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Datasheet for the decision of 5 September 2013

Case Number: T 0815/12 - 3.2.08

Application Number: 99301879.5

Publication Number: 941716

IPC: A61F2/06

Language of the proceedings: EN

Title of invention:
A delivery apparatus for a self-expanding stent

Patent Proprietor:
Cordis Corporation

Opponents:
Angiomed GmbH & Co. Medizintechnik KG
Boston Scientific Limited

Headword:

Relevant legal provisions:
EPC Art. 100(b)

Keyword:
Grounds for opposition - insufficiency of disclosure (yes)

Decisions cited:

Catchword:

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Case Number: T 0815/12 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 5 September 2013

Appellant: (Patent Proprietor)	Cordis Corporation 5200 Blue Lagoon Drive Miami FL 33126 (US)
Representative:	Mercer, Christopher Paul Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Respondent: (Opponent 1)	Angiomed GmbH & Co. Medizintechnik KG Wachhausstrasse 6 76227 Karlsruhe (DE)
Representative:	HOFFMANN EITLE Patent- und Rechtsanwälte Arabellastrasse 4 81925 München (DE)
Respondent: (Opponent 2)	Boston Scientific Limited One Scimed Place Mailstop A 150 Maple Grove, MN 55311-1566 (US)
Representative:	Peterreins, Frank Fish & Richardson P.C. Highlight Business Towers Mies-van-der-Rohe-Strasse 8 80807 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 30 January 2012 revoking European patent No. 941716 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman:	T. Kriner
Members:	C. Herberhold
	D. T. Keeling

Summary of Facts and Submissions

I. By decision posted 30 January 2012, the opposition division revoked European patent EP-B-9 417 16, on the ground of Article 100(b) EPC.

II. The appellant (proprietor) lodged an appeal against this decision on 5 April 2012, paying the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 8 June 2012.

III. Oral proceedings before the Board of Appeal took place on 5 September 2013.

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

The appellant (proprietor) requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, in the alternative, that the patent be maintained on the basis of one of auxiliary requests I to IV, all filed on 9 June 2012.

The respondents 1 and 2 (opponents 1 and 2) requested that the appeal be dismissed. The respondents additionally requested not to allow auxiliary request I into the proceedings.

IV. Claim 1 as granted reads as follows:

"A delivery apparatus (1) for a self-expanding stent (50), said apparatus comprising:
a) an outer sheath (40), comprising an elongated tubular member having distal and proximal ends (44, 42), said outer sheath comprising an outer polymeric

layer (72), and inner polymeric layer (48), and a wire reinforcing layer (70) between said inner and outer layers, said reinforcing layer being more rigid than said inner and outer layers;
b) an inner shaft (10) located coaxially within said outer sheath, said shaft having a distal end (14), extending distal to said distal end (44) of said sheath, and a proximal end (12), extending proximal to said proximal end (42) of said sheath, said shaft further including a stop (22) attached thereto, said stop being proximal to said distal end of said sheath; and
c) a self-expanding stent (50) located within said sheath, said stent making frictional contact with said inner layer (48) of said sheath, said stent located between said stop (22) and said distal end (44) of said sheath with a portion (24) of said shaft (10) disposed coaxially within a lumen of said stent, said stent adapted to make contact with said stop during deployment of said stent,
characterised in that said outer sheath (40) comprises a series of fused transitions decreasing in material durometer from proximal end (42) to distal end (44) along outer layer (72) of sheath (40)."

Auxiliary request I:

The first auxiliary request differs from the patent as granted in that paragraph [0024] of the description (col. 8, l. 11-13) has been amended by the addition of the underlined wording:
"..... The outer sheath 40 <u>can incorporate a single outer polyamide layer 72 from proximal to distal 44 or, according to the present invention</u>, is a series of fused transitions decreasing in material durometer from proximal 42 to distal 44 along layer 72 of sheath 40."

Auxiliary request II:

The second auxiliary request differs from the patent as granted in that claim 1 defines:

A delivery apparatus (1) for a self-expanding stent (50) useful for repairing blood vessels narrowed or occluded by disease, said apparatus comprising....

Auxiliary request III:

Auxiliary request III differs from the patent as granted in that claim 1 defines the "wire reinforcing layer" to be a "braided wire reinforcing layer" (col. 11, l. 10), in that the wording "said stent adapted to make contact" has been changed back to "said stent makes contact" (col. 11, l. 27) and in that claim 1 further defines that "said braided wire reinforcing layer (70) extends along a predetermined length of a distal portion of said outer sheath (40)" (added at the end of part "a").

Dependent claims 2, 4 and 5 have been deleted and the remaining claims renumbered accordingly.

Auxiliary request IV:

Auxiliary request IV differs from auxiliary request III in that the last feature of part "a)" has been amended to define that "said braided wire reinforcing layer (70) extends along the length of said outer sheath (40)."

V. The essential arguments of the appellant can be summarised as follows:

Main request:

Claim 1 defined an outer sheath comprising a "series of fused transitions decreasing in material durometer from proximal end (42) to distal end (44) along outer layer (72) of sheath (40)". The person skilled in the art would realise that the term "fused transitions" was equivalent to "fused segments" (which were well known from the state of the art), because the interpretation that the term referred to the fuse joints only made no technical sense.
Furthermore, the first part of the characterizing portion could not be read without the last part, which made it clear that the series of fused transitions was "along outer layer (72) of sheath (40)". In the light of this feature it was clear that it was the outer layer of the sheath which comprised the series of fused segments.
Even if further interpretations of the term "fused transitions" were possible, for all these interpretations the person skilled in the art would either know from the prior art how to put them into practice or would understand from the common general knowledge that such an interpretation makes no sense and consequently ignore it. Regarding in particular the information from the description that "the outer sheath is a series of fused transitions" (which admittedly could be understood in the sense that the outer sheath was made up of fused bits of 3 layered composite parts), the skilled person would know that such an embodiment was impossible to make and that an interrupted wire reinforcing layer did not make technical sense, which left the interpretation of the

outer sheath comprising fused segments of the outer layer as the only sensible one.
As to the further example envisaged by the respondents as equally falling under the independent claim of the present patent, which interpreted the "fused transitions" to be fusion points of the outer and inner polymeric layer through the openings in the wire reinforcing layer, such a sheath was acknowledged prior art. The person skilled in the art, knowing that the claim is meant to avoid the prior art, would realise that firstly this interpretation could not be meant, secondly that it did not make technical sense in view of the further feature of the decreasing durometer and thirdly, exactly because it was known from the prior art, there was no difficulty to build such a sheath.

The affidavit filed on 29 January 2013 was not used for the argumentation of the appellant at the oral proceedings. Therefore, the admissibility of this document - with the explicit agreement of the parties - was not discussed.

Auxiliary request I:

The addition of the phrase defining that the sheath could alternatively -in a non-claimed example- incorporate a single outer polyamide layer from proximal to distal put the following part of the sentence in context, thus clarifying that the sentence disclosed in fact two alternatives for the outer layer construction, namely that the outer layer could be a single layer or - according to the present invention - that the outer layer could consist of the fused transitions. The amendment thus further clarified that the transitions were segments of the outer layer, an

embodiment that clearly could be designed by the skilled person.

VI. The essential arguments of the respondents can be summarised as follows:

Main request:

The term "fused transitions" could not be understood by the skilled person. A transition was a region of change, in this case a region of change where there was also fusion, i.e. the very part joined by fusion. However it was without technical sense to make up a sheath out of a series of regions of change only. Neither the description, which in the only part relating to the claimed subject-matter also used the term "fused transitions" (see paragraph [0024], 2nd sentence), nor the specific examples, nor the drawings could provide any help in this respect. The person skilled in the art was thus at a loss how to put the invention into practice.
Regarding the "only sensible interpretation" as put forward by the appellant, i.e. that the outer sheath comprised fused segments of the outer layer, this interpretation was not carried by the words of the specification and required information only available in prior art patent documents but not from the common general knowledge. If, using the common general knowledge, the person skilled in the art was able to supplement the information in the patent in order to determine the appellant's interpretation to be the only sensible one, it should in principle be possible to rewrite the claim accordingly without violation of Article 123(2) EPC, which was clearly not the case. Further interpretations of the term "fused transitions" were possible, as for example of the fused transitions

as being fused points of contact between the outer and the inner polymeric layer through the openings in the wire reinforcing layer of the sheath, for which there was no information in the patent how these could be built.

Furthermore, the phrase "along outer layer (72) of sheath (40)" in the last part of the characterising portion only specified the direction in which the durometer had to decrease, but did not define the fused transitions to be comprised in the outer layer.

Auxiliary request I:

The amendment did not change the claims, did not provide further information with respect to the claimed subject-matter and in particular did not teach what "fused transitions" were. It should thus not be allowable under Rule 80 EPC. Moreover it should have been filed during the opposition proceedings. Therefore it was requested not to admit auxiliary request I into the proceedings. If at all, the alternative to a single layer were multiple layers and not a single layer fused from multiple segments.

Reasons for the Decision

1. The appeal is admissible.

2. Main request:

2.1 Claim 1 defines in the parts relevant for this decision:

> ...
> a) an outer sheath (40), comprising an elongated tubular member having distal and proximal ends (44, 42), said outer sheath comprising an outer polymeric layer (72), and inner polymeric layer (48), and a wire reinforcing layer (70) between said inner and outer layers, said reinforcing layer being more rigid than said inner and outer layers;
> ...,
> wherein said outer sheath(40) comprises a series of fused transitions decreasing in material durometer from proximal end (42) to distal end (44) along outer layer (72) of sheath (40).

There is further relevant information in paragraph [0024], 2nd sentence of the patent which states that:

> "The outer sheath is a series of fused transitions decreasing in material durometer from proximal to distal along outer layer of sheath".

The claim thus distinguishes between firstly the outer sheath, which is a 3 layer composite structure comprising an outer polymeric layer, an inner polymeric layer and a wire reinforcing layer in-between, and

secondly the outer layer, which is exactly the outer layer of said composite structure outer sheath.

Furthermore, whereas the claim allows the fused transitions to be located somewhere in the outer sheath ("the outer sheath **comprises** a series of fused transitions"), paragraph [0024] states that the outer sheath "**is** a series of fused transitions".

2.2 Article 83 EPC stipulates that the "European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art". In the present case the person skilled in the art following the teaching both of claim 1 and of paragraph [0024] of the patent, has to provide an outer sheath comprising a "series of fused transitions decreasing in material durometer from proximal end to distal end along outer layer of sheath". This makes an interpretation of the term "fused transitions" - which has no established meaning in the art- necessary.

The term "fused" refers to something that has been joined by fusion, i.e. in the catheter field usually two polymeric materials that have been joined by application of heat.

A "transition" is a region of change, i.e. a region where a certain property changes from a first value to a second value.

Consequently, a "fused transition" appears to be the very part of the catheter where two bits of different catheter material have been joined by fusion (referred to as "fuse joint" in the following), and where thus

the properties change from those of the first material to those of the second material.

However, this interpretation is in contradiction with the further feature that the "fused transitions" are "decreasing in material durometer from proximal end to distal end". A fuse joint, consisting of two heat-treated materials of different durometer each, does not have a well defined durometer, let alone a decrease in material durometer from proximal end to distal end of the fuse joint. Neither the drawings nor the description provide any further guidance as to the interpretation of the terms. On the contrary, the only supporting sentence in the description (see paragraph [0024] of the description) states that the "outer sheath **is** a series of fused transitions", thereby indicating that it is the fused transitions which together make up the outer sheath, which does not make sense for a series of fuse joints.

Because of the contradictory and inconsistent information in the patent, the person skilled in the art does not know what the term "fused transitions" is supposed to mean and how it can be reduced to practice. Consequently, the definition given in the claim as well as the disclosure in the only sentence in the description supporting the claimed subject-matter do not provide a sufficiently clear and complete technical teaching to allow the invention to be carried out by a person skilled in the art.

2.3 The appellant argued that the person skilled in the art, faced with the teaching of the patent, and reading the patent with a mind willing to understand, would try to make sense of the disclosure and would thus realise that the term "fused transitions" had to be understood

as "fused segments", which -- in view of the last part of the characterising portion -- had to be seen as fused segments of the outer layer.

However,the term "along outer layer of sheath" refers exclusively to the decrease in material durometer (i.e. to the part of the sentence immediately before) and thus indicates nothing more than the direction in which the durometer changes. There is no indication to relate it to the very fist part of the sentence, i.e. to the series of fused transitions in the sense of "a series of fused transitions along outer layer of sheath", as alleged by the appellant.
On the contrary, paragraph [0024] of the description states that it is the outer sheath (and not the outer layer) which **is** a series of fused transitions, thus indicating that the outer sheath - which is a composite 3 layer structure -- is made up from segments joined by fusion. This teaching, again, cannot be carried out in a straightforward way, because the wire reinforcing layer cannot be fused in the same way as the polymeric materials of the inner and outer layers. The person skilled in the art would thus have to realise that the sentence in the description cannot mean fused 3 layer segments, but has to be interpreted differently, i.e. as a connection without fusion of the wire reinforcing layer. Again, there is no teaching as to which of the polymeric layers, the outer, the inner or both are fused. As discussed above, also the wording "along outer layer (72) of sheath (40)" at the very end of the characterising portion does not restrict the fusions to being comprised in the outer layer only, because said sentence defines nothing more than the direction of the decrease in durometer.

To summarize, to arrive at "the only sensible interpretation" as put forward by the appellant, the person skilled in the art would have to realise that firstly the term "fused transitions" needs to be corrected to mean "fused segments", that secondly these segments are not to be seen as 3 layer bits of the outer sheath fused together (contrary to what is suggested by the wording "the outer sheath **is** a series of fused transitions" in paragraph [0024] of the patent), and that thirdly, of the two fusible polymeric layers it is only the the outer layer which comprises the fused segments.

Although the person skilled in the art is in principle able to recognise and rectify errors in the disclosure on the basis of common general knowledge, for consistency reasons the criteria to be applied for accepting such implicit rectifications performed in the mind of the skilled person upon reading the specification should be the same as those applied in Rule 139 EPC for accepting explicit corrections concerning the description, the claims or the drawings: the skilled person should not only be in no doubt that the information given is not correct, but furthermore the correction must be obvious in the sense that it is immediately evident that nothing else could have been intended than what is offered as the correction.

In the present case, the three consecutive rectifications required to arrive at what is offered as the "only sensible interpretation", are at least not immediately evident, making it beyond the ability of the skilled person to recognise and rectify the errors on the basis of common general knowledge.

2.4 To conclude, the teaching in the patent is contradictory and does not provide a sufficiently clear and complete technical teaching and furthermore the person skilled in the art is not able to correct or to supplement the information in the patent using common general knowledge. The European patent thus does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Consequently, the opposition ground under Article 100(b) EPC prejudices the maintenance of the patent as granted.

3. Auxiliary request I:

3.1 Admissibility: It was requested not to admit the first auxiliary request into the proceedings under Article 12(4) RPBA as well as under Rule 80 EPC, because it could have been filed in the opposition proceedings and because the amendment provided no teaching what "fused transitions" were. However, the request is an attempt to overcome the ground of opposition based on which the opposition division had revoked the patent. Nothing more is required by Rule 80 EPC. In view of the positive statement regarding sufficiency of disclosure in the summons of the opposition division, there was no need for the proprietor to submit or prepare this request before the oral proceedings in the opposition proceedings. Moreover the first auxiliary request was submitted at an early stage in the appeal proceedings, i.e. with the grounds of appeal. The Board thus sees no reason not to admit auxiliary request I into the proceedings.

3.2 Allowability:

The amendment performed in auxiliary request I leaves the claims unchanged and only adds information with respect to an unclaimed example. It is of no relevance that the first part of the sentence in paragraph [0024] of the description now discloses that in an unclaimed example the outer sheath can incorporate a single outer polyamide layer because the subject of the verb "is" in the second part of the sentence remains the "outer sheath". There is thus no change in context, because it is still the outer sheath which is defined to be a series of fused transitions. Consequently the patent as amended in auxiliary request I still fails to disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, the opposition ground under Article 100(b) EPC thus prejudicing the maintenance of the patent based on the first auxiliary request.

4. Auxiliary requests II - IV:

With respect to the parts relevant for this decision, auxiliary requests II to IV are essentially unchanged relative to the main request. As accepted by the parties, the argumentation with respect to the main request thus equally applies to auxiliary requests II to IV.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

V. Commare T. Kriner

Decision electronically authenticated