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**Datasheet for the decision
of 17 November 2009**

Case Number: T 0487/08 - 3.2.02

Application Number: 00121964.1

Publication Number: 1066804

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:

Expandable stent

Patentee:

EVYSIO MEDICAL DEVICES ULC

Opponent:

Guidant Corporation

Intervener:

Abbott Vascular Devices

Headword:

-

Relevant legal provisions:

EPC Art. 52(1), 54, 56, 87, 100(a), 100(c)

Relevant legal provisions (EPC 1973):

-

Keyword:

"Added subject-matter (no)"

"Right to priority (yes)"

"Novelty (yes)"

"Inventive step (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 0487/08 - 3.2.02

DECISION
of the Technical Board of Appeal 3.2.02
of 17 November 2009

Appellant: EVYSIO MEDICAL DEVICES ULC
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 25 February 2008
revoking European patent No. 1066804 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: M. Noel
Members: S. Chowdhury
A. Pignatelli
C. Körber
M. J. Vogel

Summary of Facts and Submissions

- I. The appellant (patent proprietor) lodged an appeal against the decision of the Opposition Division to revoke European patent No. 1 066 804.
- II. The opposition was filed against the whole patent and based on Article 100 (a) (lack of novelty and inventive step) and Article 100 (c) EPC 1973.

A notice of intervention was filed by the intervener who alleged that infringement proceedings were instituted against them by the patent proprietor.

- III. With its decision posted on 25 February 2008 the Opposition Division held that:
- The opposition was admissible.
 - The intervention was admissible.
 - Claim 1 of all the requests (main request and auxiliary requests 1 to 6) was objectionable under Article 123 (2) EPC 1973.
 - Claim 1 of the contested patent did not have the right to priority of any one of the four Canadian applications from which it claimed priority.
 - The video presentation D23 was a public prior disclosure which was not subject to any confidentiality restrictions and was prior art, accordingly.
 - The stent of claim 1 lacked novelty in view of D23.

The patent was revoked, accordingly.

A notice of appeal against this decision was filed by the patent proprietor on 7 March 2008 and the appeal fee was paid on the same day. The statement of grounds was submitted on 4 July 2008.

IV. The following prior art, cited in the opposition procedure, is of particular interest in the appeal procedure:

D1: WO-A-96/03092

D2: US-A-5 449 373

D3: US-A-5 104 404

D4: US-A-5 607 442

D6: EP-A-0 669 114

D10: WO-A-96/14028

D11: WO-A-95/26695

D19: WO-A-98/30173

D23: Video presentation at Rotterdam on 11.12.1996

D24: EP-A-0 540 290.

V. Oral proceedings were held on 17 November 2009. The following requests were submitted:

The appellant requested that the decision of the opposition division be set aside and that the patent be maintained as granted.

The respondents (opponent and intervener), who did not attend the oral proceedings, requested in their written submissions that the appeal be dismissed.

VI. Claim 1 as granted reads as follows:

"An unexpanded stent, comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of intersecting members comprising rows of a repeating pattern (A, B) comprised of a polygon having a pair of longitudinal struts (735, 740, 770, 835, 840, 870, 935, 940, 970) substantially parallel to the longitudinal axis, a first wall and a second wall connecting the longitudinal struts, longitudinal struts comprising flexure means (736, 741, 771, 836, 841, 936, 941, 971) disposed between a first straight section and a second straight section, 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; characterized in that the flexure means (736, 741, 771, 836, 841, 936, 941, 971) are curved and allow for substantially complementary extension and compression of a diametrically opposed pair of the longitudinal struts (735, 740, 770, 835, 840, 870, 935, 940, 970) upon flexure of the stent; in that the first and second walls are shaped with an apex, wherein at least one of the apices in the first and second walls is substantially flat; and in that the stent is cut out of a tubular starting material".

VII. The parties argued as follows:

Appellant

Inadmissible amendments

The first paragraph on page 20 of WO 97/32543 provided adequate support for the feature that the stent may be cut from a tubular starting material by methods other than by laser cutting, and claim 7 of this document provided support for a polygon having walls which were not necessarily concave and convex.

Priority claim

The third and fourth priority documents (Figure 6) provided a clear and unambiguous teaching of a curved non-sinusoidal or S-shaped flexure means. According to paragraphs [0017] and [0018] of the published application [the A-document] the terms "complementary extension and compression" and "diametrically opposed" should be broadly interpreted and did not require mathematical equality, and this broad interpretation of the behaviour of the stent was disclosed in all the priority documents.

Inventive step

The use of a stent with a repeating pattern and substantially flat apices had several advantages, listed in paragraph [0034] of the patent in suit. In particular the force required to expand the stent was substantially reduced, plastic deformation of the stent during expansion was facilitated, and warpage of the apex upon expansion of the stent was mitigated.

Another problem addressed by the patent in suit was that of longitudinal flexibility of the stent upon expansion thereof, and the real problem posed by the

patent was to achieve a balance between the radial rigidity of the patent in the expanded state and the lateral flexibility of the stent in the unexpanded state. This was not suggested by any prior art.

Respondents (by written submissions)

Inadmissible amendments

The opposition division was correct in deciding that the features of claim 1 "cut out of a tubular starting material" and "a first wall and a second wall connecting the longitudinal struts" contravened Article 123 (2) EPC because cutting was only disclosed in connection with laser cutting. Moreover, only walls having convex and concave shapes were disclosed originally. The omission of this feature from original claim 7 could not be considered as an unambiguous disclosure that this feature was not essential.

There was no disclosure in the application as originally filed of an arbitrarily curved flexure means, these were always disclosed as being S-shaped or sinusoidal. The addition of Figure 12 did not alter this situation as this disclosed very specific omega and U shapes and combinations thereof.

The feature that "the longitudinal struts comprise flexure means disposed between a first straight section and a second straight section" contravened Article 123 (2) EPC since neither its structure nor function was derivable clearly and unmistakably from Figures 8 to 10, the only basis for this feature.

There was also no disclosure in the application as originally filed for the feature "comprising rows of a repeating pattern".

The deletion of Figures 12a, 12b, 12c, 12h, and 12i from the application as originally filed provided the new information that there was some technical significance in the remaining flexure means. Either the shape of the flexure means provided a technical contribution or it did not, so either it was new information or not inventive.

Priority claim

There was no disclosure in any of the priority documents of a flexure means disposed in a longitudinal strut between two straight sections, that was not either sinusoidal or generally S-shaped. Similarly, the feature that "the flexure means allow for substantially complementary extension and compression of a diametrically opposed pair of the longitudinal struts" was not disclosed in any of the priority documents. Moreover, all four priority documents, when referring to the first and second walls having an apex, always specified that the first wall was concave-shaped and the second wall was convex-shaped. Owing to the omission of the terms "concave-shaped" and "convex-shaped" from claim 1 of the patent in suit, this claim was not entitled to any of the claimed priority dates.

Novelty

The subject-matter of claim 1 lacked novelty in view of D19, D23, and D1, and because of prior sales by

Biocompatibles. Regarding D1, the Figure 6 embodiment disclosed all the features of claim 1. The feature "the stent is cut out of a tubular starting material" in present claim 1 was a process feature in a device claim and should therefore be construed as "cut-able from a tubular starting material", which the stent of D1 was. Moreover, the feature "the flexure means are curved" was disclosed in the Figure 7 embodiment as being "a more rounded version", which meant that the flexure means of Figure 6 also had a degree of roundedness.

Inventive step

Starting from D1, the only feature possibly not disclosed therein was that the stent was cut out of a tubular starting material, which was a principle way of fabricating stents. Starting from D11, the only missing feature was the curved flexure means for improving flexibility, and the solution was provided by D6. Starting from D10, the only missing features were that the stent was cut out of a tubular starting material and the curved flexure means, which were known and aggregated features. Therefore, the subject-matter of claim 1 lacked inventive step starting from any one of D1, D10, or D11.

D11 could also be combined with D1, D3, D4, or D23, or D24 and general knowledge, or D24 with D1 or D6, or D9 with D1 or D6.

Reasons for the decision

1. The appeal is admissible.
2. The opposition and the intervention are admissible.
Since, at the oral proceedings, the appellant no longer contested either the admissibility of the opposition and the intervention or the occurrence of a substantial procedural violation, the Board need not go into these issues.
3. Article 100 (c) EPC 1973 - main request
 - 3.1 The respondents have raised the objection that the subject-matter of the patent in suit extends beyond the content of the parent application (WO 97/32543) in various respects. These objections are examined in turn below.
 - 3.2 Sinusoidal or S-shaped means

An object of the patent in suit is to make a stent having lateral flexibility and this is achieved by the use of longitudinal struts comprising curved flexure means disposed between a first straight section and a second straight section. The question is whether the term "curved" is unjustifiably broader than the original disclosure in this respect.

There is a statement on page 6, lines 9 to 18 of WO 97/32543 that "the precise shape of the portion is not particularly restricted and generally takes the form of an "S". Thus, the sinusoidal or S-shaped portion may be comprised of a pair of joined curved

sections wherein each curved section has an arc of about 180° - i.e. this is illustrated in Figure 8 of the present application". Therefore, the sinusoidal or S-shape is only an example of the shape of a pair of joined curved sections having an arc of about 180° , but the precise shape is not particularly restricted to this.

The description "a pair of joined curved sections wherein each curved section has an arc of about 180° " also applies to the "spiral flexure means" shown on page 22 of the intervener's letter of 27 November 2008 since this has a pair of joined curved sections having an arc of about 180° . The person skilled in the art would readily appreciate that such a section would impart the property of lateral flexibility to the stent.

Moreover, according to the last paragraph on page 21 of this letter, this flexure means is "curved". Hence, the disclosure of WO 97/32543 does indeed include longitudinal struts having a curved portion between two straight sections. This feature of claim 1 of the patent in suit is not objectionable under Article 76 (1) EPC, accordingly.

3.3 Laser cutting

Page 20 of WO 97/32543 clearly states that the manner by which the present stent is manufactured is not particularly restricted and the use of laser cutting is only a preferred technique. Moreover, in lines 12 to 14 it is stated that "The preferred tubular wall design of the present stent facilitates production and improves quality control by avoiding the use of welds and,

instead, utilizing specific cutting techniques". The reference to "techniques" means that any suitable cutting technique is envisaged, not just laser cutting. Furthermore, given that the use of cutting by laser has no bearing on the present invention, the objection that claim 1 should be restricted to laser cutting in order to be properly supported by WO 97/32543 is not sustainable.

3.4 First and second walls

The broadest definition of an invention comprising a stent including a repeating pattern comprised of a polygon is in claim 12 of WO 97/32543. This claim defines the feature "the plurality of intersecting members are arranged to define a first repeating pattern (A) comprised of a polygon having a pair of side walls substantially parallel to the longitudinal axis and the flexure means is disposed in each of the side walls".

Implicitly, this claim defines, in addition to the side walls, two additional walls connecting the side walls, in order to complete the polygon. However, there is no requirement for the additional walls to have concave and convex shapes. These shapes are, moreover, not directly related to the flatness of the apex or the problem of lateral flexibility of the stent. Therefore, the application as originally filed did disclose, as an invention, a stent having a plurality of intersecting members arranged to define a first repeating pattern comprised of a polygon, but no first and second walls of convex and concave shapes.

The failure of claim 1 of the patent in suit to define first and second walls of convex and concave shapes, respectively, does not give rise to an objection under Article 76 (1) EPC, accordingly.

3.5 Deletion of Figures 12a, 12b, 12c, 12h, and 12i

The respondents argue that in the application as originally filed there was no technical significance given to the shape of the flexure means, but the invention of present claim 1 now highlights advantages of the bowed shapes shown in the various Figures 12 over the other shapes, thereby granting the patent unwarranted advantage.

The Board does not accept these arguments. It is normal, during the course of the grant procedure, to limit the claims in order to define more precisely the subject-matter for which protection is sought. In doing so subject-matter which no longer falls within the scope of the main claim is often deleted from the description and claims. In the present case, the disclosed solution to the problem of lateral flexibility of the stent is the curved flexure means, and those embodiments of flexure means which are not curved have been deleted, thereby limiting the claims, and not enhancing their subject-matter.

3.6 Flexure means of whatever shape

The respondents argue that neither the structure nor the function of the feature of disposing flexure means between two straight sections is fully derivable from the drawings, which is the only source for this feature,

and for this reason claim 1 may not include this feature. In particular, some of the flexure means are shown in Figure 8 as being directly joined to an intersecting member instead of through a straight section.

Assuming that only some of the longitudinal struts shown in Figures 8 and 9 of WO 97/32543 have curved flexure means between two straight sections, this is still consistent with claim 1 which does not require all the struts to have flexure means between two straight sections. Only a sufficient number of the longitudinal struts must be so constructed in order to impart lateral flexibility to the stent, and the number of struts having this feature in the embodiment of Figure 8 is apparently sufficient for the purpose.

3.7 For the above reasons no objection arises against claim 1 of the patent in suit under Article 100 (c) EPC.

4. Validity of the priority claim

4.1 Sinusoidal or S-shaped flexure means

There is a statement on page 8 of CA 2 192 520 corresponding to the statement on page 6, lines 9 to 18 of WO 97/32543, that "the precise shape of the portion is not particularly restricted and generally takes the form of an "S". Thus, the sinusoidal or S-shaped portion may be comprised of a pair of joined curved sections wherein each curved section has an arc of about 180° - i.e. this is illustrated in Figure 8 of the present application".

By the same reasoning given in point 3.2 above, this is a disclosure of the feature that longitudinal struts comprising curved flexure means are disposed between a first straight section and a second straight section. This feature of claim 1 of the patent in suit is entitled to the claimed priority date, accordingly.

4.2 Complementary extension and compression of a diametrically opposed pair of the longitudinal struts

According to paragraph [0027] of the patent the term "diametrically opposed pairs of the longitudinal struts" is intended to have a broad meaning. This could mean, for example, that the struts are not exactly 180° apart, or that they are in different planes. Moreover, "substantially complementary extension and compression" simply means that the struts on the outside of the bend can extend while the struts on the inside contract correspondingly to afford lateral flexibility of the stent as shown in Figure 11, there being no need for the extension and contraction to match exactly.

This feature is described further in column 4 of the patent. According to line 46 onwards "Practically, the flexure means confers lateral flexibility to the unexpanded stent by allowing diametrically opposed pairs of the longitudinal struts to undergo substantially complementary extension and compression. 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 bend 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".

This passage and the corresponding part of claim 1 is merely a description of what occurs when the stent is flexed laterally, as shown in Figure 11 and described in column 16, lines 23-25 and is the consequence of flexure means inserted into longitudinal struts. This is not meant to be a mathematically precise definition of the arrangement of the struts.

This description of how the struts are arranged and how they expand and contract upon flexing is also present in CA 2 192 520, which discloses curved flexure means in the longitudinal struts. Page 17, lines 7-11 together with the discussion of Figure 11 on page 19, describe the same effect in different words. The structure of Figure 8 of this priority document, when folded into tubular form, will resemble the stent shown in Figure 1, and if the stent is bent diametrically opposed pairs of struts will undergo complementary expansion and contraction in the sense of the patent in suit.

The above considerations are supported by the intervener's statement of 25 May 2007. According to the section on Novelty on page 3, D23 shows stents which anticipate the claimed stent. It is stated that "The flexure means of both of the stents disclosed in D23

are curved and allow for substantial complementary extension and compression of a diametrically opposed pair of the longitudinal struts upon flexure of the stent". However, the video film (D23) only shows flexure means located in the longitudinal struts, it does not show the stent being flexed or diametrically opposed pair of the longitudinal struts. It is, nevertheless, inferred by the intervener, merely from this construction, that the curved flexure means of both of the stents disclosed in D23 allow for substantially complementary extension and compression of a diametrically opposed pair of the longitudinal struts upon flexure of the stent.

The intervener reinforces this on page 37, first paragraph, of its submission of 27 November 2008 in the discussion of D23 on page 37, and on page 41, last paragraph, in the discussion of D1. The opponent says something similar, see its statement of 28 November 2008, page 11, last complete paragraph. Its analysis of the prior art assumes this feature is disclosed in the prior art devices solely by virtue of their possessing flexure means inserted into longitudinal struts.

This feature of claim 1 of the patent in suit is also entitled to the claimed priority date, accordingly.

4.3 Concave and convex walls

Claim 58 of CA 2 192 520 defines an unexpanded stent comprising a tubular wall having longitudinal intersecting members with curved flexure members and repeating patterns comprised of polygons. In order to

complete the polygons, they implicitly have walls connecting the longitudinal intersecting members, but there is no requirement for these to be convex or concave. Thus, this document does disclose the presently claimed invention without the convex and concave walls. The absence of these features from opposed claim 1 does not result in loss of the priority claim, accordingly.

4.4 In summary, the patent in suit is entitled to the priority date 10 December 1996 of CA 2 192 520.

5. In view of the foregoing conclusion regarding the validity of the priority claim, the items D19 and D23 are not prior art and no longer relevant, as is the allegation of prior sales by Biocompatibles on 21 February 1997. D10, however, was published before the priority date mentioned in point 4.4, and is prior art, accordingly.

6. Novelty - main request

D1, which was cited as anticipating the claimed subject-matter, discloses two embodiments of an unexpanded stent with reference to Figures 1 to 6 thereof, and a third embodiment with reference to Figures 7 and 8.

6.1 The first two embodiments comprise an unexpanded stent with a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of intersecting members comprising rows

of a repeating pattern (11, 12) comprised of a polygon having a pair of longitudinal struts (15, 22) substantially parallel to the longitudinal axis, a first wall (17) and a second wall connecting the longitudinal struts, the longitudinal struts comprising flexure means (18, 20) disposed between a first straight section and a second straight section, 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, and the flexure means allowing for substantially complementary extension and compression of a diametrically opposed pair of the longitudinal struts upon flexure of the stent, and the first and second walls both being shaped with a flat apex.

The stents of these embodiments do not have curved flexure means and there is no disclosure that the stent is cut out of a tubular starting material. It is by virtue of these features that the claimed stent is novel, accordingly.

- 6.2 The respondents' argument that the flexure means of these embodiments are rounded, and therefore curved, is not accepted. Curved flexure means are employed in the stent of the patent in order to impart lateral flexibility, which means that they must have certain spring characteristics in order to function as intended. Rounding off a square shoulder will not significantly alter the spring characteristics of the shoulder, so this cannot be equated with curved flexure means.

The respondents' argument that the last feature of claim 1 is a process step is also not accepted. This

feature is a constructional feature in that if a stent is made by cutting out a tubular starting material, there will be no weld line, for example, which affects the physical characteristics of the stent. This constructional feature is not disclosed in D1.

6.3 The third embodiment of D1 is similar to the previous embodiments, except that it is a curved version of the first embodiment, so that it does possess curved flexure means. However, it also possesses a rounded apex as shown in Figure 7. Thus, the claimed stent is novel over this embodiment because at least one of the apices is flat and the stent and is cut out of a tubular starting material.

7. Inventive step

7.1 Technical problems of the patent in suit

Paragraph [0023] of the patent in suit sets out the problems which the patent seeks to solve and paragraph [0034] lists advantages of the claimed stent. The objects of the patent may be summarised as follows:

- The stent should have a desirable balance of lateral flexibility in the unexpanded state and radial rigidity in the expanded state.
- The force required to expand the stent should be substantially reduced.
- Plastic deformation of the stent during expansion should be facilitated.

- Upon expansion of the stent, warpage of the first apex and the second apex should be mitigated.

7.2 The solution

An important feature of the patent is that the apices are flat, by which is meant that there is defined a pair of shoulders (see the patent, column 7, lines 16 to 20). Although the shoulders may be somewhat rounded, as shown in Figure 8 of the patent they are, nevertheless, defined by two straight sections defining a distinct angle therebetween when the stent is in the unexpanded state.

It is by virtue of the flat shoulders that a solution is provided for the last three problems listed above. At the oral proceedings the appellant's representative demonstrated plausibly how the flat shoulders impacted on these problems. The respondents have not questioned these effects.

The balance of these properties is achieved, according to the patent in suit, by confining radial rigidity to the rings of the stent defined by the first and second walls with flat apices, and lateral flexibility to the longitudinal struts where the curved flexure means are located. The provision of a stent with variable flexibility and rigidity along its length is discussed in paragraphs [0070] and [0072] of the patent in suit.

The different properties of the different parts of the claimed stent are reflected in the different terminology used for the different parts. Those elements which are responsible for the radial rigidity

are termed "walls" whereas those elements which are responsible for the lateral flexibility are termed "longitudinal struts and flexure means".

8. Document D1 as the starting point

This describes two different types of stents, the first is described with reference to Figures 1 to 6 and comprises orthogonal meander patterns formed by rectilinear members, and the second is described with reference to Figures 7 and 8 and comprises orthogonal meander patterns having a more curved form. Each of these will be taken as starting points for the claimed stent in turn.

8.1 The object of this document is to provide a flexible stent which shrinks minimally in the longitudinal direction during expansion (D1: page 2, lines 13 to 15). This object is achieved by forming a tube from first and second meander patterns having axes extending in first and second directions wherein the second meander patterns are intertwined with the first meander patterns (page 2, lines 16 to 21). The stent is able to bend by deformation of the meander patterns, as shown in Figure 3.

8.2 The respondents have argued that the person skilled in the art would, for different reasons (e.g. avoiding stress concentrations and sharp corners), round off the shoulders of the flexure means 18, 20 of D1 and obtain the curved flexure means required by opposed claim 1.

This argument is not accepted by the Board. There is a considerable difference between a rounded and a curved

element. In order to avoid sharp corners it would be sufficient to smooth off such corners, for example, by a step of electro-polishing and coating with a polymer, which would suffice to smoothen out sharp corners and no further steps in this respect would be necessary. Such smoothening would not suffice for the purposes of the patent, however, because it would not alter the spring constant of the flexure means substantially, and there is a substantial difference in the spring behaviour of a curved spring and one with shoulders.

8.3 In the first version of the stent (Figures 1 to 6) the first and second meander patterns are similar in mechanical construction and properties, which may be ascertained from the fact that they are both termed "meander patterns", are shown in the illustrated embodiments as having the same band-like structure, and both the first and second meander patterns contribute to the flexibility of the stent, to its rigidity, and its shrinkage properties, see D1: page 6, lines 3 and 4 and 23 to 25, and page 7, lines 13 to 18. Page 7, lines 13 to 18 discusses rigidity only with respect to the meander pattern 11, but the meander pattern 12 will also possess some rigidity because it has a similar rectangular construction.

This is in contrast to claim 1 of the patent in suit which uses terminology which reflects the different properties of the different parts of the stent (see point 7.2 above).

Since the teaching of D1 is that the first and second meander patterns must be similar in mechanical construction and properties there is no suggestion in

D1 of the teaching of the patent in suit, according to which the properties radial rigidity and lateral flexibility are separated and assigned to different parts of the stent.

8.4 The above comments regarding the separation of the properties radial rigidity and lateral flexibility apply also to the more rounded version of the stent described with reference to Figures 7 and 8 of D1. Here too the first and second meander patterns must be similar in mechanical construction and properties and there is no separation of the properties radial rigidity and lateral flexibility and their assignment to different parts of the stent. Moreover, the teaching of D1 is that the entire stent be rounded, which means that there are also no flat apices and shoulders defined by flat apices in this embodiment, which are important features of claim 1 of the patent in suit.

8.5 The appellant also argued plausibly at the oral proceedings that a modern stent is designed with a view to meeting a set of different requirements. For example, the present stent should achieve a balance between the radial rigidity of the stent in the expanded state and the lateral flexibility of the stent in the unexpanded state, whereas the stent of D1 should be a flexible stent which shrinks minimally during expansion. As a result the entire stent must be carefully designed such that its various elements combine together in a complex interaction in order to provide the desired set of properties.

Consequently, an element from a stent having given properties cannot simply be lifted from its given

context and transplanted into another one without upsetting the balance of properties. For example, if the curved flexure means shown in D2 or D6 were to be imported into the stent of D1, then this would go against the teaching of D1 according to which the first and second meander patterns must both contribute to rigidity and flexibility, because the flexure means would be the predominant flexibility provider.

8.6 Another factor is that the prior art discloses different types of flexure means for enabling a stent to bend for delivery through curved passages. D2 describes individual segments connected by helical links. D3 describes individual segments articulated by hinges. D4 describes rings connected by very closely spaced (column 3, line 4) longitudinals having undulating structures. D6 describes a stent having optimal hoop strength to minimise elastic recoil and comprising ovals joined by undulating longitudinals, wherein the undulations occupy the entire space between the ovals, there being no longitudinal struts comprising flexure means disposed between a first straight section and a second straight section despite the schematic representation in Figure 8. The stent of D24 is said to be very flexible and achieves its flexibility by the placement of interconnecting elements 13 between adjacent radially expandable cylindrical elements 12 and to peaks or valleys of the undulating structure (column 6, lines 4 to 23).

Given the variety of flexure means known in the art, the respondents' argument that the person skilled in the art, starting from D1, say, would employ curved flexure means disposed between a first straight section

and a second straight section in order to obtain a flexible stent, involves selection and a deal of hindsight.

For these reasons the Board considers it to be an ex post facto consideration to argue that the use of the curved flexure means known, for example, from D2 or D6 in the stent of D1 would lead to the claimed stent in an obvious manner.

9. Other documents as starting points

D10 describes an expandable bifurcated stent and a method of delivery thereof, the stent comprising a repeating polygonal pattern. The only mention of flexibility is on page 15, lines 5 to 7 which states that to improve the flexibility of the stent some of the repeating patterns may be omitted. There is consequently no incentive to add anything, such as flexure means, in order make this stent flexible, or to combine the teaching of this document with any other document.

D11 describes two types of stents, first helical stents and then ring-based stents. D11 relates to a fundamentally different type of stent in that it is manufactured in the expanded configuration and then folded for insertion into the body. It is not clear that the problems of the opposed patent, listed in point 7.1 above, would be applicable to the stents of D11. This document also does not discuss lateral flexibility in relation to ring-based stents, and is not a promising starting point for the presently claimed stent.

10. It is clear from the foregoing analysis that no prior art document suggests the concept of the patent in suit, that radial rigidity should be the function of the rings of the stent, and lateral flexibility the function of the longitudinal struts, and that the balance of these properties should be achieved by the structure of the rings and the longitudinal struts as defined in claim 1.

The Board, therefore, considers that the unexpanded stent of claim 1 of the patent in suit involves an inventive step.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.
2. The patent is maintained as granted.

The Registrar

The Chairman

D. Sauter

M. Noël