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D E C I S I O N
of 3 March 2006

Case Number: T 0273/04 - 3.2.02

Application Number: 97904958.2

Publication Number: 0888093

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:
Expandable stent

Patentee:
EVYSIO MEDICAL DEVICES ULC

Opponent:
Guidant Corporation

Headword:

-

Relevant legal provisions:
EPC Art. 54, 56, 88, 89, 123

Keyword:
"Novelty (main request - no)"
"Inventive step (auxiliary request - yes, after amendments)"
"Multiple priorities - second priority valid"

Decisions cited:
T 0133/85, G 0001/93

Catchword:

-



Case Number: T 0273/04 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 3 March 2006

Appellant: EVYSIO MEDICAL DEVICES ULC
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Respondent: Guidant Corporation
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Representative: McLeish, Nicholas Alistair Maxwell
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 17 December 2003
revoking European patent No. 0888093 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: M. Noel
A. Pignatelli

Summary of Facts and Submissions

- I. European patent No. 0 888 093 was revoked by decision of the opposition division issued on 17 December 2003 on the grounds of added subject-matter (main request; Article 123(2) EPC) and lack of novelty over the prior art (auxiliary request; Article 54(3) EPC).

The earliest date for consideration of the prior art was deemed to be the international filing date of 5 March 1997, the patent having not been entitled to any of its priority dates.

- II. The appellant (patentee) lodged an appeal against this decision by notice received on 20 February 2004 and paid the appeal fee on the same day. A statement setting out the grounds of appeal was filed on 27 April 2004 along with amended claims according to a first and a second (2a) auxiliary requests.

As a consequence of a reply filed by the respondent (opponent), the appellant submitted, with letter dated 3 February 2006, additional amended claims according to a further second (2b) and a third auxiliary requests.

- III. Oral proceedings were held on 3 March 2006, during which the appellant withdrew his first and second (2a) auxiliary requests filed with letter of 27 April 2004 and the second (2b) and third auxiliary requests filed with letter of 3 February 2006.

At the end of the oral proceedings the request of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or on the basis of claims 1 to 14 of the auxiliary request filed during oral proceedings. He furthermore requested reimbursement of the appeal fee.

The respondent (opponent) requested that the appeal be dismissed.

IV. The following documents played a role for the present decision:

D1: WO-A-97/33532
D2: WO-A-96/03092
D7: EP-A-0 669 114
D14: US-A-5 397 355

V. Claim 1 according to the various requests reads as follows:

Main request:

"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 rows of intersecting members (750, 760, 850, 860, 950, 960), adjacent rows of intersecting members being interconnected by a series of longitudinal struts (735, 740, 770, 835, 840, 870, 935, 940, 970), 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 each longitudinal strut (735, 740, 770, 835, 840, 870, 935, 940, 970) comprises an arcuate flexure means (736, 741, 771, 836, 841, 936, 941, 971) disposed in spaced relation between adjacent rows of intersecting members (750, 760, 850, 860, 950, 960) to 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."

Auxiliary request:

"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 rows of intersecting members (750, 760, 850, 860, 950, 960), adjacent rows of intersecting members being interconnected by a series of longitudinal struts substantially parallel to the longitudinal axis (735, 740, 770, 835, 840, 870, 935, 940, 970), 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, each longitudinal strut (735, 740, 770, 835, 840, 870, 935, 940, 970) comprising an arcuate flexure means (736, 741, 771, 836, 841, 936, 941, 971) disposed in the longitudinal strut between a first straight section and a second straight section and between apices of adjacent rows of intersecting members (750, 760, 850, 860, 950, 960) to 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 **characterised** in that at least one of the apices is substantially flat, and in that the stent is produced by laser cutting techniques applied to a tubular starting material."

VI. At the oral proceedings the parties presented the following arguments:

(i) The appellant

Among the amendments brought to the claims, the word "arcuate" was a synonym of "curved" and the expression "in spaced relation" meant at a certain distance from the rows of intersecting members, i.e the arcuate flexure means could also be disposed between the valleys of two adjacent rows. These amendments, therefore, were not objectionable under Articles 84 and 123(2) EPC.

The patent was validly based on the second claimed priority date of 3 May 1996 since not only Figure 8 of the second priority document CA-A1-2175722 showed sinusoidal or S-shaped portions but also Figure 6 and the corresponding text related to curved struts.

Figure 7A of the closest prior art document D1 was ambiguous. The stent was not shown there in an unexpanded state. The deployment of the stent mentioned in the description of D1 was related to the positioning of the stent into the lumen and not to its radial expansion. The connector means shown in figures 7A to

7D were not to be compared with the arcuate flexure means of the invention, since these connector means did not provide an improvement of the flexibility of the stent. Flexibility was given, instead, by slidable attachment means as shown in figures 7E and 7F. Therefore, the subject-matter of claim 1 of the main request was novel over D1.

Document D2 was considered as representing the closest prior art with respect to claim 1 of the auxiliary request. However, the stent according to the embodiment of figures 1 to 4 had no curved portions, but only straight sections extending at right angles. In the second embodiment of Figure 7, instead, the struts comprising the curved flexure means had no straight sections and were directly connected to adjacent meanders having rounded apices. Therefore, flat apices were not suggested by D2. The disclosure according to Figure 9 of document D7 was also insufficient to suggest this feature.

Both documents D2 and D7 used etching techniques for making the stent. Even if laser cutting techniques were generally known and used for that purpose, no document suggested the application of laser cutting techniques to a tubular starting material for cutting straight and curved sections intricately in complicated patterns. The claimed features were, therefore, new and not obvious with respect to the prior art.

Furthermore the appellant submitted that the appeal fee should be reimbursed, since it was a fundamental breach of the protocol for representation before the European Patent Office for the opposition division to decide to

accept a sub-authorisation of Mr Waugh by Mr McLeish as there was no explicit permission in the file by the opponent that the representative was allowed to grant sub-authorisation.

He additionally submitted that the opposition division had exercised its discretionary power in an inequitable way, since it did not allow new requests during oral proceedings after the discussion of the matter although the communication sent with the summons to the oral proceedings was, contrary to the result of the discussion, in favour of the patent proprietor.

(ii) The respondent

The amendments made to claim 1 of the main request resulted in added subject-matter in contravention of Article 123(2) EPC. Such was the case with the incorporation of the expressions "arcuate" and "in spaced relation" which had no support in the application as filed, or with the deletion of Figures 12a, b, c, h, i from the application as filed or the deletion of the feature "disposed substantially parallel to the longitudinal axis of the stent" from claim 1 as filed, which were previously used for characterising the longitudinal struts.

The patent was not entitled to the second priority date of 3 May 1996, since the embodiments according to Figures 1 to 7 of the patent in suit were not covered by the previous invention and Figure 8 of the second priority document was restricted to sinusoidal or S-shaped flexure means. Therefore, more generally defined arcuate flexure means as claimed and illustrated by

figures 12a to 12d of the present patent were not covered by the second priority document. Moreover, the expression "disposed in spaced relation between adjacent rows" could be construed as meaning that said "arcuate flexure means" were disposed within a band comprised between the peaks of adjacent rows. This was also not covered by the priority documents, either.

Document D1 disclosed all the features of claim 1 according to the main request. In particular, Figures 7A and 7B of D1 showed an expandable and flexible stent having arcuate connectors disposed between adjacent ring frames for allowing complementary extension and compression of the opposed pairs of connectors upon flexure of the resilient stent. Therefore, the subject-matter of claim 1 of the main request was not new over the teaching of D1.

Document D2 disclosed a stent formed of a plurality of two orthogonal and intertwined meander patterns having all the features recited in the precharacterising portion of claim 1 according to the auxiliary request. In particular longitudinal struts extended parallel to the longitudinal axis of the stent and flexure means were disposed in the longitudinal struts between a first and a second straight section and between flat apices of the adjacent ring frames. Since the meander patterns were formed of sinusoids and loops, this implied that the loops were curved so as to form some arcuate flexure means, as shown i.e. in the more rounded version of Figure 7, in order to avoid damage of the vessel lumen.

For a skilled person it was obvious to leave flat portions between more or less rounded corners at the apices of the meanders so as to provide a balance between flexibility and rigidity of the stent. Moreover, Figure 9 of document D7 suggested to connect longitudinal struts to substantially flat apices of adjacent rows of intersecting members. Furthermore, stents produced by laser cutting were conventional, including those produced from a tubular starting material as disclosed for example in document D14. The subject-matter of claim 1 of the auxiliary request, therefore, did not involve an inventive step over the prior art.

As far as the breach of protocol for representation is concerned, the respondent argued that the representative not only had the power to sub-authorise a professional representative but was even instructed to do so by the opponent. He submitted a letter of the opponent as evidence covering this point. He furthermore argued that the practice followed by the opposition division was entirely normal, since the authorisation of Mr Waugh satisfied the criteria laid down by the Enlarged Board of Appeal in decision G 4/95 when setting out the criteria to be considered by the EPO when exercising its discretion to admit oral submissions by an accompanying person let alone a fellow professional representative.

The respondent also submitted that the opposition division refused the requests submitted during oral proceedings correctly exercising its discretionary power and this could not be surprising for the patent proprietor, since the opinion expressed in the

communication sent with the summons to the oral proceedings was clearly only a preliminary and non-binding opinion. He also argued that it was the normal situation to file auxiliary requests one month before the oral proceedings i.e. before the matter was discussed orally.

Reasons for the Decision

1. The appeal is admissible.
2. *Priority date of the present patent*

The present patent claims the priority dates of four priority documents. The first priority document (CA-A-2171047) does not disclose any of the embodiments related to Figures 8 to 12 of the patent. These embodiments, therefore, are not entitled to the first priority date of 5 March 1996.

The second priority document (CA-A-2175722) discloses, in reference to Figure 8, an embodiment which is similar to Figure 8 of the present patent, comprising side walls and struts modified so as to include sinusoidal or S-shaped portions adjacent flat apices of concave-shaped walls forming the rows of intersecting members (repeating patterns). It is true that the various shapes of flexure means illustrated in Figures 12a to 12d of the present patent are not disclosed by the second priority document. However, claim 1 at issue generally claims arcuate flexure means disposed in longitudinal struts, which is also covered by the

curved struts described with reference to Figures 5 and 6 of the second priority document.

Therefore, claim 1 (according to any request) of the present patent is entitled to the second priority date of 3 May 1996 in accordance with Article 88(2) and 89 EPC.

3. *Main request*

3.1 Formal aspects

"Longitudinal struts"

In the patent application as filed (see page 8, lines 27 to 28), it is stated: "Generally, the connecting strut will be substantially longitudinal, i.e. it will be parallel to the longitudinal axis of the stent". Therefore, the expression "longitudinal struts" is clearly supported by the description as filed.

It results therefrom that with respect to claim 1 as originally filed, the deletion of the expression "disposed substantially parallel to the longitudinal axis of the stent" does not lead to subject-matter being extended. During the examining procedure a more general reformulation of the claim is not precluded by Article 123(2) if the modification remains within the frame of the application as filed (T 133/85, OJ EPO 1988, 441, points 4 and 5). This is presently the case.

"In spaced relation"

According to the application as filed (page 5, lines 30 to 32 and page 16, lines 5 to 6), the S-shaped section of the strut is adjacent an apex of the polygon (the polygon is the repeating pattern defined by a plurality of intersecting members - see page 12, lines 28 to 32). "Adjacent" has to be construed in such a way that an arcuate flexure means is placed near or at some distance from the intersection point with the intersecting members, as shown e.g. in figures 8 and 9. Therefore, although the expression "in spaced relation" is not mentioned in the description, it is nevertheless supported by the drawings and interpreted as meaning "not in contact", "somewhere" between the adjacent rows of intersecting members.

Moreover, Figures 8 to 10 clearly show that the flexure means are always disposed between corresponding peaks and valleys of two adjacent rows of intersecting members. Since the repeating patterns are always in phase, it is excluded that the expression "between adjacent rows" in claim 1 could be construed as meaning between two peaks or two valleys of said adjacent rows, as was submitted by the respondent.

"Arcuate"

The parties and the Board agree that the term "arcuate" is a synonym of "curved", this latter term being supported by the application as filed (page 6, lines 12 to 16) to qualify generally the shape of the flexure means, including the alternative curved shapes

shown in Figures 12d, e, f, g of the application as filed (see from page 17, line 25 to page 18, line 7).

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

The deletion of these figures, which illustrate laterally bowed flexure means, is justified by the limitation of the claimed invention to "arcuate flexure means" and the corresponding adaptation of the description.

It results therefrom that the above expressions are clear and do not extend the subject-matter of the present patent beyond the context of the application as filed, in accordance with Article 84 and 123(2) EPC.

3.2 Novelty

Document D1 is a European patent application filed under the PCT, which has a US priority date (13 March 1996) prior to the second priority date (3 May 1996) of the present patent and a publication date (18 September 1997) later to the filing date (5 March 1997) of the present patent. Further, the designated European states are common to D1 and the present patent application. Therefore, D1 represents state of the art to be considered under Article 54(3) EPC.

Document D1 discloses (see page 25 and Figure 7A) a radially expandable tubular prosthetic structure or stent, which is deployable within tortuous body lumens. The stent comprises a tubular wall, having a longitudinal axis and disposed between the proximal end and the distal end of the stent. The tubular wall has a

porous surface defined by a plurality of rows of intersecting members (ring frames 114), the adjacent rows being interconnected by a series of longitudinal struts (connector elements 116). Since the tubular frame is radially expandable (see page 8, lines 3 to 9 and claim 24), the stent is also expandable from a first contracted position to a second expanded position upon the application of a radially outward force on the stent. Therefore, the precharacterising portion of claim 1 is known from D1. The fact that the stent is claimed in an unexpanded state has no consequence on its structure.

Further, as shown in Figure 7A, each longitudinal strut comprises an arcuate flexure means (serpentine structure), such as that illustrated in Figure 7B, which is disposed in spaced relation between adjacent rows of intersecting members (adjacent loops of the frame) (see page 8, lines 15 to 18 and claim 27 of D1). This structure allows for substantially complementary extension and compression of a diametrically opposed pair of the longitudinal struts upon flexure of the stent (see from page 25, line 34 to page 26, line 7).

Therefore, all the features of claim 1 according to the main request are known from document D1. Consequently, its subject-matter is not new within the meaning of Article 54(1), (3) and (4) EPC.

4. *Auxiliary request*

4.1 Amendments

With respect to the main request, the following features have been added to claim 1 of the auxiliary request:

"(longitudinal struts) substantially parallel to the longitudinal axis". A support for this feature is to be found on page 8, lines 27 to 28 of the application as filed.

"(arcuate flexure means disposed) in the longitudinal strut between a first straight section and a second straight section and (between) apices of (adjacent rows)". This feature is supported by figures 8 to 10 and page 5, lines 30 to 32 of the application as filed.

"(characterised in that) at least one of the apices is substantially flat". This feature is supported by the application as filed on page 7, line 13; page 13, lines 19 to 23 and from page 15, line 29 to page 16, line 7 in reference to Figure 8, for example.

"and in that the stent is produced by laser cutting techniques applied to a tubular starting material". This feature is supported by the application as filed on page 20, lines 5 to 6.

With respect to the version as granted the above added features represent a restriction of the protection. Further, since the expression "in spaced relation" is close to the meaning of "between" and fails to add any

technical contribution to the claimed subject-matter, its deletion from the version as granted does not lead to extension of the protection (G 1/93, OJ EPO 1994, 541).

Dependent claims 2 to 14 correspond to dependent claims 2 to 9, 11 to 13 and 15 to 16 as granted, respectively.

It results therefrom that the requirements of Article 123(2) and (3) EPC are met.

4.2 Novelty

Document D2 represents prior art to be considered under Article 54(2) EPC. It represents the closest prior art vis a vis the subject-matter of claim 1 according to the auxiliary request. It discloses (see page 4 and Figure 1) a stent in an unexpanded form (page 4, lines 8 to 9) comprising a tubular wall disposed between the proximal and the distal ends of the stent. The tubular wall has a longitudinal axis and a porous surface defined by a plurality of rows of intersecting members (two intertwined, orthogonal meander patterns). The adjacent rows of intersecting members (vertical meander pattern 11e, 11o) are interconnected by a series of longitudinal struts (straight sections 22 of the horizontal meander pattern 12) substantially parallel to the longitudinal axis. The stent is expandable from a first, contracted position (Figure 1) to a second, expanded position (Figure 4) upon the application of a radially outward force on the stent (implicitly and conventionally known - see page 1, lines 16 to 20).

Moreover, each longitudinal strut comprises a flexure means (loops 18, 20) disposed in the longitudinal strut between first and second straight sections 22, and between apices of adjacent rows of intersecting members (vertical meander pattern) as shown in Figures 1 and 2. This structure allows for substantially complementary extension and compression of a diametrically opposed pair of the longitudinal struts upon flexure of the stent (see Figure 3, and page 5, line 30 to page 6, line 2).

Although the orthogonal meander patterns are schematically represented in Figures 1 to 6 of D2 and show straight segments connected at right angles, such terms as "meander", "sinusoid" (page 4, line 23) or "loops" imply necessarily that the open loops forming the periodic patterns are rounded as illustrated e.g. in the embodiment of Figure 7 (and paragraph bridging pages 7 and 8), if only to prevent damage to the vessel lumen, which is a general requirement for all stents. Therefore, it can implicitly be derived from D2 that the flexure means formed by the loops are actually arcuate, the more since the stent is more roughly produced by metal etching or from twisted wire (see page 7, lines 21 to 25). It results therefrom that all the features of the precharacterising portion of claim 1 are known from D2.

Starting from the above considerations as to the arcuate flexure means, a direct consequence is that the apices of the rows of intersecting members (vertical meanders) cannot, at the same time, be regarded as

flat. Moreover, the stent of D2 is not produced by laser cutting techniques.

Therefore, the stent as claimed differs from the teaching of document D2 by the features of the characterising portion of claim 1. Consequently, the subject-matter of claim 1 is new over the teaching of D2.

4.3 *Inventive step*

Starting from document D2, the objective problem upon which the invention is based (patent specification, paragraph 10) is to provide a stent having improved properties, such as better flexibility and stability, by modifying the configuration of the meander patterns and applying an appropriate manufacturing process.

The solution is given by the characterising features of claim 1. The advantages provided by a repeating pattern, of which at least one of the apices is substantially flat are recited in the patent specification (paragraph 27). In particular, warpage of the apices is obviated or mitigated upon extension of the stent. On the other hand, the production of the stent by laser cutting techniques applied to a tubular starting material allows for facilitating the production and improves quality control (paragraph 68).

As mentioned above in relation to document D2, the loops must be rounded to form arcuate flexure means. In the more rounded version of Figure 7, the apices of the loops 20 are rounded completely, without any flat portion. On the basis of this sole practical embodiment

the skilled person had, however, no reason to leave portions of the loops with flat apices, i.e. to reduce the extent of the rounded corners with a view to adjusting the balance between flexibility and rigidity of the stent. In other words, the skilled person could modify the radius of curvature of the rounded corners, but he wouldn't in the absence of any motivation to do so. The claimed feature, therefore, is not obvious from the teaching of D2.

Document D7 discloses a stent having a plurality of closed circular structures. Figure 9 shows a one-piece structure etched out of a small diameter metal cylinder, with oval rings folded into a pre-deployment configuration, as shown in Figure 6. Longitudinals 24R have no flexure means at all and a flat portion at the apices of the folded ovals is neither mentioned nor sought. Therefore, this disclosure does not suggest the characterising features, either.

Conventional laser techniques applied to a tubular starting material may be known per se, for example from document D14 (see column 2, lines 39 to 44). However the stent described therein comprises a tubular mesh-like member forming elongated openings which deform into diamond-like shapes when expanded from inside the tubular stent. Since none of the prior art documents discloses a stent having the claimed structure, the application of known laser cutting techniques which turned out to be particularly suitable for said specific structure, is not objectionable against the inventive step of the claimed subject-matter if all features are considered in combination.

It results therefrom that the subject-matter of claim 1 according to the auxiliary request involves an inventive step within the meaning of Article 56 EPC. Claims 2 to 14 which depend thereon, are also acceptable.

5. *Reimbursement of the appeal fee*

The Board considers that Mr Waugh was authorised to represent the opponent, since he was registered as additional representative of the opponent in the official file following the instructions of the authorised representative received on 28 October 2003 and all the formal requirements for representation were fulfilled. The internal relationship between the representatives and the party does not concern the EPO.

The Board, however, allows the request for reimbursement of the appeal fee, since a substantial procedural violation occurred during the proceedings before the Opposition division as it did not allow the new requests.

In fact, the opposition division had indicated in the communication accompanying the summons to attend the oral proceedings dated 21 February 2003 that the patent appeared to fulfil the requirements of Articles 54, 56 and 123(2) EPC. Therefore, although this opinion was preliminary and non-binding, the patent proprietor had no reasons to file amended claims as a reaction to this communication under Rule 71a EPC.

As it appears from the minutes, during the oral proceedings after discussing Article 123 EPC, the

opposition division came to the conclusion that claim 1 as granted violated Article 123 EPC and asked the patent proprietor if he wanted to file new requests. The patent proprietor did so taking into account the objections raised under Article 123 EPC. Then Articles 54, 56 EPC were discussed. The opposition division came to the conclusion that the new request did not comply with these articles but did not allow the filing of further new requests. The reason was that the patent proprietor should have filed such requests within the time limit indicated by Rule 71a EPC (cf. point 6 of the decision of the opposition division).

The Board considers that this method of proceeding violated the right to be heard (Article 113(1) EPC).

Under this article, the parties have the right to react to the result of the discussion before the EPO. They can do so also by amending their requests in order to take into account the objection raised by the EPO. Under Rule 71(a), 4th sentence EPC "New facts and evidence presented after that date need not be considered, unless admitted on the grounds that the subject of the proceedings has changed." This sentence has to be read in the light of Article 113(1) EPC. This therefore means that new facts and evidence have to be admitted when the subject of the proceedings has changed and the parties had no opportunity to react earlier to the change.

The communication of the opposition division was in favour of the patent proprietor, so that no reactions in form of amendments were necessary at that moment.

As it appears from the minutes of the oral proceedings, the opposition division came to a completely new conclusion during the oral proceedings. Hence, the patent proprietor was faced with a new situation to which he had the right to react, in particular by amending his requests. Such requests could not be considered to be late, since they were caused by the new and unexpected procedural development of the case to which the patent proprietor had no previous opportunity to react.

A prima facie examination is only allowed if the requests are filed too late. Since this was not the case, a refusal based on a prima facie examination was not justified in the present case.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to maintain the patent on the basis of the following documents:

Claims: 1 filed during oral proceedings; 2 to 14
 according to the third auxiliary request
 filed with letter of 3 February 2006;

Description: columns 1 to 2 and 5 to 17 as granted;
columns 3 and 4 as filed during oral
proceedings;

Drawings: 1 to 12d as granted.

3. The request for reimbursement of the appeal fee is
allowed.

The Registrar:

The Chairman:

V. Commare

T. Kriner