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Datasheet for the decision of 16 April 2014

Case Number: T 0488/11 - 3.2.02

Application Number: 01918177.5

Publication Number: 1399213

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Language of the proceedings: EN

Title of invention:
METHODS FOR TREATING ANEURYSMS

Applicant:
Covidien LP

Headword:

Relevant legal provisions:
EPC Art. 84, 123(2)

Keyword:
Added subject-matter (yes)
Clarity (no)

Decisions cited:

Catchword:

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Case Number: T 0488/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 16 April 2014

Appellant: (Applicant)	Covidien LP 15 Hampshire Street Mansfield, MA 02048 (US)
Representative:	Elsy, David Withers & Rogers LLP 4 More London Riverside London SE1 2AU (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 21 October 2010 refusing European patent application No. 01918177.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: E. Dufrasne
Members: M. Stern
D. Ceccarelli

Summary of Facts and Submissions

I. The applicant lodged an appeal against the decision of the Examining Division dispatched on 21 October 2010 refusing European application No. 01 918 177.5 for lack of compliance with the requirements of Article 52(1) EPC in the sense of Article 54 EPC (Article 54(1), (2) with Article 54(4), (5) EPC) and of Article 84 EPC.

II. Notice of appeal was received on 13 December 2010 and the fee for appeal was paid on that same day. The statement setting out the grounds of appeal was received on 21 February 2011.

III. The appellant argued that the claims of the main and first auxiliary requests filed with the statement of grounds of appeal were formulated in the format provided for in Article 54(5) EPC 2000, which allows purpose-related protection for a substance or composition. Consequently, claim 1 was addressed at a fluid composition for a method of treatment referred to in Article 53(c) EPC.

IV. The appellant requested that the decision under appeal be set aside and that the case be remitted to the department of first instance with the order to continue with the examination on the basis of the main, or in the alternative, the auxiliary request, both filed with letter dated 21 February 2011, or of the second auxiliary request filed with letter dated 2 March 2012.

V. The Board summoned the appellant to oral proceedings and in an annexed communication dated 3 February 2014 presented its provisional opinion concerning novelty of the claimed subject-matter as well as objections under Articles 123(2) and 84 EPC.

VI. In its letter dated 14 March 2014, the appellant informed the Board that it would not be represented at oral proceedings. The letter contains no arguments regarding the objections under Articles 123(2) and 84 EPC raised by the Board.

VII. Oral proceedings took place on 26 April 2014 in the absence of the appellant in accordance with Rule 115(2) EPC and Article 15(3) RPBA.

VIII. Claim 1 of the main request reads as follows:

"A fluid composition comprising a biocompatible polymer, a biocompatible contrast agent and a biocompatible solvent which solubilizes the biocompatible polymer,
for the treatment of an aneurysm comprising an aneurysmal sac formed from the vascular wall of a parent artery, wherein the parent artery is isolated proximal and distal to said aneurysm by placement of a stent adjacent the aneurysmal sac which stent extends in both the proximal and distal directions of the parent artery beyond the aneurysmal sac and isolates blood flow to the arterial walls of the parent artery overlaid by the stent, wherein the stent is formed *in situ* by precipitation of the fluid composition, and the parent artery is isolated by at least 2 to 10 mm proximal and distal to said aneurysm."

Claim 1 of the (first) auxiliary request reads as follows:

"A fluid composition comprising a biocompatible polymer, a biocompatible contrast agent and a

biocompatible solvent which solubilizes the biocompatible polymer,
for the treatment of an aneurysm comprising an aneurysmal sac in a parent artery, wherein the treatment comprises forming a precipitate from the fluid composition in the aneurysm which precipitate extends from the neck of the sac both distally and proximally to both fill the aneurysmal sac and to isolate the parent artery from the systemic blood flow both distally and proximally by at least 2 to 10 mm."

Claim 1 of the second auxiliary request reads as follows:

"A stent obtainable by a method comprising:

(a) identifying the vascular site of an aneurysm in a mammalian patient wherein said aneurysm comprises an aneurysmal sac formed from the vascular wall of a parent artery and further wherein said aneurysmal sac participates in the systemic blood flow of said patient,

(b) inhibiting systemic blood flow into said aneurysmal sac by filling at least a portion of said sac with a fluid composition comprising a biocompatible polymer, a biocompatible contrast agent and a biocompatible solvent which solubilises the biocompatible polymer, and

(c) non-endogenously isolating the parent artery proximal and distal to said aneurysm from systemic blood flow,

wherein sufficient amounts of the polymer are employed in the fluid composition such that, upon delivery to the aneurysm, a polymer precipitate forms which fills at least a portion of the aneurysmal sac thereby inhibiting blood from therein, and

wherein isolation of the parent artery proximal and distal to said aneurysm from systemic blood flow is accomplished by formation of the stent *in situ* adjacent the aneurysmal sac which the stent extends in both the proximal and distal directions of the parent artery beyond the aneurysmal sac and isolates blood flow to the arterial walls of the parent artery overlaid by the stent."

Reasons for the Decision

1. The appeal is admissible.

2. The application

2.1 The application generally concerns a method for treating an aneurysm comprising the filling of the aneurysmal sac with a fluid composition which solidifies in the sac in order to inhibit blood flow into the aneurysm. As explained on page 3, lines 12 to 18, and page 17, lines 18 to 20, such a method is well known in the art.

2.2 In the application it is explained that the methods according to the invention particularly rely on the discovery that regions proximal and distal to the aneurysmal sac are often diseased and prone to ballooning and rupturing (page 4, lines 4 to 18). Hence these portions of the arterial wall adjacent to the aneurysm also need to be isolated from blood flow. Therefore, as indicated in the "Summary of the invention" (page 4, line 21 to page 5, line 4), the methods according to the invention not only fill the aneurysmal sac with a fluid composition which solidifies in the sac, but also provide for a non-

endogenous isolation of the parent artery proximal and distal to the aneurysmal sac from systemic blood flow.

3. Main request

3.1 The appellant argued in its statement of grounds of appeal that the claims of the main and first auxiliary requests were formulated in the format provided for in Article 54(5) EPC 2000, which allows purpose-related protection for a substance or composition. Consequently, claim 1 was addressed at a fluid composition for a method of treatment referred to in Article 53(c) EPC.

3.2 Without entering into the question of whether such purpose-related protection is to be acknowledged in the present case, the Board first finds that in claim 1 of the main request, the method of treatment of the aneurysm involving the use of the fluid composition is defined without including certain method steps which were defined in original claim 1 and which, as indicated under point 2.2 above, are highlighted in the "Summary of the invention" as being necessary for the definition of the invention (page 4, line 21 to page 5, line 4). In particular, claim 1 of the main request omits to include the step of inhibiting systemic blood flow into the aneurysmal sac by filling at least a portion of the aneurysmal sac with the fluid composition, as recited in step (b) of original claim 1. Also the aspect of non-endogenously isolating the parent artery from systemic blood flow as recited in step (c) of original claim 1 has been omitted in claim 1 of the main request.

Since the application as originally filed does not provide a basis for omitting these original limitations

of the disclosed method, the currently generalised claimed subject-matter extends beyond the content of the application as originally filed, contrary to Article 123(2) EPC.

3.3 Moreover, claim 1 contains the feature that "the parent artery is isolated by at least 2 to 10 mm proximal and distal to said aneurysm". This feature appears to mean (page 17, line 28 to page 18, line 10) that the stent is formed such that it isolates the parent artery by at least 2 to 10 mm proximal and distal to said aneurysm from systemic blood flow. In other words, the stent is supposed to extend a distance of, for example, 2 mm beyond the aneurysm in proximal and distal directions. As indicated under point 2.2 above, the extension of the stent beyond the aneurysm is seen by the present applicant as an essential contribution of the invention over the known prior art.

However, it is not feasible to identify clear and precise terminal points in proximal and distal directions along an artery at which the aneurysmal sac may be said to end and the "normal" portion of the artery to start, as can be seen from the schematic representation of an aneurysm in Fig. 6. The application presents also no information in this respect. It is consequently uncertain from which point along the aneurysmal contour a distance as small as, for example, 2 mm specified in claim 1 should be measured.

Hence, the feature that the parent artery is isolated by at least 2 to 10 mm proximal and distal to said aneurysm lacks clarity, contrary to the requirement of Article 84 EPC.

3.4 Regarding the aforementioned non-compliance with Articles 123(2) and 84 EPC, the appellant did not present any comment in its written reply to the Board's communication, and moreover did not avail itself of the oral proceedings. The Board therefore sees no need to address in the present decision the fulfillment of further requirements of the EPC, such as those related to the novelty of the claimed subject-matter.

4. First auxiliary request

4.1 Claim 1 recites the formation of "a precipitate", an expression which encompasses, according to examples given in the application, the formation of an *in situ* stent (page 25, lines 10 to 15 and 24 to 26). However, a "precipitate" is a broader term than the specific precipitate disclosed throughout the original application, namely a *polymer* precipitate. Such a polymer precipitate is disclosed in original claims 5 and 8; page 5, lines 20 to 26; page 10, lines 11 to 16; page 13, lines 16 to 18; page 17, lines 21 to 25; and page 18, lines 7 to 17.

Consequently, the subject-matter of claim 1 of the first auxiliary request extends beyond the content of the application as originally filed, contrary to Article 123(2) EPC.

4.2 Moreover, claim 1 of the first auxiliary request also contains the feature ambiguously specifying the extension of the stent beyond the aneurysm mentioned under point 3.3 above.

Consequently, the subject-matter of claim 1 of the first auxiliary request lacks clarity for the mentioned reasons, contrary to Article 84 EPC.

4.3 The appellant also did not provide any comments as to the aforementioned non-compliance of the first auxiliary request with the EPC.

5. Second auxiliary request

5.1 Claim 1 of the second auxiliary request is addressed at a stent exclusively defined in terms of its suitability for being obtained by a specified surgical method (disclosed in original claims 1, 5 and 11; and page 6, lines 19 to 24).

The stent according to claim 1 also encompasses, for example, an extracorporeally manufactured polymeric cylindrical tube of a certain length (capable of extending proximally and distally to an aneurysmal sac) having an external protrusion (the protrusion being capable of filling a portion of an aneurysmal sac). Such an extracorporeally manufactured tube was however not disclosed in the application as originally filed.

Consequently, the definition of the stent according to claim 1 of the second auxiliary request introduces subject-matter extending beyond the content of the original application, contrary to Article 123(2) EPC.

5.2 Moreover, the stent is exclusively defined in terms of a surgical method relating to an aneurysm. In particular, the length of the stent is defined in terms of its extension beyond an aneurysm in a patient, which constitutes an extraneous non-standardised and non-specified entity. The definition is thus indeterminate.

Consequently, claim 1 does not provide a clear definition of the subject-matter for which protection

is sought, contrary to what is required by Article 84 EPC.

5.3 The appellant also did not provide any comments as to the aforementioned non-compliance of the second auxiliary request with the EPC.

6. Since none of the main, first or second auxiliary requests is deemed to be allowable for the reasons given above, the appellant's request for the case to be remitted to the department of first instance with the order to continue with the examination of the case on the basis of any of these requests is refused.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

K. Götz E. Dufrasne

Decision electronically authenticated