations of anti-coagulant drugs. But these had highly undesirable side effects, including bleeding into the bowel or strokes.

29. Despite these problems, pioneer investigators remained convinced that coronary stenting could become a standard therapy. To test these convictions, two important randomised trials were initiated comparing balloon angioplasty with elective coronary stenting using Palmaz-Schatz stents. These trials, known as BENESTENT in Europe and STRESS in North America, began recruitment of patients in 1991.

30. It gradually became apparent that these landmark trials were producing positive results. In 1994 the results of both trials were published and showed that the elective placement of stents significantly reduced the incidence of restenosis in particular patients. This was a turning point and led many clinicians to accept stents as a promising alternative to angioplasty, including for elective use. Attention then focussed on improving technical aspects of stent implantation, optimising associated therapy and minimising complication rates. In this regard, important work was carried out by another pioneer, Dr Columbo, who appreciated that thrombosis might be the result of suboptimal stent deployment causing disturbance of the coronary blood flow. He suggested that improved deployment might allow for a reduction in anticoagulation therapy.

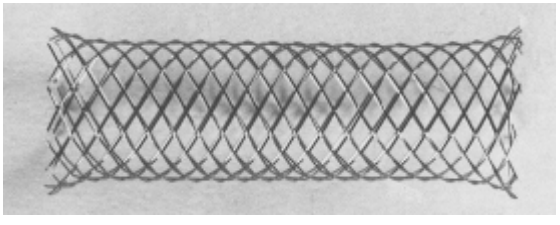
31. These developments were reflected in a significant increase in the number of stents implanted and a corresponding increase in the number of interventional cardiologists interested in using them. In Europe, the number of stents used doubled from 1992 to 1993, tripled from 1993 to 1994 and quadrupled from 1994 to 1995. Over 80,000 stents were implanted in Europe by the end of 1995 and almost 148,000 by the end of 1996. By 1995, they were being used by doctors in 26 different European countries.

32. By 1996, I am satisfied that the initial mood of gloom and scepticism had largely changed to one of optimism. As Professor Rothman accepted, those interested in designing stents were enthusiastic that they were going to be a part of the future of interventional cardiology, that there was a "huge" level of interest and even that there was "a mania" for the production of stents by different companies.

Key stent designs

(i) The Wallstent

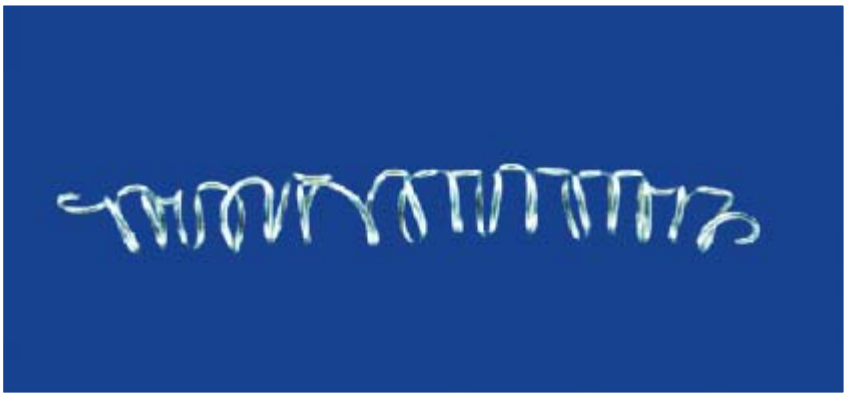
33. As mentioned, the first stent to be implanted in a human coronary artery was the Wallstent. It was a self-expanding wire mesh with a weave design. Prior to implantation it was compressed onto a delivery system and covered in a sleeve. At implantation, the sleeve was withdrawn allowing the stent to self-expand:



34. The Wallstent was withdrawn in 1990 due to its high occlusion rates. It was reintroduced, with modifications, in 1994 and subsequently received regulatory approval in 1995. The stent was extremely flexible prior to expansion which was a desirable characteristic in that it facilitated delivery to the diseased site. However it suffered from a number of serious disadvantages. It was found to shorten significantly in length upon expansion which had the effect of exerting a force on the lining of the vessel along its longitudinal axis. This led to the build-up of scar-tissue and an increase in the likelihood of restenosis. It also lacked radial strength.

(ii) The Gianturco-Roubin

35. Dr Gianturco and Dr Roubin invented the Gianturco-Roubin ("GR") stent in about 1987. This was made of an open coil in a "clamshell" pattern:

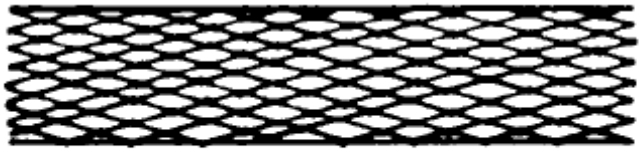


36. It was first placed into humans in 1987 and in 1993 became the first coronary stent to be approved by the FDA for bailout (but not elective) use. It was extremely flexible along its length and therefore able to navigate tortuous vessels, but it had poor radial strength upon expansion and a tendency to recoil from its expanded state. There was also a tendency for the coils to separate which led to the risk of tissue prolapse into the vessel lumen.

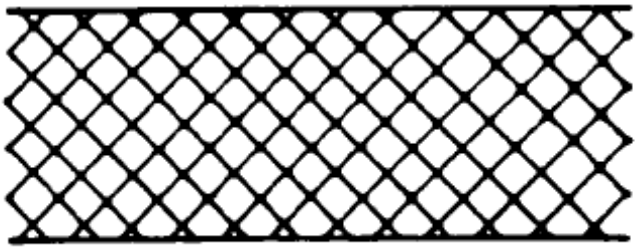
37. A second generation GR Stent (the "GR-II") was developed with the same basic design but the stent coils were flattened to give the device a lower profile, allowing it to fit into a smaller catheter, and it had a longitudinal spine designed to stop the coils separating. The first human implant of the GR-II stent was performed in May 1995 and regulatory approval was obtained from the FDA in June 1996.

(iii) The Palmaz & Palmaz-Schatz

38. A very different approach was taken by Dr Palmaz as early as 1985. He invented a balloon expandable stent consisting of a tubular, stainless steel wire mesh shown below in its unexpanded (a) and expanded (b) forms:

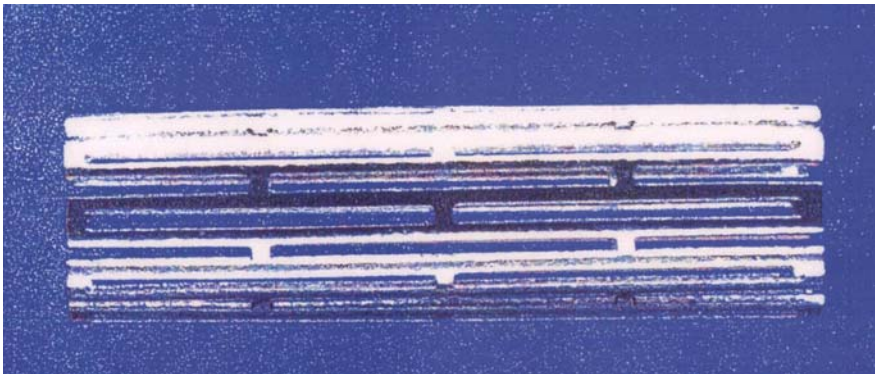


a.

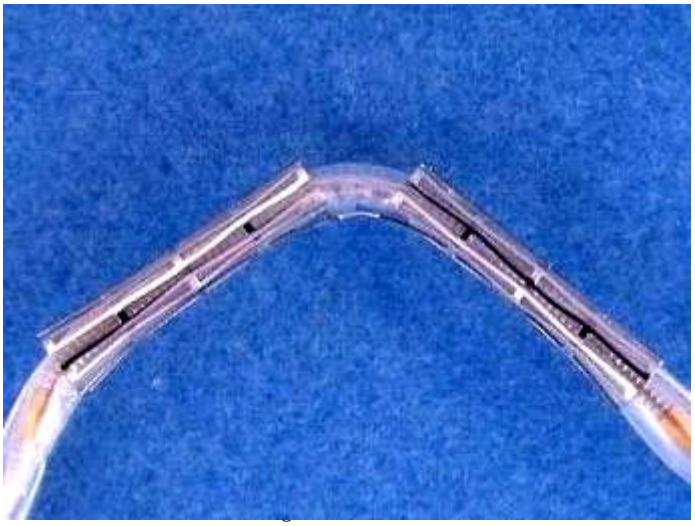


b.

39. At the same time he described another stent structure that became the basis for one of the most popular stents in the world. It was a balloon expandable stent which formed a diamond lattice structure upon expansion, providing significant radial strength. Its problem was that in its unexpanded state it had poor longitudinal flexibility, making it very difficult to deliver through tortuous blood vessels:



40. The inflexibility problem was addressed at first by shortening the stent and placing two or three independent stent segments onto a balloon. Later, to eliminate the possibility of telescoping and migration of the segments, a bridge between them was added. This development by Dr Palmaz and Dr Schatz was called the Palmaz-Schatz stent and was used in the BENESTENT and STRESS clinical trials. It is depicted below:



41. The single bridge avoided the problem of migration of the smaller independent Palmaz stents but the device still had a number of practical difficulties associated with its use. First, because it comprised rigid sections, it was found to be too inflexible to deliver through highly curved vessels. Second, it had a tendency to overly straighten curved vessels into which it was placed so causing the vessels to kink on either side of the stent segments. Third, the single longitudinal strut meant that the unconnected ends of the tubular structures were prone to flair out on the surface of the balloon when the device was manipulated around the curve in a vessel. Fourth, the stent tended to shorten on expansion. Finally, there was a concern that the gap between the individual stent segments could permit tissue prolapse.

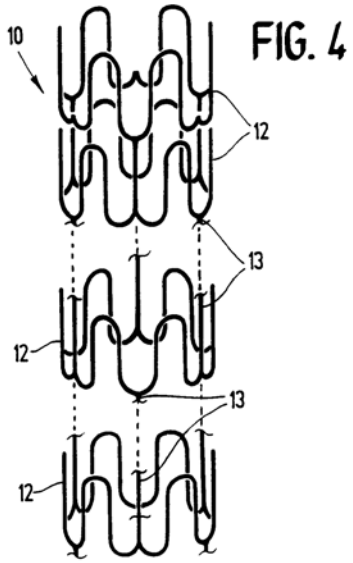
42. In about 1995 a further development was launched in which the individual stent segments were linked, not with a bridge, but with a set of spiral connectors. This had the benefit of preventing tissue prolapse between the individual segments but it reduced the flexibility of the device as a whole. To address these problems the "Improved Spiral" was later introduced with modifications to the number of connectors and the thickness of the struts. A number of sharp corners in the original design were also rounded off:

(iv) The AVE Microstent

43. The AVE Microstent was launched in October 1994. This was a balloon expandable, sinusoidal-shaped ring design with, in its second generation, the individual rings welded together. The aim of the design was to provide maximum flexibility but high radial strength. It is illustrated below:

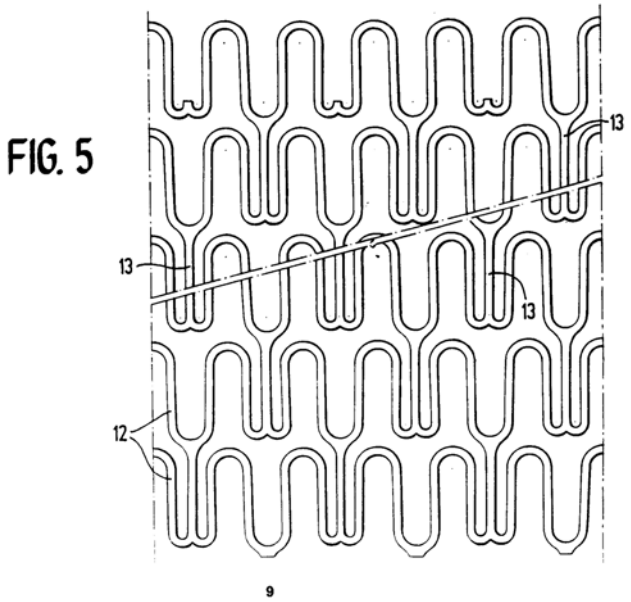
(v) The ACS Multi-Link

44. I now come to various stents described by Abbott as "ring and link" stents. One such design was developed by ACS and the concept can be seen in this figure taken from an ACS patent application, EP 540 290 A2 ("Lau"):



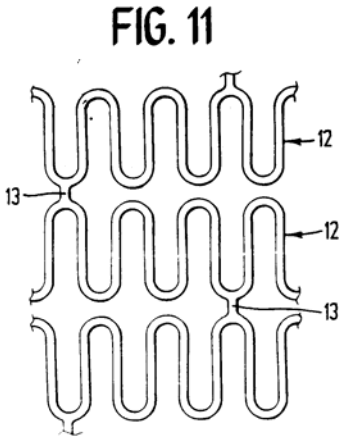
45. The rings or cylinder elements are interconnected by links. The aim was to produce a device which was very flexible prior to its expansion and so could be navigated through tortuous blood vessels but which, upon expansion, had a very high radial strength.

46. The stent illustrated above can be seen to have a particular and repeating geometric pattern. If rolled flat it would have the following appearance:

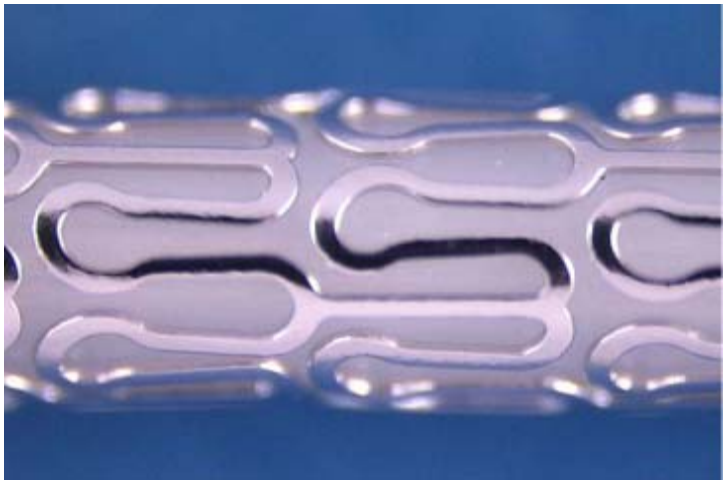


47. In the above figure, it can seen that the peaks of the undulations in the rings are pointing in the same direction and so are "in-phase". However they can also be

arranged so that the peaks of the undulations point towards each other and so can be said to be "off-set" or "out-of-phase":



48. The commercial embodiment of the Lau patent was the ACS Multi-Link. Using Abbott terminology, it was an "in-phase" ring and link stent, in which the undulations in the rings were of various complex shapes:



(vi) The NIR

49. Finally, I must refer to the NIR stent from Medinol. It is depicted below:

50. Abbott described this as an "out-of-phase" design with curved connector links. Medinol themselves preferred to describe it as a system based on uniform cells, each

of which was capable of elongating or shortening, so conferring flexibility upon the stent as a whole. Upon expansion, the geometry of the cell changed so that the vertical loops of the cell aligned with the horizontal loops to form a diamond shaped cell with straight struts. This was said to produce a strong and rigid structure with high radial strength.

Common general knowledge

The law

51. The notional skilled addressee lacks inventive capacity but is deemed to be equipped with the common general knowledge in the field to which the invention relates. Identification of the common general knowledge is important. It permits the court to identify the mental attitude and understanding of the addressee which he brings to bear in considering many questions including what he would have understood the patentee to be using the language of the claims in issue to mean, whether it was obvious in the light of the prior art to make a device falling within the scope of the claims and whether the claims are so unclear that it is, for practical purposes, impossible to work the invention at all.

52. The correct approach to identifying the common general knowledge was explained by the Court of Appeal in *General Tire & Rubber Co v Firestone Tyre & Rubber Ltd* [1972] RPC 457 at 482. In short, it is all that knowledge which is generally known and generally regarded as a good basis for further action by the bulk of those engaged in the particular art or, in other words, when it becomes part of their common stock of knowledge. Individual patent specifications and their contents do not normally form part of the common general knowledge. Nor is it sufficient that matter has been published in a scientific journal, absent evidence as to how widely that journal is read and to what extent its contents are accepted. However, as Laddie J said in *Raychem Corp.'s Patents* [1998] RPC 31 at 40, the common general knowledge is not limited to material to which the skilled person has memorised and has at the front of his mind. It includes all of the material in the field in which he is working which he knows exists, which he would refer to as a matter of course if he cannot remember it and which he understands is generally regarded as sufficiently reliable to use as a foundation for further work.

53. It is also important to remember that information does not become part of the common general knowledge simply because it is known by some. Aldous LJ put it this way in *Beloit Technologies Inc v Valmet Paper Machinery Inc* [1997] RPC 489 at 494:

> "It has never been easy to differentiate between common general knowledge and that which is known by some. It has become particularly difficult with the modern ability to circulate and retrieve information. Employees of some companies, with the use of libraries and patent departments, will become aware of information soon after it is published in a whole variety of documents; whereas others, without such advantages, may never do so until that information is accepted generally and put into practice. The notional skilled addressee is the ordinary man who may not have the advantages that

> some employees of large companies may have. The information in patent specification is addressed to such a man and must contain sufficient details for him to understand and apply the invention. It will only lack an inventive step if it is obvious to such a man.
>
> It follows that evidence that a fact is known or even well-known to a witness does not establish that that fact forms part of the common general knowledge. Neither does it follow that it will form part of the common general knowledge if it is recorded in a document."

54. Likewise, it may be difficult to establish something which has never in fact been used is part of the common general knowledge. But this is not a rule. All must depend upon the evidence. As Jacob LJ explained in *Angiotech Pharmaceuticals Inc v Connor Medsystems Inc* [2007] RPC 20 at [18]:

> "'Common general knowledge' is not formulaic – it is a term used in patent law to describe what the notional skilled person would know and take for granted. If the evidence shows that he knows people are looking at drug eluting stents as a way forward, then even if that has not been proved to work, it is nonetheless part of his mental equipment, not on the basis that he knows it will work but on the basis that it may."

Common general knowledge in this case

55. There was a certain amount of agreement as to the common general knowledge in this case, but there were also significant areas of dispute.

56. It was common ground that the following matters were common general knowledge.

    i) The nature and purpose of stents summarised in paragraphs [23] to [25] above.

    ii) The following stents:

        a) the Wallstent;

        b) the GR stent;

        c) the AVE Microstent;

        d) the Palmaz and Palmaz-Schatz family of stents.

57. I am also satisfied that by 1996 the following were considered to be desirable technical features of stents:

    i) Strength about the radial axis upon expansion of the stent, to prevent the vessel wall from prolapsing.

    ii) Strength along the longitudinal axis, to prevent the stent structure becoming "strung out" or shortened or compressed longitudinally.

iii) Flexibility about the longitudinal axis prior to expansion to make it possible to deliver the stent through tortuous blood vessels.

iv) Conformability, so that the stent could be deployed and expanded in a curved vessel without the vessel being unduly distorted.

v) Sufficient coverage of the vessel wall by the metal of the stent, to prevent the wall from prolapsing through gaps in the scaffolding.

vi) A sufficiently open structure to prevent vessel intersections (side branches) being blocked.

vii) A limited degree of longitudinal shortening on expansion.

viii) Low pressure expansion for balloon expandable stents. If too high a pressure was required it might result in damage to or even rupture of the vessel wall.

ix) The avoidance of flaring of any portions of the stent as it negotiated the curves in the blood vessels to prevent it from catching the vessel walls and consequently slipping off the balloon or damaging the walls themselves.

58. To these points, which were all made by Professor Rothman, I would add that it was common general knowledge that a stent should be shaped so as not to cause trauma to the blood vessel, the balloon used to inflate the stent or the stent itself upon expansion, and that for this reason sharp corners were to be avoided where possible. Indeed this was one of the reasons that rounded corners were introduced into the Palmaz-Schatz spiral design. As Professor Rothman put it, "in nature we don't very much like corners".

59. As Professor Rothman also explained, and I accept, the skilled person would also have well understood that many of these technical features were interrelated. Strength about the radial axis can be obtained by incorporating rigid circumferential rings and longitudinal struts. But both of these features reduce longitudinal flexibility. Reducing the number of longitudinal struts increases the flexibility of the stent before expansion but may lead to a lack of support for the vessel wall and increase the risk of prolapse. Conversely, increasing the coverage can increase the force required to deploy the stent and lead to the obstruction of side branches to the main vessel. As Dr Segal accepted in cross-examination, a stent designer would be conscious that small changes could have unpredictable results during deployment of a stent or upon its implantation.

60. Three areas of dispute remain: (i) the content of conferences, patents and patent applications; (ii) the ACS Multi-Link and the NIR stents; and (iii) whether any designs of stent were perceived to be in a particular phase relationship.

Conferences, patents and patent applications

61. Dr Segal suggested that all stents displayed at conferences or published in patents and patent applications before March 1996 were common general knowledge. Indeed, he considered that any stent discussed at a conference was common general knowledge despite the fact that each presentation tended to last for only five to ten minutes.

Further, he considered the Medinol patent application relied upon as prior art became common general knowledge immediately after its publication on 8 February 1996.

62. I reject Dr Segal's approach. There was no evidence before me that interventional cardiologists or engineers interested in stent design and development attended all conferences or studied the details of all the stents presented at each of them. By 1996 about 40 different stent designs had been proposed. Nor was there evidence that such persons routinely studied the contents of all patents and patent applications relating to stent design. I am confirmed in this conclusion by the fact that Dr Segal did not himself attend every conference and was unable to describe the differences between various stent designs about which he was asked. Typical of these were the Wiktor and Cordis stents, both of which had been discussed at conferences and one of which (the Cordis) was in clinical trials, yet neither of which had been studied by Dr Segal in any detail.

The ACS Multi-Link

63. The ACS Multi-Link stent was first implanted in ten patients at the Royal Brompton Hospital in London in 1993. That same year it was presented at the annual European Society of Cardiology Conference in Nice, France. In 1994, it was featured in *The Textbook of Interventional Cardiology* by Eric Topol, a major textbook. He described it as being composed of individual corrugated rings interconnected by a number of bridges which made it very flexible.

64. In 1994 and 1995, Abbott enrolled the first patients into the WEST study which examined patients with *de novo* coronary artery lesions and looked at the effects of Multi-Link stent implantation on acute and long-term clinical and angiographic results. This was a multicentre trial and the various clinical sites had information on the stent design, including pictures of it and instructions for its use.

65. ACS and Abbott also presented the Multi-Link stent at the Thoraxcenter courses on coronary stenting which took place in Rotterdam in December 1994, 1995 and 1996. Although not large, there were several hundred attendees and for those interested in coronary stenting, these there important events to attend. Feedback following the first course suggested that the stent had generated much excitement and that physicians were impressed with its design and flexibility. Ms Veldhof, who worked at that time as the European Clinical Research Manager for ACS with responsibility for conducting stent trials, including those on the Multi-Link, explained that in the mid 1990s a considerable number of coronary stents were coming on to the market from small start-up companies but the reputation for quality which ACS and Abbott had secured for themselves generated extra interest in the Multi-Link. It duly received its CE approval in Europe in December 1995. By May of 1996, over 5,000 stents had been sold.

66. When asked about the Multi-Link, Professor Rothman accepted that anybody involved in design at one of the manufacturing companies such as Guidant, Johnson & Johnson and Cordis, would have known of it, as would all stent innovators, by which I understood him to mean interventional cardiologists with an interest in stent design. He also accepted that as of 1996, the Multi-Link was one of the stents at the forefront of consideration by those in the field and that following its introduction it very rapidly became the stent of choice. It was Professor Rothman's view that

interventional cardiologists were very willing to move to what was perceived to be a better and more flexible design than the Palmaz-Schatz. Indeed, he agreed that "everybody was screaming for it and those with the biggest muscle got what they could".

67. In light of all these materials and the evidence of Professor Rothman, I am satisfied that the ACS Multi-Link Stent was common general knowledge amongst interventional cardiologists and engineers interested in stent design by March 1996.

The NIR stent

68. In 1996 the NIR stent did not have regulatory approval in the US; nor did it have CE approval in Europe. Between December 1995 and March 1996 it was the subject of local trials but it was not openly sold until March 1996. It was discussed in the course of a five minute slot one evening at the Rotterdam conference in December 1995.

69. Professor Rothman considered that those working at companies such as Boston Scientific, Johnson & Johnson and Guidant would have been aware of the stent but generally he thought it was a device which was not well known by March 1996. From his recollection, it was a device that he had not used and, although it had been discussed at various meetings, interventional cardiologists had not got "a handle" on it. As I have explained in discussing the law, it is not enough to show that a design was known to the major businesses involved in a particular art. It must have been known to the ordinary interventional cardiologist or engineer interested in stent design. The evidence falls far short of establishing that was so. Overall, I have reached the conclusion that the NIR stent was not a matter of common general knowledge by March 1996.

Phase relationship

70. Abbott contended that the skilled person would have been well aware of the concept of phase relationship and that this provided a means of balancing rigidity and flexibility. I do not accept this submission. Professor Williams explained that any engineer would understand the concepts of "in-phase" and "out-of-phase" and could recognise whether a design was one or the other. But this was not a significant consideration at the time. A decision would be made as to the design and for this purpose the phase was largely irrelevant. A particular phase relationship might be a consequence of the design process but did not form a material part of it. There was no material before me to suggest that Professor Williams was wrong and I accept his evidence.

The disclosure and scope of the patents in suit

71. All three patents have a very similar description and drawings but their claims are different. In the discussion which follows I therefore concentrate primarily upon the description of 093 and then consider, so far as necessary, the descriptions of 094 and 804. But I must refer to all the contested claims.

The law on interpretation

72. The general principles to be applied to the interpretation of a patent have been authoritatively stated by the House of Lords in *Kirin-Amgen v Hoechst Marion Roussel* [2004] UKHL 46; [2005] RPC 9. The patent must be construed purposively. The question is what the skilled person would have understood the patentee to be using the language of the claim to mean. Lord Hoffmann explained the process of analysis thus at [34] to [35]:

> "34. Purposive construction" does not mean that one is extending or going beyond the definition of the technical matter for which the patentee seeks protection in the claims. The question is always what the person skilled in the art would have understood the patentee to be using the language of the claim to mean. And for this purpose, the language he has chosen is usually of critical importance. The conventions of word meaning and syntax enable us to express our meanings with great accuracy and subtlety and the skilled man will ordinarily assume that the patentee has chosen his language accordingly. As a number of judges have pointed out, the specification is a unilateral document in words of the patentee's own choosing. Furthermore, the words will usually have been chosen upon skilled advice. The specification is not a document *inter rusticos* for which broad allowances must be made. On the other hand, it must be recognised that the patentee is trying to describe something which, at any rate in his opinion, is new; which has not existed before and of which there may be no generally accepted definition. There will be occasions upon which it will be obvious to the skilled man that the patentee must in some respect have departed from conventional use of language or included in his description of the invention some element which he did not mean to be essential. But one would not expect that to happen very often.
>
> 35. One of the reasons why it will be unusual for the notional skilled man to conclude, after construing the claim purposively in the context of the specification and drawings, that the patentee must nevertheless have meant something different from what he appears to have meant, is that there are necessarily gaps in our knowledge of the background which led him to express himself in that particular way. The courts of the United Kingdom, the Netherlands and Germany certainly discourage, if they do not actually prohibit, use of the patent office file in aid of construction. There are good reasons: the meaning of the patent should not change according to whether or not the person skilled in the art has access to the file and in any case life is too short for the limited assistance which it can provide. It is however frequently impossible to know without access, not merely to the file but to the private thoughts of the patentee and his advisors as well, what the reason was for some apparently inexplicable limitation in the extent of the monopoly claimed. One possible explanation is that it does not represent

> what the patentee really meant to say. But another is that he did mean it, for reasons of his own; such as wanting to avoid arguments with the examiners over enablement or prior art and have his patent granted as soon as possible. This feature of the practical life of a patent agent reduces the scope for a conclusion that the patentee could not have meant what the words appear to be saying. It has been suggested that in the absence of any explanation for a restriction in the extent of protection claimed, it should be presumed that there was some good reason between the patentee and the patent office. I do not think that it is sensible to have presumptions about what people must be taken to have meant, but a conclusion that they have departed from conventional usage obviously needs some rational basis."

093 - the teaching

73. The specification begins with a description of the "Background Art". Paragraphs [0002]-[0005] summarise the nature of stents and their purpose. They describe how the first stents, such as the Wallstent, were self expanding but that these were found by some investigators to be deficient because, when deployed, they could place undue stress on the walls of the lumen and would shorten in length in an uncontrollable fashion. These problems led to the development of controllably expandable stents which only required the application of sufficient force to expand the stent within the occluded passageway.

74. Paragraphs [0007] and [0008] describe the Palmaz-Schatz and GR stents as being of "some notoriety" and, after referring to various other stents of the expandable type, the specification explains in paragraph [0010] that, while they had achieved varying degrees of success, the art was in need of new stents having improved flexibility and stability while being readily implantable with little or no trauma to the lumen.

75. The specification then refers to an earlier Canadian application 2,134,997 ("997") of the same inventors. It explains that this describes an improved stent with a porous surface defined by a plurality of intersecting members arranged to provide a repeating pattern of polygons defined by a pair of longitudinal walls joined at each end by a concave and a convex shaped wall. However, in paragraph [0013], this is said to suffer from the drawback that a significant force is required to achieve expansion and also from a lack of flexibility such that delivery through a significantly curved pathway is difficult.

76. In short, therefore, it is said to be desirable to provide an expandable stent which is more flexible prior to expansion but which requires less force to achieve expansion.

77. Two paragraphs follow which form the basis of one of the added matter attacks on the patent. During the course of prosecution, acknowledgements of the Fischell and Medinol prior art publications were added and these appear at paragraphs [0015] and [0016] respectively (where Medinol is referred to as "Brun"). Importantly, the description explains that these stents comprise longitudinal elements which contain undulations which occupy the entire space between adjacent rings, with the result that

the forces exerted on the undulations are focussed at the point where the elements connect to the rings. I return to this disclosure when dealing with the validity attacks.

78. The specification then turns to the "Disclosure of the Invention". It is said that an object of the invention is to provide a novel expandable stent which obviates or mitigates at least one of the described disadvantages. Paragraph [0018] explains this is achieved by a stent which has a number of features which can be summarised as:

i) arcuate flexure means situated between two straight sections of the longitudinal struts and between the apices of adjacent rows of intersecting members;

ii) the arcuate flexure means allow for substantially complementary extension and compression of a diametrically opposed pair of the longitudinal struts upon flexure of the stent; and

iii) at least one of the apices is substantially flat.

79. An idea of what is meant by these features is gained from figure 9:

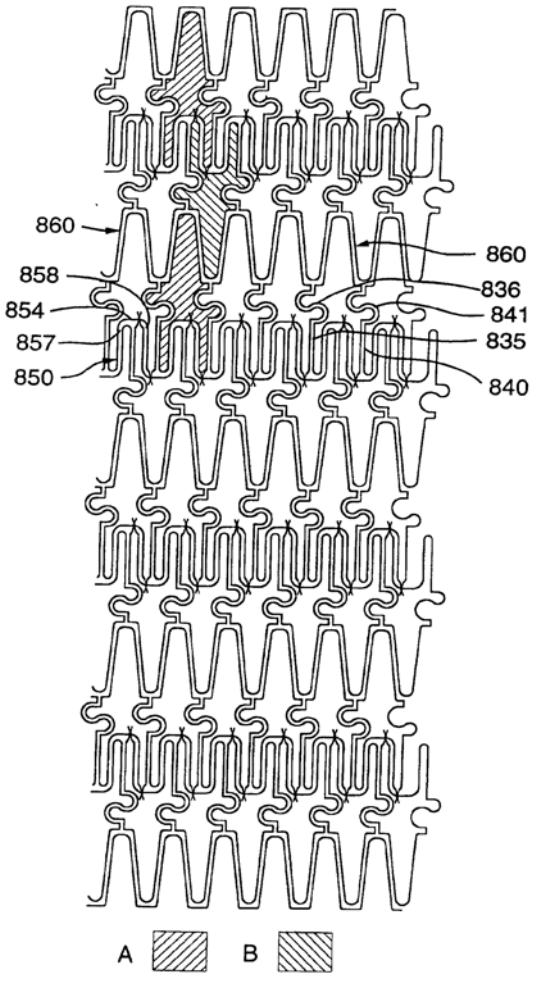


FIG.9

80. This shows two repeating patterns marked A and B. Each comprises two longitudinal side walls or struts (835, 840). Each of these struts contains a sinusoidal or S shape portion (836, 841) which is contained between two straight sections.

81. The longitudinal struts are connected by intersecting members. One of these (850) is concave and the other (860) is convex. The concave wall (850) is said to have a flat apex (854) having a pair of rounded shoulders (857, 858).

82. Paragraph [0019] explains that the use of flexure means in the series of longitudinal struts leads to a very desirable balance between lateral flexibility of the unexpanded stent and radial rigidity of the expanded stent. Practically, it says, the flexure means confer lateral flexibility on the unexpanded stent by allowing diametrically opposed pairs of longitudinal struts to undergo substantially complementary extension and compression. It elaborates in an important passage:

> "If one considers a stent in a flexed state, a first longitudinal strut disposed at the tangent of the bend (i.e. in two dimensions) will expand in response to the bending moment. In contrast, a second longitudinal strut disposed diametrically opposite (this can mean above, below or in the same radial plane as) the first longitudinal strut will compress in response to the bending moment. Generally, the degree of extension and compression will be substantially complementary. In other words, in most cases, the first longitudinal strut will expand and lengthen a first distance and the second longitudinal strut will compress and shorten a second distance. Preferably, the first distance is greater than the second distance and most preferably, the sum of the first distance and the second distance is substantially equal to the sum of the original lengths of the first longitudinal strut and the second longitudinal strut."

83. Paragraph [0020] continues that the shape of the flexure means is not restricted provided it allows diametrically opposed pairs of longitudinal struts to undergo substantially complementary extension and compression. The notion of diametrically opposed pairs of struts is then expanded upon in another important passage:

> "The term "diametrically opposed pairs of the longitudinal struts", as used in this specification, is intended to have a broad meaning. Thus, the "pair" can include opposed struts in the same horizontal plane (i.e. the same ring of polygons) or in different horizontal planes (e.g. one strut in a first ring of polygons and the other diametrically opposed strut in a second ring of polygons above or below the first ring)."

84. So the term "diametrically opposed" expressly has a broad meaning. Moreover, a pair of longitudinal struts can be diametrically opposed even if they are not in the same ring.

85. Finally, the paragraph returns to the flexure means and explains that preferably it comprises at least one lateral section disposed in the longitudinal strut. By lateral

section it means a section of the strut which is bowed in or out of the strut and, it says, the apex of the lateral section *may* be rounded.

86. Paragraphs [0021] and [0022] address the benefits of an S shaped flexure means. They explain that preferably one or both of the longitudinal struts contain such a flexure means and that preferably this is disposed at the end of the longitudinal strut to improve the lateral flexibility of the stent and mitigate shortening of the stent upon expansion. Interestingly, this appears to teach precisely the opposite of what is described as part of the invention, namely that the flexure means should be situated between two straight sections of the longitudinal strut.

87. The benefits of a flat apex are discussed in paragraphs [0027] and [0028]. Paragraph [0027] identifies the following five advantages:

    i) the force required to expand the stent is substantially reduced;

    ii) the stent is subjected to less traumatic stress during expansion;

    iii) plastic deformation during expansion is facilitated;

    iv) construction of the stent is facilitated; and

    v) upon expansion of the stent, warpage of the first apex and the second apex is obviated or mitigated.

88. In the light of the evidence I am satisfied these amount to one point only: ease of expansion. On this, there was substantial disagreement between the experts, as I shall explain in dealing with construction.

89. Paragraph [0028] identifies a further six advantages of having a flat apex with rounded shoulders. Once again I am satisfied that there is nothing in any of them, save that rounded corners reduce the risk of trauma and damage to the lumen as the stent is delivered. I have no doubt this is correct, but it was obvious in the light of the common general knowledge.

90. The description turns to consider the "Best mode for carrying out the invention" from paragraph [0042]. At the outset it explains one of the rather curious features of the specification. The stent designs illustrated in Figures 1-7 are not covered by any of the claims even though they depict a number of the features which are said to be characteristic of the claimed invention. Thus figure 1A shows the repeating patterns of polygons marked A and B:

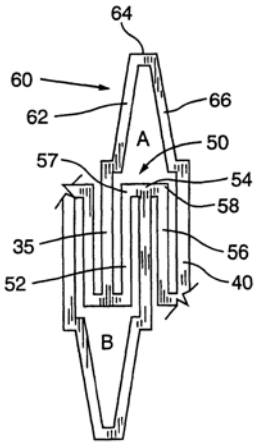


FIG.1A

91. Paragraph [0045] explains that the concave shaped wall (50) is made up of a trio of segments (52, 54, 56). Segment (54) is the apex of the wall and is said to be flat with a pair of substantially square shoulders. By contrast, the convex shaped wall (60) is made up of a trio of segments (62, 64, 66), of which segment (64) is the apex and, by inference, is not flat.

92. Paragraph [0047] explains that the shape of the convex and concave shaped walls can be modified without departing from the function and performance of the stent provided that at least one of them retains a substantially flat apex. For example, it says, the trio of segments can be replaced by a curved or arcuate wall or more than three segments can be used.

93. Paragraph [0048] is also of some importance. It says that various walls of the repeating patterns may be omitted at selected points along the body of the stent without departing from the spirit and scope of the invention. For example, it explains, it is possible to omit one or both of the side walls (35) and (40) at various points along the body of the stent with a view to improving its longitudinal flexibility. Further, it is possible to omit one or more of the segments (62, 64, 66) at selected points along the body of the stent with a view to improving its lateral flexibility.

94. Figure 2 is described in paragraph [0051] and provides another illustration of the use of a flat apex:

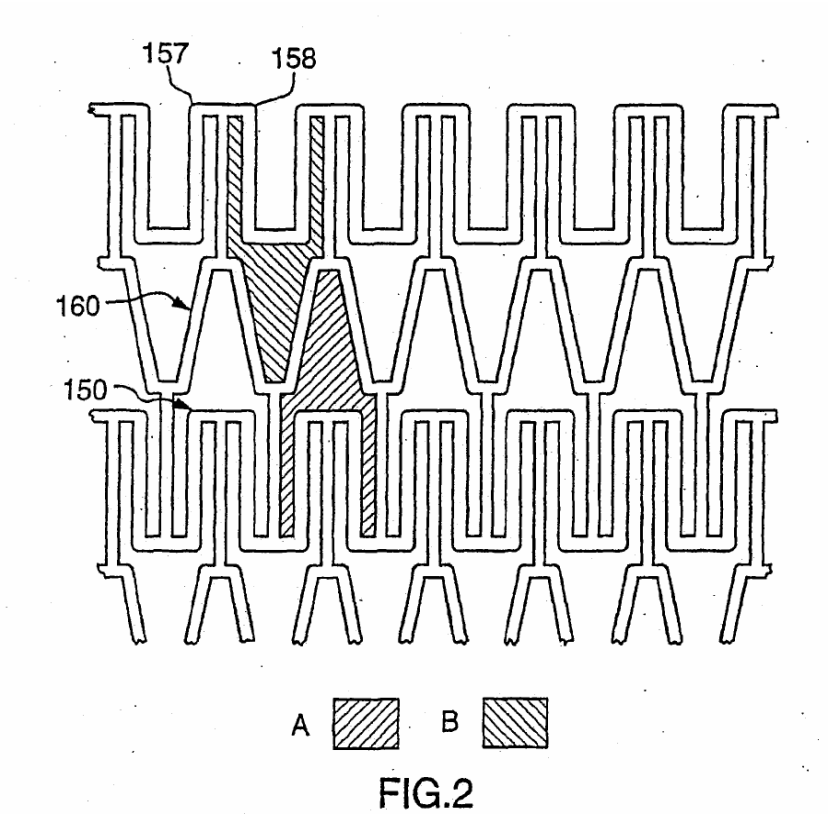
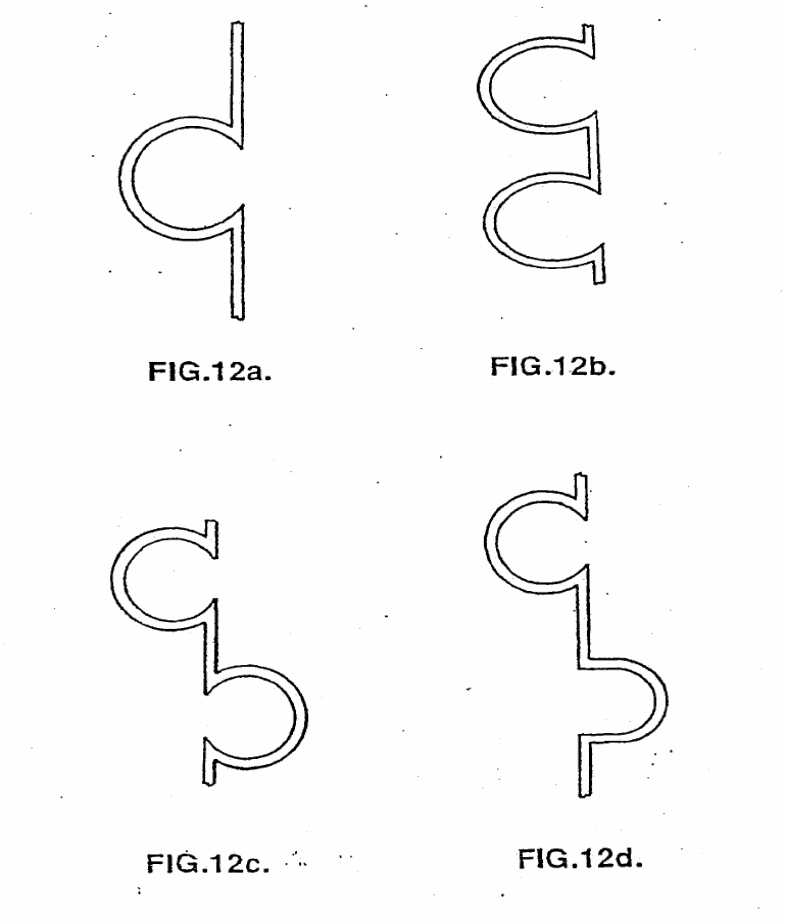


FIG.2

95. The concave shaped wall (150) is said to have a flat apex with rounded shoulders (157) and (158). But the convex shaped wall (160) apparently does not.

96. Paragraph [0062] again refers to the benefits of the use of flexure means. It explains that the use of flexure means, such as the sinusoidal (or S-shaped) portions in the design of the stents illustrated in figures 8-10, provides the benefit of improved flexibility of the stent in the unexpanded state. Specifically, it explains, during flexure of the stent, provision of such a feature allows the inner stent surface adjacent the bend to compress while concurrently allowing the outer stent surface adjacent the bend to extend, and all the while maintaining substantially intact the integral strength of the stent and avoiding buckling.

97. Paragraph [0063] elaborates that the provision of such flexure means in the longitudinal struts is another feature of the invention. It explains that figures 12a-12d illustrate various alternatives of bowed lateral sections which can be used in place of S shaped portions:



093 - the claims

98. That brings me to the claims. In the case of 093, I am only concerned with claim 1 which has helpfully been broken down into integers:

(a) An unexpanded stent comprising

(b) a proximal end and a distal end in communication with one another,

(c) a tubular wall disposed between the proximal end and the distal end, the tubular wall having

(d) a longitudinal axis

(e) and a porous surface

(f) defined by a plurality of rows of intersecting members,

(g) adjacent rows of intersecting members being interconnected by a series of longitudinal struts

(h) substantially parallel to the longitudinal axis,

(i) the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force on the stent;

(j) each longitudinal strut comprising

(k) an arcuate flexure means

(l) disposed in the longitudinal strut

(m) between a first straight section and a second straight section

(n) and between apices of adjacent rows of intersecting members

(o) to allow for substantially complementary extension and compression

(p) of a diametrically opposed pair of the longitudinal struts

(q) upon flexure of the stent

CHARACTERISED IN THAT

(r) at least one of the apices is substantially flat, and in that

(s) the stent is produced by laser cutting techniques applied to a tubular starting material.

093 – construction

99. A number of points of interpretation arise and I will address them in turn.

Integer (k): *Arcuate flexure means*

100. This has a bearing on infringement and validity. As for infringement, Abbott has not admitted that its stents have arcuate flexure means. As for validity, there is an issue as to whether an obvious modification of Medinol would produce a stent falling in the scope of the claim.

101. Evysio submits, and I accept, that integer (k) simply requires a curved flexure means, which integers (l) and (m) specify must fall between two straight portions of the longitudinal strut. As mentioned above, the purpose is explained in paragraph [0020] as being to confer flexibility on the unexpanded stent by allowing diametrically opposed pairs of the longitudinal struts to undergo substantially complementary extension and compression. Otherwise, as that paragraph says, the specific shape of the flexure means is not particularly restricted. As I have also mentioned, the same paragraph explains that the apex of the lateral section or bow *may* be rounded. It follows that provided the flexure means can fairly be described as curved or arcuate

and that it fulfils its function it will fall within the scope of the integer. I do not believe the skilled person would understand the integer excludes a flexure means which is generally curved and which fulfils its function but which also includes a portion which is not curved. This is supported by the flexure means shown in figure 12, and specifically figure 12c and 12d reproduced in paragraph [97] above. These have a generally S shaped configuration but comprise two curved bows which are joined by an apparently straight portion.

Integers (o) and (p): ***substantially complementary extension and compression of a diametrically opposed pair of the longitudinal struts***

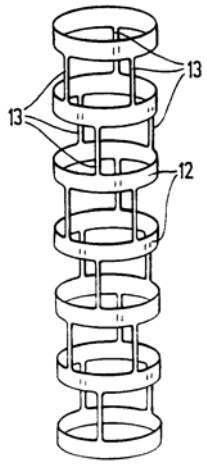
102. The interpretation of these integers is important to infringement and to validity. There are two elements to be considered: (i) "diametrically opposed pair of longitudinal struts"; and (ii) "substantially complementary".

103. Evysio accepts that the expression "diametrically opposed pair of longitudinal struts" requires the presence of struts which are diametrically opposed. However, it says it is clear from paragraph [0020] of the description that the claim does not require the struts to be exactly 180 degrees apart, nor that they must be found in the same horizontal plane. Abbott, on the other hand, accepts the struts do not have to be in the same horizontal plane but maintains they do have to be 180 degrees apart.

104. As for the phrase "substantially complementary extension and compression", Evysio contends that this is explained in paragraphs [0019] and [0062] of the description and simply means that the struts on the outside of the bend can extend whilst the struts on the inside of the bend can contract. It says that paragraph [0019] of the description makes clear that the degree of expansion does not need to match the degree of compression. Abbott takes a very different line. It says the feature means that when any opposed pair of struts is considered, the degree of compression in one must match the degree of extension in the other. The word "substantially" makes clear that a modest degree of difference is permitted but that is all. Moreover, the length of extension in one strut and the length of extension in the other have to be measured and compared.

105. I have set out paragraph [0020] of the description in paragraph [83] above. It explains the meaning of "diametrically opposed" and says the term is intended to have a broad meaning and that the "pair" can include opposed struts in the same horizontal plane or in a different horizontal plane. One strut can be in one ring of polygons and the other, opposed strut, can be in a second ring of polygons above or below the first ring. This deals with the case where there are, for example, three struts per ring but not in the same position between adjacent pairs of rings. Abbott provided this illustration taken from Lau to explain the point:

FIG. 10



106. The struts in each ring are set 120 degrees apart and it is not suggested they are diametrically opposed. However, those in alternate rings clearly are.

107. That brings me to the question whether the struts need to be set precisely 180 degrees apart. I am not persuaded that they do. Paragraph [0020] expressly says that the term is intended to have a broad meaning. Moreover, the teaching of paragraph [0048] is that the side walls of selected polygons can be removed in order to improve flexibility. As soon as one side wall is removed then its previous counterpart no longer has a strut set 180 degrees opposite to it. Further, as Professor Rothman explained in cross-examination, the limitation contended for by Abbott would mean the claim is limited to stents with an even number of links (as he called them) and he could see no purpose in such a limitation. He has seen many stents with an odd number of links and could not think of any reason why they should be excluded. His concern would have been to ensure there was a sufficient number of links to prevent tissue prolapse and to prevent the rings from moving apart. This would not require them to be precisely 180 degrees apart.

108. In the light of all these matters, I have reached the conclusion that Evysio's interpretation is to be preferred. The skilled person would understand that the stent must have longitudinal struts which are on opposite sides of the stent and which can fairly be regarded as being opposed to each other so that, absent the claimed flexure means, the two will act together to restrict the flexibility of the stent. The skilled person would understand two longitudinal struts to be diametrically opposed even if they are not set precisely 180 degrees apart.

109. The second element calls for the struts to experience substantially complementary extension and compression. I have not found this easy to interpret. The expression "substantially complementary extension and compression" implies that if the stent is bent laterally around a corner then the strut on the inside of the stent must compress and the strut which opposes it on the outside of the stent must extend, in each case to substantially the same degree.

110. Professor Williams gave evidence under cross-examination much to this effect. He explained that if a tube (such as a stent) is bent around a corner then, under uniform conditions and if the axis of bending remains down the centre of the tube, the inside

of the tube will compress by a certain length and the outside of the tube will extend by that same length. If, however, the axis of bending does not remain down the centre of the tube and if its bending is not uniform then the length of compression will be less than the length of extension, although the difference between the two will be marginal.

111. However, the teaching of paragraph [0019] of the specification is clear and set out in paragraph [82] above. It explains what the patentee meant by this element of the claim in saying: "*In other words, in most cases the first longitudinal strut will expand and lengthen a first distance and the second longitudinal strut will compress and shorten a second distance.*" So all that is required for the two to be complementary is that one expands while the other contracts. There is no requirement that the two distances must be the same or substantially the same. This is confirmed by the following sentences which describe first, a *preferred* situation in which the length of expansion is greater than the length of compression and second, a *most preferred* situation in which the sum of the first and second distances is substantially equal to the sum of the lengths of the first and second longitudinal struts.

112. I have reached the conclusion that, in the light of the way the patentee has chosen to define this element of the claim, the interpretation advanced by Evysio must be accepted. It simply means that the struts on the outside of the bend extend whilst the struts on the inside of the bend compress. I can also see some sound practical reasons for adopting this interpretation. First, I do not think this element can be divorced from the meaning of the term "diametrically opposed struts". As I have explained, these can be in different rings; further, as I have construed the term, they do not need to be set precisely 180 degrees apart. One can readily imagine circumstances where, for example, the bend in a vessel is irregular and tortuous and in which the degree of expansion required of one strut is different to the degree of compression required of an opposed strut. Second, I do not understand the claim to require all the extension and compression experienced by the stent to be accommodated by the flexure means, although clearly their purpose is to confer flexibility upon it. Again, the degree to which the other structural members of the stent bend or twist as it navigates a bend in the artery may affect the degree of compression and expansion of individual flexure means.

113. In conclusion, I accept the submissions advanced by Evysio that the struts do not need to be exactly 180 degrees apart although they must be opposed; and second, they must contain flexure means so that the struts on the outside of the bend can extend and the struts on the inside of the bend can compress upon flexure of the stent.

Integer (r): *at least one of the apices is substantially flat*

114. This integer has a bearing on infringement and validity and it gave rise to a another very substantial dispute between the parties. I begin by summarising their rival contentions.

115. Evysio contends that "substantially flat" are words of degree which take their meaning from their context. In the present case, the relative nature of the requirement of the claim is emphasised by the use of the term "substantially". Literal, geometric flatness is plainly not required. In order to answer the question "how flat?" one needs to consider the purpose for which it is used. That purpose is apparent from

paragraphs [0027] and [0028] of the specification and is to reduce the force required to expand the stent. Substantially flat apices (which necessarily have two shoulders in contrast to pointed or curved apices) create a more uniform distribution of the potential stress points around the circumference of the stent. This reduces the average force required for radial expansion, as compared to a configuration with a few major points of stress at narrow more pointed apices. It also reduces the angle through which the elements of the circumferential rows must be bent when the stent is expanded. Absolute flatness is irrelevant to this purpose. The apices need to be sufficiently flat to achieve the purpose and improve on the prior art referred to in the patent.

116. Abbott, on the other hand, contends that the teaching of the patent is so unclear that the skilled person is left completely in the dark when trying to determine what is or is not flat and that the accordingly the specification is insufficient or cannot be infringed. Alternatively, and if a meaning is to be given to "flat" in the context of the patent, Abbott contends that the only sensible meaning is the standard geometric meaning of the word and further, the integer is referring to the shape of the *internal* surface of the apex in question.

117. In assessing these rival submissions and attempting to arrive at the correct interpretation I think the starting point must be to identify what the patent means by the apex. Even on this point, the parties were unable to agree. Evysio contended that the apex was the entirety of the upper segment of each intersecting member. Abbott argued that the apex is the internal surface where the longitudinal strut joins the ring.

118. I have no doubt that Evysio's interpretation is the correct one. As mentioned earlier, paragraph [0045] of the specification explains that in figure 1 the concave wall is made up of a number of segments, (52, 54, 56) and segment (54) is described as the apex. This is itself provided with square shoulders (57, 58). So the apex is the whole upper segment including the shoulders. The same applies to the other figures. Figure 2 is one example (see paragraphs [94]-[95] above) and figure 9 is another (see paragraphs [79]-[81] above). This is described in paragraph [0058] of the patent as having a flat apex (854) with a pair of rounded shoulders (857, 858).

119. What then is the meaning of the word "flat" in the context of the patent? Flatness is a property of a surface. As matter of English, one would expect a surface which is substantially flat to be substantially level and Professor Prendergast read the specification in just that way. Throughout it distinguishes between surfaces which are rounded, curved or arcuate and those which are flat (see, for example, col.4, lines 50-51; col.6 lines 34-40; col.10, lines 49-58). Moreover, the flat apices of, for example, figures 1A, 2 and 9 clearly have a substantially flat upper surface albeit, on occasion, with rounded shoulders. Interestingly however, the lower surfaces of the flat apices in figure 9 are plainly curved. This would suggest the patent is concerned primarily with the *upper* or *external* surface of the apex in question. Otherwise the patentee has defined his claim in such a way as to exclude one of the preferred embodiments.

120. A second complication arises in relation to this geometric analysis. There are some apices which have the appearance of being flat but which the patent suggests are not. A number were explored in cross examination. I do not propose to relate them all but the following examples provide a flavour. Evysio suggested that the patentee has sought to draw a distinction between the apices in the Canadian 997 patent application referred to in paragraph [75] above (which are not flat) and those of the invention

(which are). However, its own expert, Professor Rothman, considered that the apices in the 997 application *are* flat. Similarly, Figure 1A (shown in paragraph [90] above) contains one apex (54) which is said to be flat and another (64) as to which the specification is silent but which, by inference, is not. But both appear to have flat upper surfaces, although it is fair to say that (54) certainly appears broader. Figure 9 shows two sorts of apices, only one of which (854) is described as flat. Yet this appears no flatter than apex (64) in Figure 1A.

121. Turning to consider the purpose of the flat apex, this is said by Evysio to reduce the force required to expand the stent, as I have explained. However, it begs the question "reduced compared to what?". Presumably it must mean reduced compared to something that is not flat – whether curved, pointed or some other more complex shape.

122. This gave rise to a very lively dispute between Professor Prendergast and Professor Williams as to whether or not a flat apex is relevant to this purpose at all. When it became apparent to me from their reports that they were unable to agree I directed they should meet and seek to identify points of agreement and disagreement. As a result, I was presented with a joint statement from which the following emerged:

i) complex physical phenomena are ongoing in stents on expansion and it was not easy for either of them to predict stress patterns. They considered this to be the explanation for their difference of opinion;

ii) it is plastic deformation of the metal which is crucial for stent expansion;

iii) plastic deformation initiates at the *inner* corner of an apex and is then progressive;

iv) the smaller the included angle between two members the higher the stress concentration factor;

v) as the stent expands, work hardening will increase the level of the stress at the corners. However, they disagreed as to how important work hardening is in practice and the degree to which it influences the force required to expand the stent. Professor Williams thought it a significant factor but Professor Prendergast disagreed. They also noted that plastic deformation occurs more easily at sharp corners than in "more open" corners but they were unable to agree as to whether this is relevant.

123. During the course of cross examination it became apparent there is yet another factor to consider, namely the effect of moments. A moment is the force multiplied by the perpendicular distance from the point about which it is acting, that is to say the apex. As a stent expands, the arms become increasingly oriented in a circumferential direction and it becomes increasingly difficult for the balloon to expand them any further.

124. A good deal of time was taken cross examining the two Professors as to the forces required to expand a stent with a "saw tooth" strut pattern and a stent with a "castellated" strut pattern. In the end the evidence came to this. They agreed that the sharper the initial angle the higher the stress concentration and hence the lower the

force required to create a given stress and so to bring the struts to the point of their elastic limit. It will therefore require a lower force to reach this point for the saw tooth pattern than the castellated pattern. Thereafter the struts will start to undergo plastic deformation and work hardening as the angle between them grows. Professor Williams considered this to be the major factor. Since the struts in the saw tooth pattern have to pass through a greater angle than those in the castellated pattern to achieve a certain overall degree of expansion of a stent, he thought the force required to expand the saw tooth pattern would be greater than that required to expand the castellated pattern. Professor Prendergast thought it would all depend upon the overall degree of expansion required because he thought work hardening would have much less of an effect than Professor Williams. But he also accepted that in one particular arrangement, exhibited as DFW-3 to Professor Williams's report, more force would be required to achieve the depicted degree of expansion in the saw tooth pattern than in the castellated pattern, partly as a result of work hardening and partly as a result of the effect of moments.

125. DFW-3 depicts one comparison only but, as Abbott fairly submitted, there are many other non flat apices which could also be considered. A number of these were put to Professor Williams in X/9. But he did not feel able to comment, saying he would need to test them to find out.

126. In the light of all of the above, I believe the skilled person would reach the following conclusions. First, he would understand the term 'substantially flat apex' to be referring to the surface characteristics of the entirety of the upper segment of the intersecting member.

127. Second, he would understand that the patentee intended to draw a distinction between the terms 'curved', 'arcuate', 'rounded', 'square' and 'flat' in referring to the various elements of the stent. Indeed, in describing this particular integer the patentee has deliberately distinguished between a flat apex having square shoulders and a flat apex having rounded shoulders. All the apices which the patentee has described as flat do indeed have that appearance on their upper surfaces, although some are rounded on their lower surfaces. Accordingly, he would conclude the patentee is concerned with, at least, the *upper* or *external* surface of the apex.

128. Third, he would be conscious that the patentee has depicted other apices which have a small flat portion but are generally of a more pointed nature (such as apex (64) in Figure 1A) and has chosen not to describe these as flat. So he would conclude the patentee intended these to be excluded.

129. Fourth, he would appreciate the stated purpose of the flat apex is to reduce the force needed for expansion. However, he would understand this force depends upon a number of factors which interrelate in a far from straightforward way. He would also understand these factors include whether the plastic deformation takes place in two places rather than one and the angle through which the longitudinal struts have to move to achieve a given overall degree of expansion. But he would understand these factors are primarily a feature of the extent to which each of the struts are spaced apart, their angle and the shape of the inside surface of the apex rather than the outside (because it is here that the plastic deformation starts).

130. Fifth, he would understand the patentee has nevertheless chosen to limit the apex to one which is substantially flat. The patentee has not chosen to define the apex as a member which causes the plastic deformation of the struts to take place in two places rather than one. Nor has he chosen to define it as a member which causes the ends of the struts to be spaced apart. Why the patentee has chosen to limit the claim in this way would not be apparent. It might have been with a view to avoiding the prior art – such as the ACS Multi-Link - or to avoid arguments over enablement, perhaps because he appreciated the complexity of the interrelationship between the various factors involved. Whatever the reason, he would understand this to be a feature by which the patentee intended to limit the scope of his monopoly.

094 – the teaching

131. The teaching of 094 is essentially the same as that of 093. However the invention now includes a requirement that there be a repeating pattern of polygons having a concave shaped first wall and a convex shaped second wall.

132. Broadly it describes a stent with the following features:

i) A repeating pattern of polygons with a concave-shaped first wall having a first apex and a convex shaped second wall having a second apex.

ii) at least one of the first apex and the second apex being substantially flat;

iii) wherein the first apex and the second apex are of different lengths.

133. The general arrangement of the polygons envisaged by the invention is depicted in figure 1A and figure 2 of the patent which I have reproduced in paragraphs [90] and [94] above. It can be seen they comprise what is described in the specification as an "arrow head" configuration in which the point of the arrow head is the convex shaped wall and the tail of the arrow is the concave shaped wall (094 at [0042]). The benefit of this arrangement is described in paragraphs [0016] and [0017] of the specification as being an improved stent which, in conjunction with the flat apex, produces the advantages to which I have referred in paragraph [87].

134. However the specification introduces two complexities. The first is that a longitudinal strut may be added between the convex and concave shaped walls. This is illustrated in figure 3 where it is marked (270):

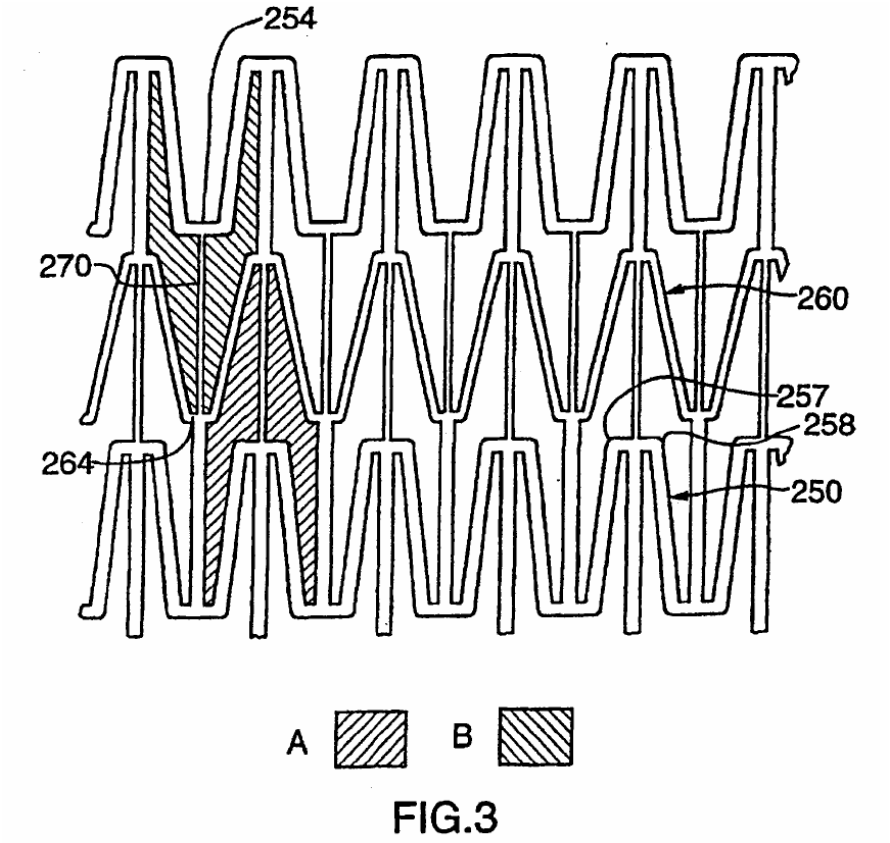


FIG.3

135. And in figure 8 where it is depicted as being no different from the other longitudinal struts and incorporates the S shaped flexure means:

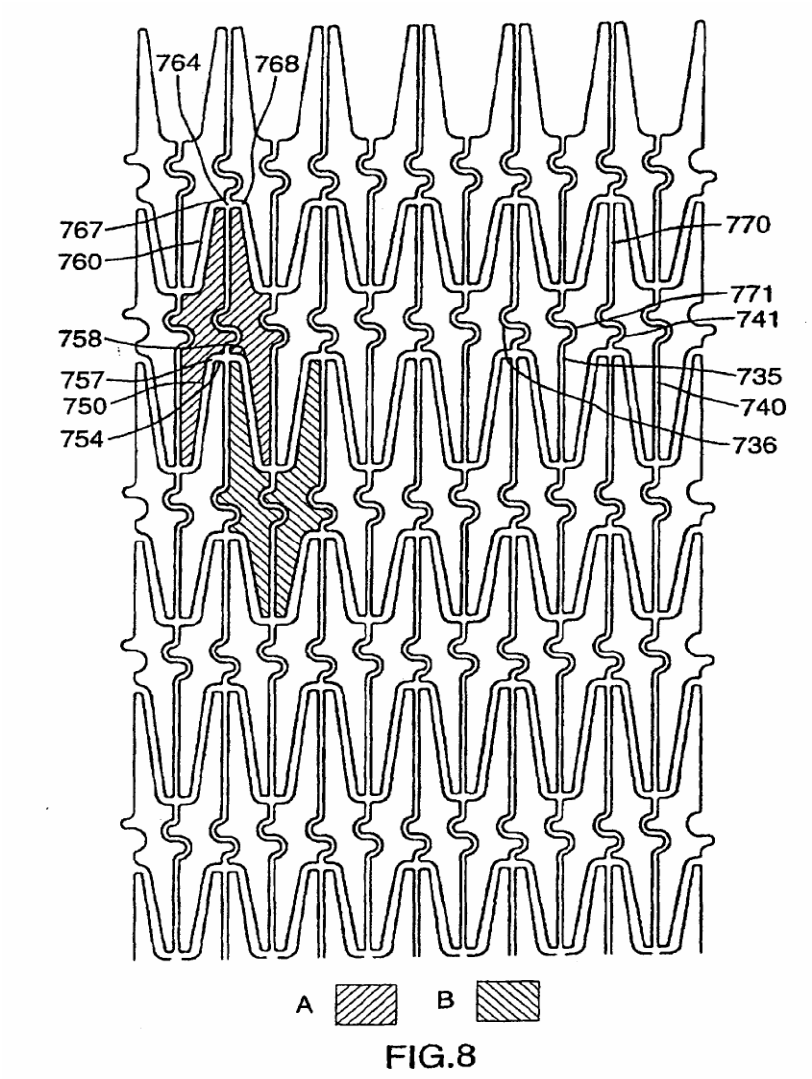


FIG.8

136. The second is the teaching to which I have referred in paragraph [93] above that various walls of the repeating patterns A and B may be omitted at selected points along the body of the stent without departing from the spirit and scope of the invention. The same paragraph appears in 094 at [0044]. For example, in referring to figure 1A, it says it is possible to omit one or both of the side walls at selected points along the body of the stent with a view to improving its longitudinal flexibility. If the basic configurations of figure 1A or figure 2 (see paragraphs [90] and [94] above) are considered, it can be seen that this will produce a shape without a definable arrow head and arrow tail configuration because there will be concave and convex portions in the walls at both ends.

094 – the claims

137. Claim 1 has been broken down into the following integers:

(a) An expandable stent, comprising

(b) a proximal end and a distal end in communication with one another,

(c) a tubular wall disposed between the proximal end and the distal end, the tubular wall having

(d) a longitudinal axis and

(e) a porous surface

(f) defined by a plurality of intersecting members

(g) arranged to define a first repeating pattern (A)

(h) comprised of a polygon having

(i) a pair of side walls substantially parallel to the longitudinal axis,

(j) a concave shaped first wall

(k) having a first apex, and

(l) a convex shaped second wall

(m) having a second apex,

(n) the first wall and the second wall connecting the side walls,

(o) at least one of the first apex and the second apex being substantially flat,

(p) the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force on the stent,

(q) wherein the first apex and the second apex are of different length.

138. Claim 6 adds the requirement that the strut comprises flexure means for substantially complementary extension and compression of a diametrically opposed pair of side walls. Unlike 093, there is no requirement that the flexure means be arcuate and located between two straight sections of the strut.

139. The real issue of construction arises in relation to integers (g) to (n) of claim 1. These call for a repeating pattern comprising a polygon which has two walls connecting the side (longitudinal) walls. One of these connecting walls (the first) must have a concave shape and the other (the second) must have a convex shape. So far so good; this clearly describes the arrow head design. But the question then arises as to how the skilled person would understand these requirements of the claim in the light of the teaching that selected side walls can be omitted. As soon as a side wall of such a polygon is omitted, the first wall ceases to be distinguishable from the second wall on the basis that one has a concave shape and the other has a convex shape because they now both have undulations. Each of them has both concave and convex portions. If

alternate side walls are now omitted all the way around the stent there will not be any first and second connecting walls which can be distinguished from each other on the basis that one is concave and the other is convex. Instead they will *all* undulate and have both convex and concave portions.

140. I have to say that I find it very hard to reconcile the words of claim with the teaching about the omission of selected side walls. In my judgment the only way the skilled person can make sense of the two is to conclude that alternate walls cannot be omitted all the way around the stent. It must still be possible to identify a pattern of polygons which have longitudinal walls connected by a first wall of concave shape and a second wall of convex shape. That is what the claim expressly requires and it is a feature said to produce the benefit described in the paragraphs [0016] and [0017] of the body of the specification.

804 – the teaching

141. The teaching of 804 is essentially the same as for the other patents. The only claims in issue are 1 and 23 and there is an unconditional application to amend to combine them together. In summary, the invention is a stent comprising:

i) a repeating pattern of polygons wherein the first wall contains a concave shape and wherein the second wall contains a convex shape (derived from claim 23);

ii) longitudinal struts comprising a curved flexure means disposed between a first straight section and a second straight section

iii) to allow for substantially complementary extension and compression of a diametrically opposed pair of the longitudinal struts; and

iv) at least one of the apices in the first and second walls is substantially flat.

804 - the claims

142. Claims 1 and 23 have been broken down into the following integers:

(a) An unexpanded stent, comprising

(b) a proximal end and a distal end in communication with one another,

(c) a tubular wall disposed between the proximal end and the distal end, the tubular wall having

(d) a longitudinal axis

(e) and a porous surface

(f) defined by a plurality of intersecting members comprising

(g) rows of a repeating pattern (A, B) comprised of

(h) a polygon having

(i) a pair of longitudinal struts substantially parallel to the longitudinal axis,

(j) a first wall and a second wall connecting the longitudinal struts,

(k) longitudinal struts comprising flexure means

(l) disposed between a first straight section and a second straight section,

(m) the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force on the stent;

CHARACTERISED IN THAT

(n) the flexure means are curved

(o) and allow for substantially complementary extension and compression

(p) of a diametrically opposed pair of the longitudinal struts upon flexure of the stent;

(q) IN THAT the first and second walls are shaped with an apex, wherein

(r) at least one of the apices in the first and second walls is substantially flat; and

(s) IN THAT the stent is cut out of a tubular starting material.

and wherein (by claim 23)

(t) the first wall contains a concave shape and wherein

(u) the second wall contains a convex shape.

143. Two points of construction arise.

Integer (g): ***rows of a repeating pattern (A, B)***

144. In contrast to 093 and 094, this feature calls for rows of a repeating pattern (A,B). Abbott accepts that the feature is not particularly clear textually but submits that, in the context of the specification as a whole and given the consistent contents of the drawings, what the claim calls for is a tessellation of two different polygons, each row in the surface consisting of a single type of polygon, the one type being a mirror image of the other.

145. I am unable to accept this submission for two reasons. First, it is clear from paragraphs [0053] and [0054] that the specification contemplates shapes other than those illustrated and, moreover, it seems to me that whether one regards the second row of polygons in the illustrated embodiments as being of a different type depends on where one chooses to draw them. In figure 8, for example, they can be drawn, as they are, as inverted (see paragraph [135] above). Alternatively, the second row could simply be stacked under the first row in which case they are exactly the same.

146. Secondly, in accordance with Rule 43(7) of the Implementing Regulations of the EPC, the reference signs (A,B) are not limiting. So the claim simply calls for rows of a repeating pattern.

Integers (t) and (u): *the first wall contains a concave shape and wherein the second wall contains a convex shape*

147. It is to be noted that there is a material change in wording between this pair of integers and integers (g) to (n) of 094. In this case the claim only requires the first and second walls to *contain* a concave *shape* and a convex *shape* respectively. This change in wording is clearly intentional and is to be contrasted with claims 19 and 20 which call for a convex shaped wall and a concave shaped wall respectively. So the polygons can be of a more complex configuration. The first and second walls do not themselves need to be concave and convex, as in the case of 094. But they can still contain a strut down their centre, as I explained in paragraphs [129] to [131] above.

Infringement

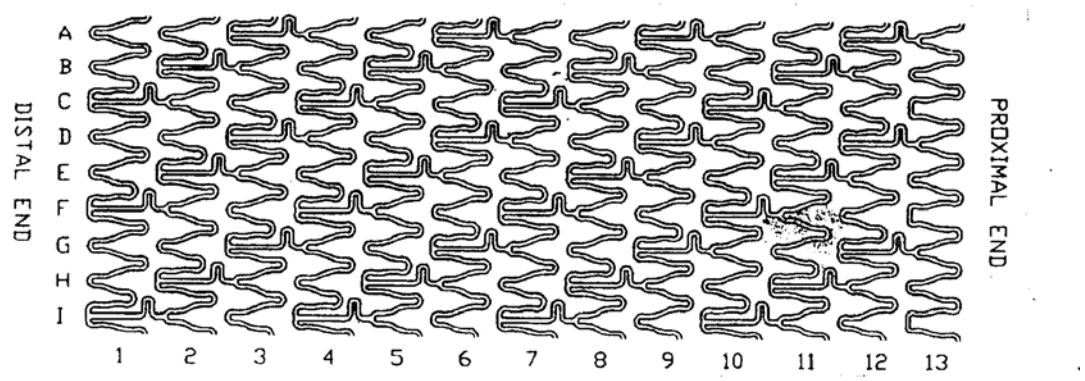
148. There are six non infringement points. Some arise in relation to only some patents and some in relation to only some products. I will take them in turn.

No flat apices

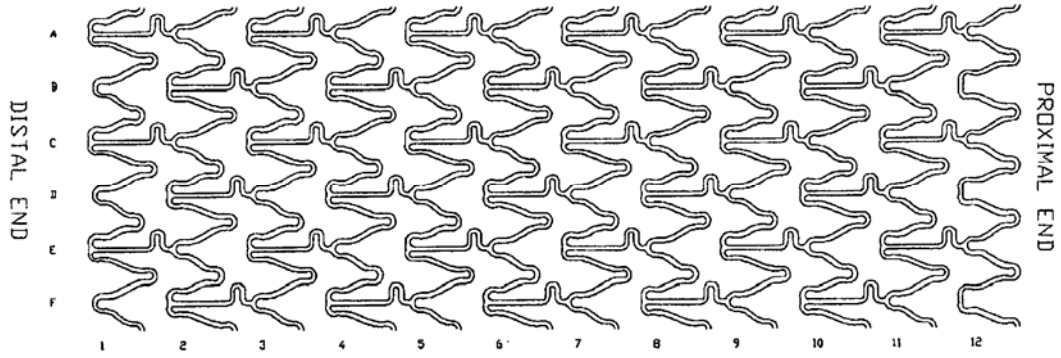
149. This is raised in respect of all three patents and in respect of all products. The point of construction is the same for all the patents but there is a significant difference between the original and modified products alleged to infringe.

The original products

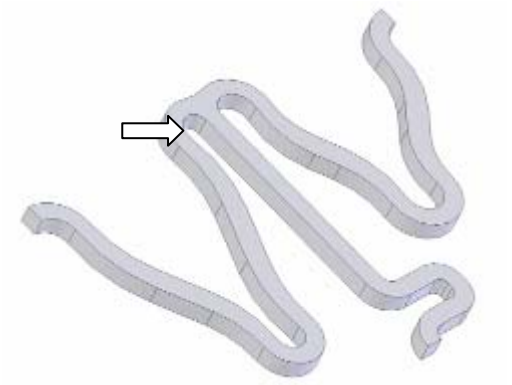
150. Evysio says the original products have, on any sensible view, at least one substantially flat apex. This can be seen in the SEM images at MTR 18 and 19 and in this plan view of the 15mm “medium” Multi-Link Vision where the flat apices are said to be present at, for example, coordinates C1 and B2:



151. The "small" product is similar, the difference being it only has six crests, as shown in the plan view below. Here Evysio says the flat apices can be seen at, for example, coordinates B2 and C3:



152. Abbott, on the other hand, contends that none of its products have flat apices because the inside surface of what is said to be a flat apex is plainly curved, as shown in the following diagram:

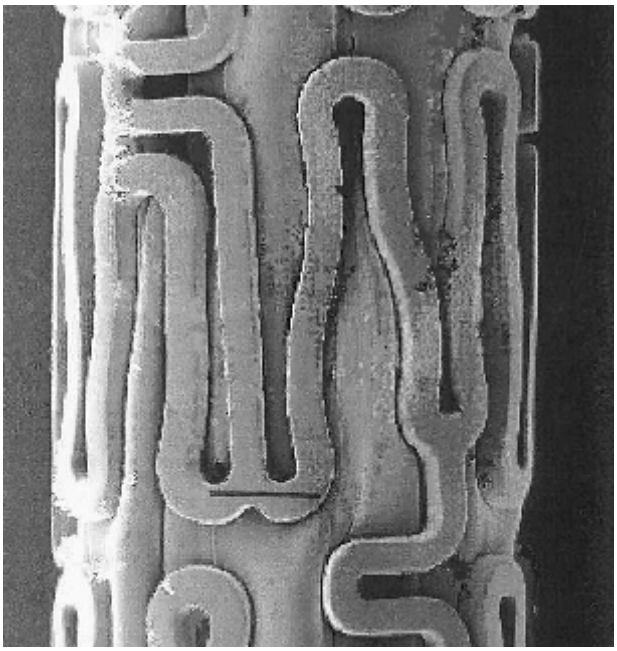


153. I am unable to accept Abbott's contention. I have dealt with the interpretation of this integer at paragraphs [114] to [130] above. I agree that the inside of the apex is curved at the point identified in the above diagram. But so is the equivalent apex shown in figures 8 and 9 of the patents and, for the reasons I have given, I have concluded the

patentee is primarily concerned with the *upper* or *external* surface of the apex. In my judgment one of the apices in the original products is substantially flat and this feature of claim 1 of each of the patents is satisfied.

The modified products

154. The modified products contain a substantial dimple on the upper surface of what Evysio identifies as the flat apices. It can be seen clearly in this SEM which forms part of Exhibit MTR 16 to Professor Rothman's report:



155. In contrast to the original products, it seems to me that, as a matter of appearance, this apex is plainly not substantially flat. It has a curved surface on both its outside and inside. I would add that it is also, for practical purposes, indistinguishable in this respect from the ACS Multi-Link.

156. Nevertheless, Evysio submits that the equivalent apices are indeed substantially flat, for two reasons. The first is that Professor Rothman was able to draw an imaginary line (shown on the above SEM) inside the metal of the stent which was not cut by the dimple. I do not find this persuasive. There is no suggestion in any of the patents that this is the correct way to approach the question. Flatness is a surface characteristic. It is possible to draw a line through the centre of the earth but no one would suggest it is flat.

157. The second and more substantive point is that Professor Prendergast accepted in cross examination that the presence of the dimple in the modified design would make no practical difference to the force needed to expand the stent. This was also supported by a declaration of a Professor Taylor submitted by Abbott in opposition proceedings before the EPO. So, Evysio submits, the apices of the modified products are still sufficiently flat to achieve the purpose of the patentee, which is to reduce the force needed to expand the stent. They are therefore substantially flat.

158. The flaw in this argument is that it is not the flatness of the surface of the *upper* or *external* apex which makes the stent easier to expand in the first place. I have explored this issue in detail in considering the question of construction. The skilled person would understand that it is the distance between the shoulders, the angle of the struts and the inside surface of the apex which matter for this purpose. The first two are not features of the claim and as for the third, the internal surface is not substantially flat in either the original or the modified products.

159. It follows that none of the modified products infringe any of the patents.

No substantially complementary extension and compression

160. This is a requirement of claim 1 of 093, claim 6 of 094 and claim 1 of 804.

161. It is apparent from experiments which Abbott has conducted for this litigation that when its stents are flexed, the compression of the struts on one side is different from the extension of the struts on the other. Accordingly, it says, the flexure means do not allow complementary extension and compression.

162. This argument turns on the proper construction of this limitation. For the reasons I have given, I do not accept that the claims require the extension and compression to be substantially the same. The experiments establish that, as the stents bend, the struts on the outside will extend by a first distance and the struts on the inside will compress by a second distance. Accordingly, this requirement of the claims is satisfied by all the products in issue.

No diametrically opposed struts

163. This is related to the immediately preceding point and it again applies to claim 1 of 093, claim 6 of 094 and claim 1 of 804. However, it can only be taken in relation to the medium sized products. In the case of these products, the closest any two struts come to being diametrically opposed is an angular displacement of 160 degrees. Abbott argues that Evysio has provided no proof that a stent with struts offset by this amount provides substantially complementary extension and compression.

164. Once again, this argument turns on the proper construction of the claims. For the reasons I have given, I do not accept that the struts need to be set 180 degrees apart. They must be opposed and one must compress whilst the other extends as the stent negotiates a bend. There is no requirement that the degree of compression and extension must the same. In my judgment this integer is satisfied by struts set 160 degrees apart.

No concave and convex walls

165. This arises in relation to claim 1 of the 094 and 804 patents (in the latter case after the collapse of claim 23 into claim 1) and in relation to all products.

166. The point emerges from a consideration of the plan view of, for example, the medium Vision product set out in paragraph [151] above. Abbott argues that in all its products the relevant walls produce complex shapes which may appear to be convex in discrete places and concave in others. As a whole, however, the walls that connect the

longitudinal struts cannot properly be described as convex or concave, because they are neither.

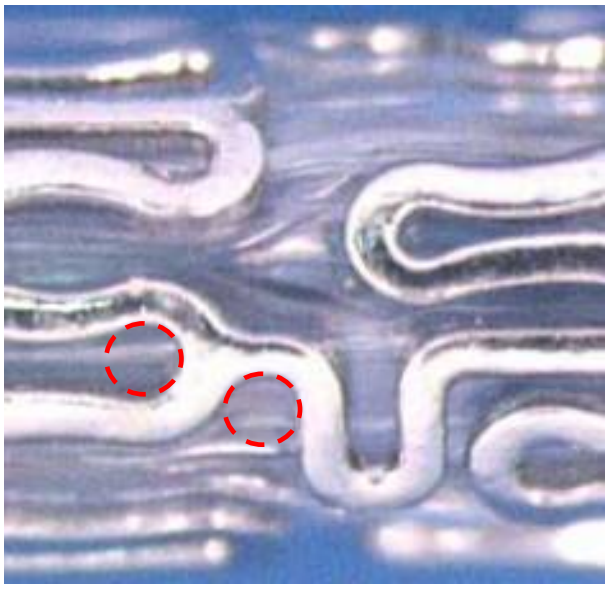
167. Evysio says this ignores the teaching of the patents (paragraph [0044] in the case of 094 and paragraph [0054] in the case of 804) that the side walls of the polygons can be omitted.

168. I think this point must be considered separately in relation to 094 and 804. In the case of 094, I have construed the relevant integers (g) to (n) in paragraphs [139] to [140] above. In my judgment it must be possible to identify a repeating pattern of polygons which have two walls connecting the side walls, one of which has a concave shape and one of which has a convex shape, and that must still be so even if selected side walls have been removed. That is simply not possible in the case of the Abbott products. The connecting walls cannot be distinguished on this basis because they have an undulating shape.

169. In the case of 804 the position is different. The relevant integers are (t) and (u) and I have construed them in paragraph [147]. They simply require the first and second walls to *contain* a concave shape and a convex shape. There is no prohibition against them containing other shapes too. I believe the Abbott products do have connecting walls which contain such shapes and accordingly they satisfy this feature of the claim.

No straight portions connecting the flexure means in the small Vision product

170. This applies to claim 1 of 093 (integer (m)) and claim 1 of 084 (integer (l)). The relevant section of the Vision product is depicted below with the material part circled:



171. Professor Williams was asked about this in cross examination and accepted that laser cutting involves creating a radius and that in 1996 it would not necessarily have been possible to make the radius any tighter than depicted above. I think it is tolerably clear that the flexure means is situated at the end of the strut and is not disposed between

two straight sections. It is joined to the ring by a short curved section of metal which is close to the limit of what could have been achieved at the relevant date. I am not persuaded that the forces exerted on the flexure means are not focused at the point where the flexure means connects to the ring. In my judgment this feature of the claims is not satisfied by the small products

No repeating pattern as required by 804

172. The Abbott products all consist of a single tessellated polygon. Accordingly, Abbott says, claim 1 of 804 is not infringed because it requires rows of two different patterns. I reject this argument for the reasons given in considering the question of construction in paragraphs [144] to [146] above.

Infringement - conclusions

173. To summarise:

i) None of the modified products infringe any of the patents (no substantially flat apices).

ii) None of the products infringe 094 (the polygons do not have a first concave wall and a second convex wall).

iii) The small Vision products do not infringe 093 or 804 (the flexure means is not disposed between two straight sections of the longitudinal struts).

iv) Conversely, the medium original Vision products infringe 093 and 804.

Validity over the prior art

174. The parties dealt with the validity of each of the patents over the prior art before addressing the priority issue because Evysio formally conceded that any claim which loses priority is invalid in the light of the Rotterdam disclosure. In this judgment I shall therefore do the same.

Novelty

175. The attack of lack of novelty based upon the prior art can be dealt with quite shortly. There are only two points:

i) As to claim 1 of 094, Evysio accepts that it is anticipated by the ACS Multi-Link if, as it claims, Abbott's products have flat apices. I have addressed this question in considering infringement. The apices of the original medium Vision product appear almost totally flat and the apices of the original small Vision product have what appear to be a very slight indentation but are still substantially flat. By contrast, the apices of the modified products have a substantially indented external surface and curved internal surface which is virtually indistinguishable from that of the Multi-Link illustrated in paragraph [48] above. In my judgment neither the apices of the modified products nor those of the Multi-Link can be described as substantially flat. This anticipation case therefore fails.

ii) Abbott contends that claim 1 of 093 is anticipated by Medinol if the term "arcuate flexure means" includes any flexure means which is not straight and includes enough slack to allow flexing. I deal with the Medinol disclosure in addressing obviousness but can dispose of this argument now. As I have construed the term (see paragraph [101]), it must have a curved component. The figures of Medinol which are said to deprive 093 of novelty do not. Accordingly, this case also fails.

176. That brings me to the real attack which is obviousness over Medinol and the common general knowledge, including the Multi-Link.

Obviousness – the law

177. The correct approach to obviousness was recently re-stated by Jacob LJ in *Pozzoli v BDMO* [2007] EWCA Civ 588, [2007] FSR 38 as follows:

i) Identify the notional "person skilled in the art"; and identify the relevant common general knowledge of that person.

ii) Identify the inventive concept of the claim in question or, if that cannot readily be done, construe it.

iii) 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.

iv) Ask: 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?

178. So much for the general approach but the parties were both concerned to emphasise important considerations as to how it should be followed. From Evysio's perspective, I accept I must have particular regard to the starting point, which is for the court to assume the mantle of the skilled addressee and to have regard to the nature of the art and both the positive and negative aspects of the common general knowledge.

179. Further, in addressing the fourth and crucial question it is important to recognise that it is easy to be misled by the simplicity of a solution into believing that it must have been obvious. The court has to consider what would have been obvious to the notional skilled but uninventive person in the art at the priority date. As Laddie J reiterated in *Haberman v Jackel* [1999] FSR 683, the simpler a solution, the easier it is to explain. And the easier it is to explain, the more obvious it can appear. This is not always fair to inventors.

180. It is also particularly important to be wary of hindsight when considering an obviousness attack based upon the common general knowledge. The reason is straightforward. In attacking a patent, attention is focussed upon the particular development which is said to constitute the inventive step. With this development in mind it may be possible to mount an attack which is unencumbered by any detail which might point to non obviousness: *Coflexip v Stolt Connex Seaway* (CA) [2000] IP&T 1332 at [45]. It is all too easy after the event to identify aspects of the common

general knowledge which can be combined together in such a way as to lead to the claimed invention. But once again this has the potential to lead the court astray. The question is whether it would have been obvious to the skilled but uninventive person to take those features, extract them from the context in which they appear and combine them together to produce the invention.

181. Conversely, there is no invention in stipulating a feature which is arbitrary and serves no useful purpose. It has long been established that a patent cannot be used to prevent a person from doing what is merely an obvious extension of what has been done or was known in the art before the priority date. The public are entitled to make obvious products using obvious and ordinary techniques. The selection of a number of these products by reference to an arbitrary parameter which has no technical significance does not involve an inventive step and does not create a patentable invention. It involves no technical ingenuity and solves no technical problem.

Obviousness – mere collocation

182. There is one further general matter which I must consider before turning to the particular obviousness attacks. Abbott submits, and I accept, that care is needed where the patent claims a combination of features which merely serve their own purpose within the combination. The mere placing together of old integers so that each performs its own function independently of the others is not a patentable invention. As the House of Lords explained in *Sabaf v MFI Furniture* [2004] UKHL 45; [2005] RPC 10, one must not try to consider as a whole what are in fact two separate inventions. The first step is to determine whether the claim is concerned with a single invention or not. If two integers interact upon each other, if there is synergy between them, they constitute a single invention having a combined effect. If each integer performs its own proper function independently of the others then each is a separate invention and can be considered as such for obviousness purposes.

183. Abbott submits this is just such a case. It says that it became clear from the evidence that the various features of the claimed stents do not interact and that they each simply serve their ordinary function as they did in the prior art. Thus, for example, the curved flexure means provide flexibility, just as they did in Medinol, and the flat apices perform the same function they did in the Multi-Link.

184. I accept Abbott's submission, but only to a point. The flexure means in the longitudinal struts contribute to flexibility and the flat apices are primarily concerned with the behaviour of the stent upon and after expansion. However, I have no doubt that the various elements of the stent geometry do interact to some degree to produce a satisfactory balance of properties. This emerged from the evidence of Professor Rothman and is a matter to which I have referred in addressing the common general knowledge (see paragraph [59]). A structure with flat apices and straight longitudinal struts, such as that of the Palmaz stent and the "box car" of the Palmaz-Schatz stent, has very high radial strength upon expansion because it produces a diamond shaped lattice. But it has very poor flexibility prior to expansion. The coil shaped stents such as the Wallstent and the GR stents are, in one sense, comprised entirely of flexure means and consequently are extremely flexible but have poor radial strength. The AVE and Multi-Link stents each have a ring structure which provides both a measure of flexibility prior to expansion and a measure of radial strength after expansion. In the Multi-Link, this flexibility prior to expansion is derived both from the ability of

the arms of the rings to flex and also from the ability of the longitudinal struts to move relative to those arms. In the case of the NIR, the whole cell elongates or shortens and so confers flexibility on the stent. But, on expansion, a diamond shaped cell is formed which has considerable radial strength. So also Professor Williams agreed in cross-examination that the greater the amount of material in the flexure means of the longitudinal struts, the greater their flexibility; but then it might be more difficult to compress the stent into its pre-expanded position. Overall, he too considered it was fundamental to the design of stents to get a balance of the various competing factors.

185. In the light of the evidence I am satisfied that these patents cannot be considered as simply a collocation of elements which perform their own functions independently of each other. There is an interaction between them which the designer of the stent must take into consideration. Each element cannot be regarded as an individual invention for obviousness purposes.

Medinol – the disclosure

186. Medinol is a PCT application published in February 1996. It discloses two different but related designs of rink and link stent. Both have flexure means in the links and consist of two orthogonal intertwined meander patterns.

187. The first design is clearly revealed from figure 1 shown here with the meander patterns helpfully coloured by Dr Segal:

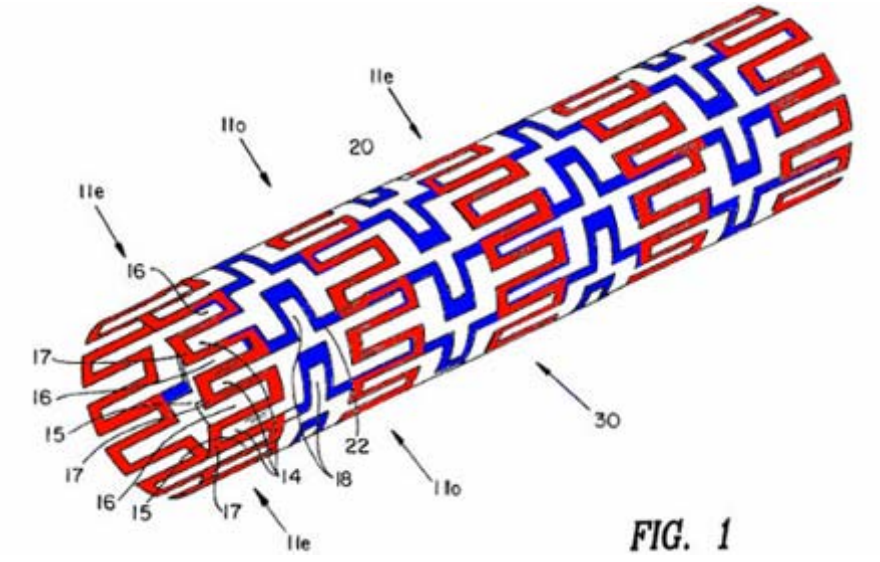


FIG. 1

188. This embodiment has flat apices, square corners and the flexure means situated between two straight sections of the longitudinal struts. The application explains that

the stent is easily deformable and very flexible prior to expansion. As it bends, both meander patterns are involved. The loops on the inside compress and those on the outside expand, as illustrated in figure 3:

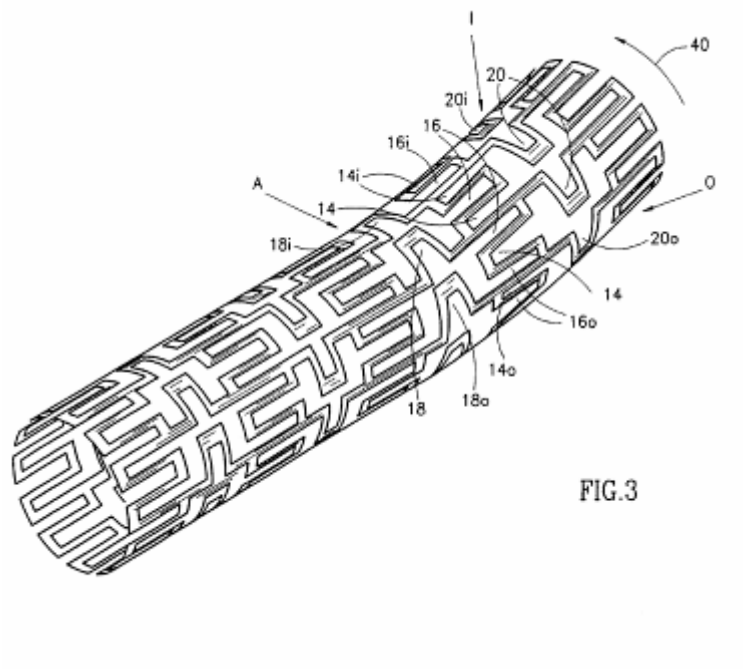


FIG.3

189. Upon expansion, the length of the stent does not change significantly. The expansion of the loops which tend to shorten the stent is matched by the expansion of other loops which tend to extend it.

190. The second design is more rounded and was commercialised as the NIR, as I have described. In this embodiment there are no straight sections and the connectors are entirely curved. It is depicted in figure 7:

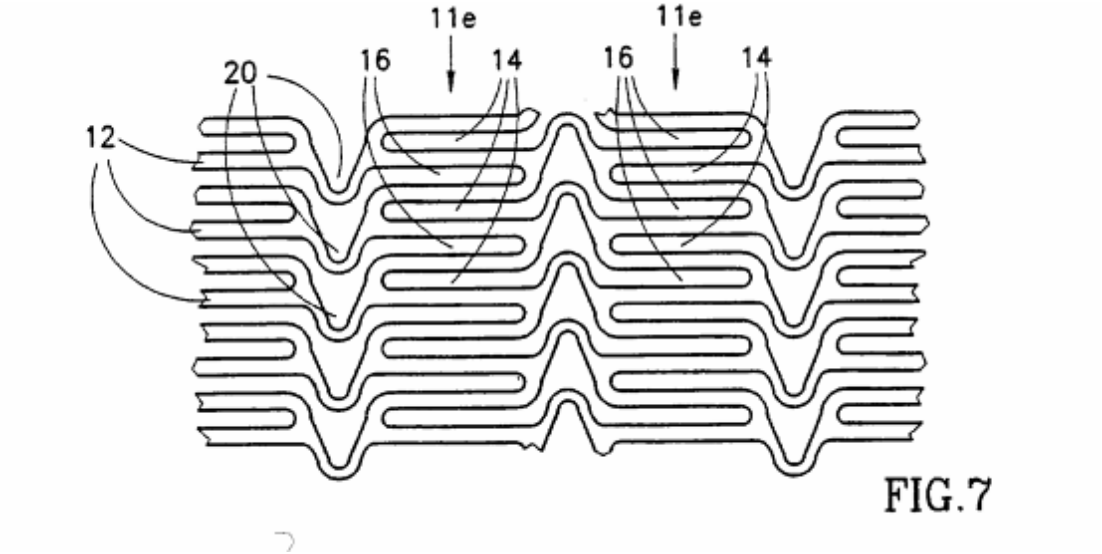


FIG.7

191. Both designs can be recognised as being "out-of-phase" stents, in contrast to those of the patents in suit. This has a particular bearing on the attacks on 094 and 804.

Obviousness – 093

192. There are two attacks on 093 over the prior art: the first based upon a combination of the Multi-Link and Medinol and the second based upon Medinol alone. As for *Pozzoli* questions (i) and (ii), I have identified the person skilled in the art and the common general knowledge and I have construed claim 1 of the patent. I can therefore focus on questions (iii) and (iv).

The Multi-Link and Medinol

193. This attack really begins with the Multi-Link, which Abbott says it was obvious to modify in the light of Medinol. So it is convenient to start by identifying the differences between the Multi-Link and what is claimed. Evysio relies upon only one: the Multi-Link has no arcuate flexure means in the longitudinal struts, as called for by integers (j) to (q).

194. Abbott's case is that it was obvious to introduce flexure means into the longitudinal struts of the Multi-Link in the light of Medinol. It will be immediately apparent that this is a rather unusual attack. What is said is that it was obvious to modify a stent which was part of the common general knowledge in the light of the prior publication of another stent design which was not. It involves a mosaic of these two designs. In my judgment there is nothing to prevent such an attack succeeding as a matter of law, but it must be established on the evidence.

195. The attack was founded upon the following cross examination of Professor Rothman (Day 3, pages 359-360)

> "Q. Now, one of the problems you have with being an expert witness is people put things to you on assumptions. I am about to do that and we see where we get to. The assumption I want you to work on is that in 1996 somebody came to you with the Multi-Link and said, look, this is jolly good, but it is not sufficiently flexible. OK? That is the assumption we are working on. Somebody came to you to do that and sought your advice as to what they should do next. You then did a search through the patent literature to have a look for ideas that might help and you came up with the Medinol patent. So in your left-hand you have the Multi-Link -- I am told this is not sufficiently flexible -- and in your right-hand you have Medinol. OK? That is the assumption that is being put to you."
>
> A. Right.
>
> Q. Obviously you, having read Medinol, would have seen that one of the objectives of Medinol was to make something more flexible and that the way they were achieving that was to put a loop in the middle of the strut or instead of the strut. Correct?
>
> A. That is what Medinol were doing, yes.

> Q. So if Multi-Link was too rigid and you were shown Medinol, it would disclose to you, would it not, the concept of enhancing flexibility by putting a loop in the connecting strut?
>
> A. Yes, it would be putting some form of curve in the connecting strut."

196. It is clear this answer was given upon a number of assumptions: (i) the skilled person was told the Multi-Link was not sufficiently flexible, (ii) the skilled person thereupon undertook a patent search, (iii) the patent search threw up Medinol (perhaps amongst others), (iv) the skilled person identified Medinol as being relevant to the problem with which he had been presented.

197. These assumptions were not explored further with Professor Rothman and Evysio attacked them at every stage. As to assumption (i), I did not have a great deal of evidence. It was not something Dr Segal had suggested in his first report. To the contrary, he said that the Multi-Link was seen as a radical departure from the conventional use of coiled stents for flexibility or "box car" stents for radial strength and that it was perceived to provide both radial strength and longitudinal flexibility in a single structure. He nowhere suggested it was perceived as inflexible although it is fair to say that in his second report he suggested that the flexure means of Medinol could be incorporated into the Multi-Link. Under cross-examination he initially confirmed the radical nature of the Multi-Link design and that it took over the market in the US very quickly. But later, and when asked specifically about inflexibility, he suggested, repeatedly, that one would always try and make a design more flexible. Finally, he was asked if he could think of any technical reason why curved flexure means were not introduced into the Multi-Link at the time of its launch if it was an obvious thing to do. He responded that he could think of a number of reasons, including the fact that that the introduction of flexure means might have other effects. As he explained, once one started incorporating "zigzag" shapes, other structures might have to be changed too. This would involve a design train and many iterations. In consequence there might have been "many, many design aspects that needed to be looked at". As for assumptions (ii) to (iv), I had even less evidence and I was not referred to any cross-examination.

198. In considering Dr Segal's evidence on the question whether it was obvious to seek to modify the Multi-Link, I also take into account that he thought that all designs and all published patents and patent applications in this field were common general knowledge, an approach which I have rejected. Moreover, as I have mentioned, it was quite clear that he had the patents in mind in considering what changes it would have been obvious to make to the prior art – a classic hindsight approach. His evidence on Day 4 at 532 is illustrative:

> "Q. So you had the end result in mind when considering the changes obviously?
>
> A. I had a number of changes in mind and then clearly I had read the patent. So they would have been in my mind at some point.

> Q. Of course. You had the end result in mind when you were considering what changes were obvious.
>
> A. I had the patents in mind, that there were a number of possible changes and I did end up with the result that looked remarkably similar to what was described in the patent."

199. Overall, I am not satisfied in the light of the expert evidence that it was obvious to modify the Multi-Link in the light of Medinol. I am confirmed in this view by the history of the Multi-Link. It obtained European CE approval in December 1995 and FDA approval in October 1997. Thereafter it underwent a series of modifications. But curved flexure means were not incorporated until 2002.

Medinol

200. The obviousness case was essentially mounted on the basis of the first embodiment described in Medinol and illustrated in figure 1. The only difference between this design and the claim is integer (k) in that although Medinol has flexure means as called for by the claim, they are not "arcuate".

201. The case that it was obvious to make this modification is very simple. As I have found, it was common general knowledge that it was desirable to avoid sharp corners (paragraph [58] of this judgment). So, it was submitted, it was entirely obvious to round them off and to make the flexure means arcuate. This would remove the problems of trauma, damage to the balloon and snagging.

202. I believe this to be an extremely powerful argument. Evysio's only answers are these. First, there is no suggestion in Medinol that the angles of the flexure means have any particular significance or should be the focus of possible alteration. Second, if a skilled person was to consider rounding off the loops, why would he not round them all off? Indeed this is what is disclosed in figure 7. But this alteration would also remove the substantially flat apices on which Abbott also needs to rely.

203. I agree that there is no suggestion in Medinol that the angles of the flexure means have any particular significance. The flexure means themselves are important and must be retained. But there is no teaching that they must have sharp angles at their corners and the skilled person would immediately realise the disadvantages of such an arrangement. So it would be obvious to round them off. This would produce arcuate flexure means within claim 1 of 093 as I have construed it, even if those flexure means retained flat portions on one or more of their surfaces. As the patents themselves all make clear, the particular shape of the flexure means is not particularly restricted provided they confer flexibility on the unexpanded stent (see paragraphs [0020] of 093, [0021] of 094 and [0027] of 804). Further, it would have been a trivial modification to round them off completely and to produce flexure means with surfaces which are entirely curved. This would simply be a matter of design choice and another obvious alternative.

204. As for the second point, I accept that yet another obvious alternative would be to round off all the loops and produce a device having the configuration shown in figure 7. But the fact that this is one of the obvious things to do does not make the other

routes I have described any less obvious, as Laddie J explained in *Brugger v Medic-Aid* [1996] RPC 635 at 661.

205. I am conscious that a stent designer would be aware that small changes can produce unpredictable consequences and that the technical features of a stent are often interrelated. However the change required here is small and would bring well recognised benefits. In my judgment the case of obviousness based upon Medinol and the common general knowledge is unanswerable. Claim 1 of 093 is invalid.

Obviousness – 094

206. There are two attacks on 094 over the prior art. The first is based upon Medinol and the second upon the Multi-Link. I can again go straight to *Pozzoli* questions (iii) and (iv).

Medinol

207. The attack is based upon the first embodiment, as shown in figure 1. In relation to claim 1 of 094 the differences which are said to exist, as I have construed the claim, are (i) there is no repeating pattern comprised of a polygon having a concave shaped first wall and a convex shaped second wall as called for by integers (h) to (l); and (ii), the first apex and the second apex do not have different lengths as called for by integer (q). It is to be remembered that claim 1 does not require flexure means at all. This is introduced by claim 6, but the flexure means are not required to be arcuate or between two straight sections of the longitudinal struts. Consequently, no further differences are relied upon in relation to claim 6.

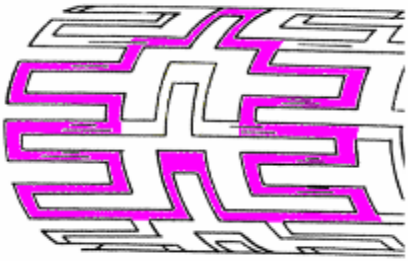
208. The key difference comes down to this: the Medinol design is "out-of-phase" whereas 094 requires a design which is "in-phase". Abbott says this is a mere workshop modification. Thus claims 1 and 6 are obvious over Medinol, based upon the routine decision to consider an "in-phase" variation of it. In support of this argument, Abbott particularly relies upon the evidence of Professor Williams on Day 5 at 715-717:

> "Q. I am now talking to you as a quasi-engineer. If you are going to have a ring and link design, as a designer you have to decide how you are going to connect the rings to the links.
>
> A. Well, I think by definition, yes.
>
> Q. And some designers would choose to have it in-phase and some would choose to have it out-of-phase?
>
> A. No, I don't agree.
>
> Q. You don't think there is scope for having a design with in-phase and a design .... Well, let's start from the beginning. You would appreciate that you could design with something in-phase and something out-of-phase?
>
> A. I appreciate that the design you produced could be in-phase or out-of-phase, but I do not think that the phase itself was of any significance. Phase is not part of the design specification.

> The phase that you see, whether it is in or out, is a consequence of your design, not a driver of the design.
>
> Q. Right, the consequence of the design being that you know you would get different mechanical properties if you organize something in-phase as opposed to out-of-phase.
>
> A. Possibly.
>
> Q. And you would use your engineering knowledge in any particular case to decide whether it was better to have in-phase or out-of-phase.
>
> A. Whether it is in or out-of-phase is a very, very minor consideration as to how you design it. That is what I am trying to say.
>
> Q. I understand that, but you would have to make a decision.
>
> A. You would make a decision on your design. Whether it is in-phase or out-of-phase largely is not relevant. You can see whether it is in-phase or out-of-phase afterwards, but that is not how you design it."

209. I have to say I understood the evidence of Professor Williams in a quite different way, as I have explained in paragraph [70] of this judgment. He was not saying that choice of phase was a common general knowledge option but rather something that one might consider once the design had been arrived at. To turn Medinol into an "in-phase" design would involve a substantial redesign. The rings would have to be "flipped" over and the connectors appropriately modified. There is no suggestion in Medinol that this is contemplated and I am not satisfied in the light of the evidence as a whole that it was an obvious thing to do.

210. At this point I should make clear that I have reached this conclusion on the basis of the claim as I have construed it. However, it is to be noted that, in addressing the question of infringement, Evysio urged a broader interpretation on the basis that the patent taught that selected side walls could be omitted and that it was enough that the two walls contained, respectively, a concave and a convex portion. Had I accepted this argument, then the effect of the phase difference disappears, as the following diagram shows:

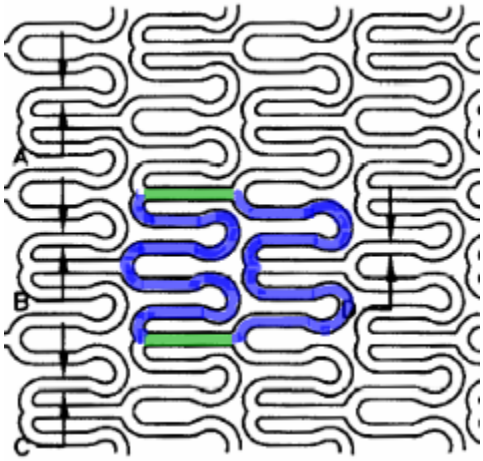


211. The colouring shows a complex polygon which includes a concave portion in one wall and a convex portion in the other. Of course, it has a strut running down its centre. But the 094 patent specifically contemplates that this may be the case, as I have explained in paragraphs [134] and [135] above.

212. The only other arguable difference is that the apices are not of different lengths. Dr Segal considered that in Medinol the apices are of different lengths once the strut has been taken into account. I am not persuaded that is so. However, I have no doubt that the decision as to what length each should be is an entirely routine part of the design process and affected by such things as space considerations as illustrated, for example, in the Multi-Link itself. Accordingly, had I accepted the broader interpretation of 094, I would have found claims 1 and 6 invalid.

Multi-Link

213. The only difference between the Multi-Link and claim 1 upon which Evysio relies is the absence of a substantially flat apex, and it is one that depends upon construction. It will be recalled that Evysio's primary argument is that the Multi-Link does have a substantially flat apex as called for by integer (o), as does the modified Vision stent. But this is an argument I have rejected in dealing with construction and infringement. Accordingly, it is a relevant difference. But, as I have construed the claim, there is another one too. The Multi-Link does not have a repeating pattern comprised of a polygon having a concave shaped first wall and a convex shaped second wall as called for by integers (g) to (n). Instead, it has a complex repeating pattern as shown in the illustration at paragraph [48] of this judgment and highlighted in this diagram of how the stent would appear if rolled out flat:



214. This diagram also conveniently illustrates the absence of a substantially flat apex. The relevant apex to consider for this purpose is the wider one in the right hand wall and from which the two arms and a strut depend. The question to be answered is whether it was obvious to make it substantially flat. In my judgment this question admits of only one answer. It plainly was. The experiments and the arguments in relation to infringement show that flattening the outer surface makes no difference to how the stent functions. The arms are spaced a substantial distance apart and oriented orthogonally to the apex. In such an arrangement, it is an entirely arbitrary design choice as to whether to make the surface flat or curved. Moreover, it is a choice which

involves no technical ingenuity, solves no technical problem and brings no technical advantage.

215. The second difference is more substantial. As can be seen, the Multi-Link does not have two connecting walls, one of which is concave and one of which is convex, and to modify it so that it does would require the addition of further longitudinal walls. I have no evidence that this would have been an obvious step to take and it would, no doubt, have reduced the flexibility of the stent.

216. I conclude that claim 1 is not obvious over the Multi-Link. However, had I construed the claim in the way urged by Evysio then a finding of obviousness would have followed.

217. As to claim 6, the difference is that the longitudinal struts of the Multi-Link contain no flexure means. It was not established on the evidence that it was obvious to take this step in the light of the common general knowledge and this attack on claim 6 therefore fails.

Obviousness - 804

218. I can now deal with this quite shortly. In the light of my previous findings the case only runs over Medinol. The only arguable differences between the first embodiment of Medinol and claims 1 and 23 are the absence of repeating walls containing concave and convex shapes (integers (t) and (u)) and the absence of curved flexure means (integer (n)).

219. As to the first, Medinol does comprise a repeating pattern of polygons having a first wall which *contains* a concave shape and a second wall which *contains* a convex shape, as I have explained in paragraphs [210]-[211] above. As in the case of 094, it matters not that there is a strut down the middle of the polygon for in this respect the teaching of 804 and 094 is the same.

220. As to the second, it was obvious to make the flexure means curved for the reasons I have given. Accordingly the obviousness case based upon Medinol and the common general knowledge succeeds.

Obviousness – conclusions

221. The attacks on 093 and 804 over Medinol and the common general knowledge succeed. The attacks on 094 fail.

Priority and added matter

222. As mentioned at the outset, Evysio filed four patent applications in Canada during the course of 1996, the first on 5 March and the last on 10 December. On 5 March 1997, it filed two PCT applications which are extremely similar to each other and claimed priority from each of those earlier Canadian applications. In due course, 093 and 804 were granted upon application WO/1997/032543 and 094 was granted upon application WO/1997/032544. The claim to priority is vital to validity because the Rotterdam disclosure took place on 11 December 2006. Eyysio maintains that each of

the patents is entitled to priority, at least from the fourth and final Canadian priority application, but this claim is challenged by Abbott.

223. Abbott also contends that the 093 and 804 patents are invalid because they have been amended in such a way that they disclose matter which was not disclosed in the PCT applications as filed. As will be seen, this is a closely related objection both in law and on the facts and so it is convenient to deal with the law on both issues at the outset. However, as will also be seen, it ultimately adds little or nothing to the priority attack.

Priority – the law

224. An invention in a patent application is entitled to the date of an earlier priority application in the circumstances provided for in section 5(2)(a) of the Patents Act 1977, namely the invention is "supported by matter contained in the earlier relevant application or applications". Section 5 is one of the sections said by section 130(7) to have been framed to have, as nearly as practicable, the same effect in the UK as the corresponding provisions of the European Patent Convention (the "EPC"), in this case Articles 86-88.

225. Evysio submits that the correct approach is to consider the invention in the claims of the patents said to lack priority and decide what they claim to enable the skilled man to do. Then the disclosure of each of the priority documents as a whole must be considered and the question asked "would a skilled man reading their disclosure with the common general knowledge have obtained enough information to work the invention now claimed?" To put it another way, is the disclosure of the priority document limited to specific embodiments or is it capable of more general application?

226. I do not accept this submission. Enablement is certainly one of the requirements of a successful claim to priority. Such was established by the House of Lords in *Asahi Kasei Kogyo Application* [1991] RPC 485. However, it is not the only one. The general and overriding requirement was established by the Enlarged Board of Appeal of the EPO in *G02/98 Same Invention*, [2001] OJ EPO 413; [2002] EPOR 167:

> "The requirement for claiming priority of 'the same invention', referred to in Article 87(1) EPC, means that priority of a previous application in respect of a claim in a European patent application in accordance with Article 88 EPC is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole."

227. This was explained by the Court of Appeal in *Unilin Beheer v Berry Floor* [2004] EWCA (Civ) 1021; [2005] FSR 6 at [48]-[50]:

> "48. …….The approach is not formulaic: priority is a question about technical disclosure, explicit or implicit. Is there enough in the priority document to give the skilled man essentially the same information as forms the subject of the

> claim and enables him to work the invention in accordance with that claim.
>
> 49. Before going to the details of the priority document in this case I should deal with Mr Carr's submission about the main claim or consistory clause of the priority document, *i.e.* that although not determinative it is nearly so. That he could not get out of *GO2/98* or indeed any other authority. *GO2/98* refers to "the previous application as a whole," not the main claim nor the "main statement of invention" nor the "consistory clause". Likewise there is nothing in Art.87 which compels or suggests this conclusion. And Art.4H of the Paris Convention is positively against it. The claims (if any—there is no rule that there should be) of the priority document are not determinative. They are just part of its disclosure. For the purposes of priority one just looks at the disclosure as a whole.
>
> 50. If the rule were otherwise one of the main functions of a priority document would be lost. Inventors and their advisors would have to start worrying not only about the technical information disclosed in the document but how it was to be claimed: have I drafted my main claim or consistory clause broadly enough? That is not the purpose of the system: the purpose at this point is to get the information justifying the later claim into a patent office of a Union country. If you do that, you can have your priority, whether you express that in a proposed claim, consistory clause, statement of invention, other text or drawing or in any combination of these. Time is of the essence because the world-wide system (except for the Americans) works on the first to file basis. The detailed framing of a claim based on that information may then be done within the Convention year."

228. So the important thing is not the consistory clause or the claims of the priority document but whether the disclosure as a whole is enabling and effectively gives the skilled person what is in the claim whose priority is in question. I would add that it must "give" it directly and unambiguously. It is not sufficient that it may be an obvious development of what is disclosed.

Added matter – the law

229. Section 72(1)(d) of the Act provides a power to revoke a patent if the matter disclosed in the specification of the patent extends beyond that disclosed in the application for the patent as filed. This is another provision said by section 130(7) to have been framed to have, as nearly as practicable, the same effect in the UK as the corresponding provision of the EPC, in this case Article 123(2).

230. The test for added matter was explained by Aldous J in *Bonzel v Intervention Ltd* [1991] R.P.C. 553 at 574:

> "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:
>
> (a) To ascertain through the eyes of the skilled addressee what is disclosed, both explicitly and implicitly in the application.
>
> (b) To do the same in respect of the patent as granted.
>
> (c) 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."

231. It is apparent that the approach to be adopted is essentially the same as that for priority. In *European Central Bank v Document Security Systems* [2008] EWCA Civ 192 the Court of Appeal approved at [12] this elaboration of the test from the judgment at first instance:

> "97. …..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] R.P.C. 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."

232. These principles prohibit the patentee from altering his claims in such a way that they claim a different invention from that disclosed in the application when read as a whole. This includes a prohibition against what is called intermediate generalisation, as the Court of Appeal explained in *LG Philips v Tatung* [2006] EWCA Civ 1774; [2007] RPC 21 at [30]-[32]:

> "30. In *Southco Inc v Dzus Fastener Europe Ltd* [1990] R.P.C. 587, Aldous J. said this at 616:
>
> > "There is no definition in the Act of what is meant by the word 'matter' and I believe that this word is wide enough to cover both structural features of the mechanism and inventive concepts … What the Act is seeking to prevent is a patentee altering his claims in such a way that they claim a <u>different invention</u> from that which is disclosed in the application. Thus, provided <u>the invention</u> in the amended claim is disclosed in the application when read as a whole, it will not offend against section 76 …".
>
> 31. Assistance is also to be derived from the observations of Pumfrey J. in *re Palmaz's European Patents (UK)* [1999] RPC 47 at 70 and 71. At 70, he said that, following the decision

of the Enlarged Board of Appeal in G01/93 *Advanced Semiconductor Products* [1995] EPOR 97:

> "It is the settled practice of the EPO … to permit amendments … to add references to prior art in the body of the specification, and to permit limitation of the claim by reference to the prior art so acknowledged. … The acknowledged prior art will itself disclose the distinguishing feature, which is obviously unlikely to be disclosed in the patent in suit, but of course caution must be exercised where the patentee himself describes the prior art in terms which he proposes to use in the limitation of his claim."

32. Pumfrey J. expanded on this on the following page, where he said this:

> "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 are not disclosed as having any inventive significance and introduce them into a claim deprived of that context. That is a process sometimes called 'intermediate generalisation'."

He then went on to allow two amendments on the basis that they did not "add matter not in substance disclosed in the specification". He then turned to a third amendment which he disallowed because it represented:

> "the selection of a particular feature whose significance is nowhere disclosed, and its incorporation into the inventive concept shorn of its original context.""

233. But they permit the inclusion of a disclaimer if it is added to avoid an accidental anticipation and has nothing to do with the invention, as the Court confirmed in *LG Philips* at [33] to [34]:

> "33. The law on added matter was considered again by the Enlarged Board of Appeal, in a case where the amendment involved a disclaimer narrowing the claim, in G1/03 *PPG Industries Disclaimer* [2004] EPOR 33. The effect of that decision is that a specific disclaimer does not add matter (contrary to Art.123(2) of the European Patent Convention — equivalent to s.76), if it is inserted into a claim to avoid an "accidental" anticipation, but it does add matter if it is inserted to avoid a "non-accidental" anticipation—see part 2 of the decision. An accidental anticipation involves a:

> "disclosure … belong[ing] to a remote technological field or [one whose] subject-matter suggested it would not help to solve the problem [addressed by the patent in question]".

In other words, "the disclosure has to be completely irrelevant for assessing the inventive step"—see [37].

34. A little later in the same paragraph, the Enlarged Board identified an accidental anticipation in slightly different words, but to much the same effect, namely that:

> "the disclosure in question must be so unrelated and remote that the person skilled in the art would never have taken it into consideration when working on the invention".

In conclusion on this topic, in [44], the Enlarged Board said that :

> "When an anticipation is taken as accidental, this means that it appears from the outset that the anticipation has nothing to do with the invention. Only if that is established, can the disclaimer be allowed.""

234. Article 123(2) does not prohibit the derivation of features from the drawings of an application and they are to be treated on an equal footing with other parts of the document. However, it is the practice of the EPO only to allow amendments to introduce such features into the claims where the structure and function of such features is clearly and unambiguously derivable from the drawings and it is possible to isolate them from the other features shown.

The priority points

235. There are five priority objections and I will deal with them in turn. In doing so I will refer, where necessary, to the fourth priority document. This contains all the disclosures of the earlier three, and a little more.

(i) *Flexure means permitting substantially complementary extension and compression*

236. This objection is taken against claim 1 of 093, claim 6 of 094 and claim 1 of 804. It is said the priority documents do not disclose the claimed feature of flexure means permitting substantially complementary extension and compression of a diametrically opposite pair of struts.

237. Abbott submits that while the priority documents disclose that the flexure means assist the stent as a whole to bend and flex as it travels through tortuous blood vessels, they do not disclose the amount of extension or compression in any individual strut. Specifically, they do not include the explanation which appears in paragraph [0019] of 093 which I have discussed in addressing the teaching of that specification. Further, they certainly do not disclose that the length of compression of one strut must be equal to the length of extension of a corresponding (diametrically opposed) strut.

238. It seems to me that the merit of this argument must depend upon the proper construction of this feature. For the reasons I have given, I have concluded that it does not call for any particular degree of compression or extension in each individual strut. It simply means that, as the stent flexes, the struts on the inside of the bend compress while those on the outside of the bend extend. In this way there is substantially complementary extension and compression of diametrically opposed struts Although this may not be the immediately obvious interpretation of the feature, it is how the patentee has chosen to define it. Figure 8 depicts S shaped flexure means and the fourth priority document explains that these improve the lateral flexibility of the stent. It would be perfectly clear to the skilled person that, as the stent flexes, the struts on the inside of the bend must compress and those on the outside of the bend must extend. Moreover, the fourth priority document contains a passage at page 17, lines 5 to 11, which is very similar to that of paragraph [0062] of 093. This says in terms that the provision of the S shaped portions allow the inner stent surface to compress while concurrently allowing the outer stent surface adjacent the bend to extend. This attack therefore fails.

(ii) No disclosure of or support for a definition of "diametrically opposed" struts permitting such struts to be in different horizontal planes

239. This objection is again taken against claim 1 of 093, claim 6 of 094 and claim 1 of 804.

240. Abbott says, correctly, that the definition of "diametrically opposed" in the patents (for example, at paragraph [0020] of 093) did not appear in any priority document.

241. Moreover, the argument goes, the definition discloses for the first time that if a flexure means in a given ring on one side of the stent compresses, then that compression may be compensated for by the extension of a flexure means on the other side of the stent (and not necessarily even truly diametrically opposed, but only approximately) in a *different* ring.

242. Once again it seems to me this objection depends upon the proper interpretation of this and the immediately preceding feature. Had I construed them to require, as Abbott argued, there must be struts set 180 degrees apart which extend and compress to the same degree then I think I would have found the objection unanswerable. However, I have not. All these features require is that the struts on the outside of the bend extend whilst those on the opposite side, that is to say the inside of the bend, compress. The fourth priority document discloses, as do the patents, that one or both of the side walls can be omitted at selected points to improve the flexibility of the stent. Moreover, it would be a nonsense to suppose the patentee intended to limit his monopoly to stents with only an even number of struts. All these points would make it plain to the skilled person that the patentee intended opposed struts to extend and compress whether or not they are set at precisely 180 degrees to each other and even if they are in adjacent rings. In summary, the teaching of paragraph [0020] of 093 makes clear that the patentee meant no more by this limitation than would have been immediately apparent to the skilled person on reading the fourth priority document and considering its figures. Accordingly, this attack also fails.

(iii) *There is no disclosure, or support for, curved flexure means disposed between two straight sections other than curved flexure means in the form of a generally "S" shaped double bend. There is no support in the priority documents for such a generalised feature.*

243. This objection applies to 093 and 804 and it relates to the flexure means. In summary, Abbott says that the only disclosure of flexure means between two straight sections in the priority documents involves the use of an S shaped flexure means, whereas the granted claims allow the use of any arcuate or curved shaped flexure means between two straight sections.

244. The argument begins with the disclosure of the fourth priority document. This includes figures 8, 9 and 10, which essentially correspond to figures 8, 9 and 10 of 093. They are the only figures to show flexure means between two straight sections (and then not always) but the flexure means so situated always has an S shape. Importantly, the fourth priority document does not include a figure corresponding to figure 12 of 093.

245. The text of the fourth priority document describes how, in a preferred embodiment, the strut is curved with respect to the longitudinal axis and how, in another preferred embodiment, the strut or the side walls comprise a sinusoidal or S shaped section. However, in so far as it describes the positioning of this section, it says that it is preferable that the S shaped portion is *adjacent the second apex of the polygon* or *disposed at an end of the side wall.* In other words, it says that the flexure means should be joined directly to the ring at one end. It is said this improves the lateral flexibility of the stent, thereby facilitating implantation, and that it may mitigate longitudinal shortening of the stent upon expansion (page 7, line 26 – page 8, line 10).

246. In summary, the fourth priority document only discloses two straight sections in conjunction with an S shaped flexure means and even then attaches no weight to this positioning. It is silent as to the purpose of having two straight sections. Indeed, it says that preferably the S shaped flexure means is not placed between two straight sections at all but rather adjacent to the ring.

247. Turning now to the claims of 093 and 804, these generalise the S shaped portion to any curved or arcuate shape. Abbott says that Evysio has taken part of the figures (two straight sections) out of context (by omitting the S shaped flexure means) in the absence of any teaching of the purpose of the feature in question and this amounts to an illegitimate intermediate generalisation. Worse still, Evysio relies upon the feature of two straight sections as bringing a technical advantage, namely that it isolates the deformation of the flexure means from the rings.

248. Evysio's answer to this allegation takes as its starting point figures 1 to 3 of the fourth priority document. These depict longitudinal struts which are straight and the document teaches that the benefit of such struts is that they mitigate the lifting of the shoulders of the stent as it flexes.

249. Evysio then turns to the description on page 7, lines 19-25 of the fourth priority document. This explains that in a preferred embodiment the strut is curved and that this feature improves the lateral flexibility of the stent. Such curved struts are illustrated in figures 4 to 7.

250. Finally, Evysio relies on the passage from page 7, line 26 to page 8, line 23 which discloses the S shaped flexure means. It points specifically to the statement on page 8, lines 11-14 that the precise shape of the S shaped portion is not particularly restricted.

251. In the light of all these passages Evysio submits that the use of straight sections is not dependent on what comes between them. The disclosure of the priority document is to start with straight sections and then do various things to them to improve flexibility. They can be curved completely or flexure means can be added in, the shape of which is not particularly restricted. Further there is a disclosure of curved shapes which are not directly connected to the apices but are separated by straight sections. There is no suggestion that the straight sections can only exist with S shaped portions or that they are dependent on having S shaped portions.

252. I believe Evysio's submissions require a little qualification. As to the first point, I accept that figures 1 to 3 of the fourth priority document depict longitudinal struts which are straight and the document itself teaches that the benefit of such struts is that they mitigate the lifting of the shoulders of the stent as it flexes. However, the straight struts comprise no flexure means and so can provide no support for the placement of flexure means in any particular position.

253. As to the second point, I accept that figures 4 to 7 depict curved struts. But the struts are curved along their whole length. The curves are not disposed between two straight sections. Once again, they cannot provide support for the placement of curved portions at any particular location along the strut.

254. As to the third point, the teaching about the S shaped flexure means on page 8, lines 11-14 must be considered with care. It is not saying that the precise shape of the flexible portion is not particularly restricted, but rather that the precise shape of the S is not restricted. It is to be contrasted with the statement in the 093 patent at [0020] that the specific shape of the flexure means is not particularly restricted provided that it confers lateral flexibility upon the stent. However, this statement is not entitled to priority.

255. After careful consideration, I have come to the conclusion that Abbott's submissions on this point are to be preferred. The fourth priority document discloses that the longitudinal strut may preferably be curved and may preferably contain an S shaped section. It contains figures which show that the S shaped section has been placed sometimes (but not always) between two straight sections of the strut. However, there is no teaching that placing the S shaped section in this position has any technical significance or is any part of the inventive concept. Nor is there any teaching that the S shaped portion, still less any other curved flexure means, is desirably placed between two straight sections for any other reason. To the contrary, the priority document teaches that the S shaped section is preferably placed adjacent to the ring. Yet the inventions of the 093 and 804 patents now extend to and require the use of two straight sections with any curved flexure means. The feature of two straight sections has been stripped out of the limited context in which it appeared in the fourth priority document and introduced into the claims of the patents. The use of two straight sections is now suggested to have a technical significance and relevance to the claimed inventions for any curved flexure means. I do not believe that the skilled person could derive this feature directly and unambiguously from the priority application. In my judgment these claims are not entitled to priority.

(iv) *As to the 804 patent, the disclosure of the priority documents are limited to polygons with concave and convex walls connecting the side walls and there is no disclosure of the generalised feature of polygons without each having such a concave and a convex wall*

256. The objection is to claims 1 and 23. Abbott argues that the description and figures of the fourth priority document only disclose a repeating pattern of polygons with a convex shaped wall at one end and a concave shaped wall at the other end. It says this provides no support for claim 1 of 804 in which the shape of the wall is completely unspecified, or claim 23 which only requires the first and second walls to *contain* a convex and a concave shape. In this respect claim 23 is to be contrasted with claims 19 and 20 which call for the walls themselves to *have* a concave and convex shape.

257. Evysio responds to this objection by making an unconditional application to amend the patent by combining claims 1 and 23. But Abbott says this does not go far enough because the claims still describe and encompass a polygon which has complex, undulating walls which *each* have *both* convex and concave shapes and this is not disclosed in the fourth priority document.

258. Once again, I have reached the conclusion that Abbott's objection is a good one. Page 5 of the fourth priority document describes how the invention provides a stent with a surface of intersecting members so arranged as to define a repeating pattern of polygons which comprise a concave shaped first wall and a convex shaped second wall, with each of these walls having an apex, at least one of which is substantially flat. Page 5, line 21 to page 6, line 6 explains that the use of such a specific pattern is particularly advantageous. It also explains that the terms "concave-shaped" and "convex-shaped" are intended to have a broad meaning and include a shape having an apex. However, it continues, the first apex (ie of the concave-shaped first wall) is directed into the polygon whereas the second apex (ie of the convex-shaped second wall) is directed away from the polygon. As shown in the figures, such an arrangement does indeed produce a repeating pattern. Moreover, this description is of a polygon which has a first wall which is recognisably concave and a second wall which is recognisably convex. The two walls are therefore distinguishable because of their respective concave and convex shapes. This arrangement, with at least one flat apex, is said to produce the advantages described on page 6.

259. Thus far, the description is relatively clear. However, the fourth priority document also contains the teaching to which I have referred in considering the proper interpretation of the 094 and 804 patents in paragraphs [93], [136], [139]-[140] and [147] of this judgment. This teaching appears on page 13, lines 5 to 12 of the fourth priority document and again says that it is possible to omit one or both side walls at *selected* points along the body of the stent. In the context of a description of a stent which has a repeating pattern of polygons comprising a concave shaped first wall and a concave shaped second wall, I believe the skilled person would understand there must still be a recognisable pattern of the kind described, even if occasional side walls have been omitted. I do not believe he would understand this to be a description of a stent comprising only polygons of complex shapes with first and second walls which each have both concave and convex portions, that is to say shapes of the kind depicted in paragraphs [150] and [151] of this judgment. As I have explained, he would only come to the conclusion that the patentee had contemplated such stents in the light of clear words to that effect; words such as are to be found in claim 23 of 804 which

simply require the first and second walls to *contain* a concave shape and a convex shape. These words are, as I say, to be contrasted with the words of claim 1 of 094 and claims 19 and 20 of 804. They do not appear in the priority documents. This priority objection therefore succeeds.

(v) *As to the 804 patent, the disclosure of the priority documents are limited to laser cutting the stents from tubular starting materials and there is no disclosure of the generalised feature of cutting the stent from tubular starting materials by any means*

260. Abbott says that the claims of the 804 patent are generalised in that they are to stents made by cutting from a tubular material, but means of cutting is not specified and, in particular, there is no limitation to laser cutting which is the only means of cutting described in the fourth priority document.

261. I reject this attack. The fourth priority document says in terms at page 19, lines 23-24:

> "The manner in which the present stent is manufactured is not particularly restricted"

262. It is true that it goes on to say the stent is preferably produced by laser cutting, but there is plainly a disclosure of manufacturing by any means. I should also note that Evysio offered to amend to limit the claims to laser cutting had I come to a contrary conclusion.

Added matter

263. There are three added matter objections and they are closely related to the priority objections. The first is an attack on 093 and 804 and concerns the requirement that there be arcuate or curved flexure means between two straight sections, a feature added during the course of prosecution. The second and third are directed to 804 only. They are the same as the priority objections (iv) and (v) and are accepted to stand or fall with them.

264. The first objection is that the application for the 093 and 804 patents did not disclose that having arcuate flexure means disposed between two straight sections was of technical and inventive significance. However, when the claims were amended to introduce this feature, such a disclosure was made. Moreover, paragraphs [0015] and [0016] of 093, which were introduced during the course of prosecution (and to which I have referred in paragraph [77] of this judgment), disclose the nature of this technical significance by reference to the prior art in explaining, for the first time, that the advantage of the claimed arrangement is that it avoids focussing the stress directly on the point where the longitudinal strut joins the adjacent rings.

265. Abbott properly drew my attention to the fact that the application contains an additional relevant disclosure in the form of figure 12. In the light of this figure, Abbott accepts that its case on added matter is no better than its case on priority. If it does not win on the latter, it cannot win on the former. I propose therefore to say no more about it, save for this. I believe that paragraphs [0015] and [0016] of 093 do add matter in a way I have not expressly addressed in considering the priority objection. These describe the technical significance of the two straight sections and confirm that the limitation to the claim is relied upon as providing an inventive advance which, in

my judgment, is simply not disclosed in the fourth priority document or in the application.

Sufficiency

266. I have construed the claims. The term "substantially flat" can be understood and I accept Evysio's submission that the skilled person can construct a stent with a substantially flat apex. The allegation that the patents are insufficient therefore fails.

Conclusion

267. My conclusions are as follows:

i) 093 and 804 are invalid but would have been infringed by the original medium Vision and Xience stents.

ii) 094 is valid but not infringed.