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**Datasheet for the decision  
of 6 October 2014**

**Case Number:** T 1088/10 - 3.2.02

**Application Number:** 02707655.3

**Publication Number:** 1357969

**IPC:** A61M29/00

**Language of the proceedings:** EN

**Title of invention:**

STENT IMPLANTATION DEVICE WITH FLUID DELIVERY

**Patent Proprietor:**

Cummings, Charles

**Opponent:**

Jackson, Derek Charles

**Headword:**

**Relevant legal provisions:**

EPC Art. 100(a), (b), (c)

EPC R. 76(2)(c)

**Keyword:**

Admissibility of opposition - (yes)

Novelty (no) - main request

Added subject-matter (no); insufficiency of disclosure (no) -  
auxiliary request I

**Decisions cited:**

**Catchword:**



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Case Number: T 1088/10 - 3.2.02

**D E C I S I O N  
of Technical Board of Appeal 3.2.02  
of 6 October 2014**

**Appellant:** Jackson, Derek Charles  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 11 March 2010  
rejecting the opposition filed against European  
patent No. 1357969 pursuant to Article 101(2)  
EPC.**

**Composition of the Board:**

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

## Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal against the decision of the Opposition Division rejecting the opposition against European patent No. 1 357 969.
- II. The Opposition Division held that the grounds for opposition raised under Article 100(a), (b) and (c) EPC did not prejudice the maintenance of the patent. In particular, it took the view that claim 1 of the patent was novel having regard to document

D1: US-A-5 772 669.

- III. Oral proceedings took place on 6 October 2014.

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked. The request for reimbursement of the appeal fee was withdrawn.

The respondent (patent proprietor) requested that the appeal be dismissed or, in the alternative, that the decision under appeal be set aside and that the patent be maintained on the basis of one of auxiliary requests I to VII filed with letter dated 25 January 2011.

- IV. Claim 1 of the main request (i.e. claim 1 of the patent as granted) reads as follows:

"A stent delivery system (100) comprising:

- an inner member (104) having a proximal region (108) and a distal region (112) and a stent receiving region (124) at the distal end of the inner member for receiving a stent thereabout;

- a stent sheath (132) having a proximal end, the stent sheath being disposed about the stent receiving region (124), the stent sheath movable relative to the inner member,
- a stent sheath retraction device (136) extending proximally from the stent sheath (132),
- an outer sheath (140) disposed about the inner member (104), the outer sheath (140) having a proximal and a distal end (144), the distal end (144) of the outer sheath (140) terminating proximal of the stent receiving region (124), the stent sheath (132) movable relative to the outer sheath (140),

characterized in that

- the stent sheath (132) has a hypotube (136) or a pull back wire extending proximally from the stent sheath (132) to the proximal end of the stent delivery system, and
- so that the outer sheath disposed about a portion of the stent sheath retraction device (136), the distal end (144) of outer sheath (140) is separated from the proximal end of the stent sheath (132) by at least the length of the stent to be received, when the stent sheath (132) is in its extended position."

Dependent claim 14 of the main request (patent as granted) reads as follows:

"The stent delivery system of claim 1, wherein a length of the inner tube remains exposed to the body lumen between the distal end of the outer sheath and the proximal end of the stent sheath when the stent sheath is extended, and the stent delivery system is inserted."

V. Claim 1 of auxiliary request I reads as follows (amendments with respect to claim 1 of the main request are highlighted by the Board):

"A stent delivery system (100) comprising:

- an inner ~~member~~ tube (104) having a proximal region (108) and a distal region (112) and a stent receiving region (124) at the distal end of the inner ~~member~~ tube (104) for receiving a stent thereabout;
- a stent sheath (132) having a proximal end, the stent sheath being disposed about the stent receiving region (124), the stent sheath movable relative to the inner ~~member~~ tube (104),
- a stent sheath retraction device (136) extending proximally from the stent sheath (132),
- an outer sheath (140) disposed about the inner ~~member~~ tube (104), the outer sheath (140) having a proximal and a distal end (144), the outer sheath disposed about a portion of the stent sheath retraction device (136), the distal end (144) of the outer sheath (140) terminating proximal of the stent receiving region (124), the stent sheath (132) movable relative to the outer sheath (140),

characterized in that

- the stent sheath (132) has a hypotube (136) or a pull back wire extending proximally from the stent sheath (132) to the proximal end of the stent delivery system, and
- ~~so that the outer sheath disposed about a portion of the stent sheath retraction device (136),~~ the distal end (144) of outer sheath (140) is separated from the proximal end of the stent sheath (132) by at least the length of the stent to be received, when the stent sheath (132) is in its extended position, and

- wherein the proximal end of the stent sheath (132) abuts in its retracted position the distal end (144) of the outer sheath (140)."

Claims 2 to 12 are dependent claims.

VI. The arguments of the appellant (opponent) relevant for the present decision are summarised as follows:

(i) For an opposition to be admissible, it was sufficient that one of the grounds for opposition had been sufficiently substantiated. In the present case, the notice of opposition contained substantiated grounds for opposition under Article 100(a), (b) and (c) EPC.

(ii) Article 100(c) EPC

- There was no basis in the application as filed for the following features in claim 1 of the granted patent: "the stent to be received" and the "extended position" of the stent sheath. In particular, the passage on page 5, lines 27 to 28 did not specify the separation between the proximal end of the stent sheath and the distal end of the outer sheather by at least the length of the stent "to be received". Moreover, this passage didnot specify that the mentioned separation was the separation when the stent sheath was in "its extended position". In fact, the expression "its extended position" was nowhere mentioned in the application as originally filed. It was unclear what the "extended position" of the stent sheath should be. In particular, it was ambiguous whether the stent sheath in Figure 1, depicted as not fully covering the stent, was to be considered to be in "its extended position" or not.

- There was no basis in the application as filed for the features of dependent claim 14 of the granted patent, since they concerned a method step which was not derivable from the original application, in particular its page 5, line 29 to page 6, line 3. Moreover, the figures not only showed the inner tube to be exposed, but also the hypotube or pullback wire, whereby claim 14 was based on extraction of isolated features from a set of features which were disclosed in combination.

(iii) Article 100(b) EPC

Since stents could have a multitude of lengths, a stent delivery system according to claim 1, which referred to such a stent, could not be built by a person skilled in the art.

(iv) Novelty

In D1, sheath 40 corresponded to the stent sheath of the claim. It was irrelevant that it was glued to the dual lumen member 48. Figure 1 of D1 showed that the distal end of slide 49 at position 50 was separated from the proximal end of the distal sheath 40 by at least the length of the stent 35 to be received. The claimed separation was not to be interpreted as a gap between the outer sheath and the stent sheath, as in the contested decision, but as a length between two points of the stent delivery system.

(v) At oral proceedings it was confirmed that there were no specific objections against auxiliary request I.



VII. The arguments of the respondent (patent proprietor) relevant for the present decision are summarised as follows:

(i) The opposition was not admissible since the opponent had not substantiated in its notice of opposition where in D1 it was disclosed that the stent receiving region was at the distal end of the inner member.

(ii) Article 100(c) EPC

- In claim 1 of the granted patent, the expressions "the stent to be received" and the "extended position" of the stent sheath were directly and unambiguously disclosed on page 5, line 16 to page 6, line 3 in conjunction with the example of Figure 1.

- The objection under Article 100(c) EPC against dependent claim 14 of the granted patent should not be admitted since it had not been raised in the first-instance proceedings. In any case, there was a basis for the features of this claim on page 5, lines 24 to 30 and Figures 1 and 3.

(iii) Article 100(b) EPC

- The objection under Article 100(b) EPC should not be admitted either, since it had not been raised in the first-instance proceedings. However, the drawings of the opposed patent, for example Figures 1 to 3 in conjunction with the specification, for example paragraphs [0021] to [0028], clearly disclosed an embodiment according to the invention which could easily be carried out by a person skilled in the art.

(iv) Novelty

In D1, the retractable sheath 40 was affixed to the tubular member 48 which served as an extension of the retractable sheath 40. They were therefore formed into one structural unit which corresponded to the stent sheath according to claim 1. Consequently, D1 did not disclose the inventive separation between the distal end of the outer sheath from the proximal end of the stent sheath of at least the length of the stent to be received, when the stent sheath was in its extended position. As held by the Opposition Division in its decision, this separation should be understood as meaning that there was indeed a gap between the outer sheath and the stent sheath. Otherwise, the advantages of the invention explained in paragraph [0043] of the patent could not be achieved.

**Reasons for the Decision**

1. The appeal is admissible.
2. *Admissibility of the opposition*
  - 2.1 The respondent questioned the admissibility of the opposition on the grounds that the opponent had not substantiated in its notice of opposition where in D1 a certain claimed feature was disclosed (the stent receiving region being at the distal end of the inner member).
  - 2.2 It is established case law that for an opposition to be admissible, it is sufficient that one of the grounds for opposition has been sufficiently substantiated according to the requirements of Rule 76(2)(c) EPC (Case Law of the Boards of Appeal, 7th edition, 2013,

IV.D.3.2.). In the present case, it is undisputed that the notice of opposition contained not only a novelty objection based on D1, but also several other substantiated objections, inter alia on grounds under Article 100(b) and (c) EPC. It is therefore irrelevant for the admissibility of the opposition whether or not the notice of opposition contained an indication of the disclosure of a certain claimed feature in D1.

2.3 The Board is thus satisfied that the opposition is admissible. Moreover, the ground of novelty is to be considered in the present appeal, at least because it was also considered in the impugned decision (point II above).

### 3. *Main request*

#### 3.1 *Article 100(c) EPC*

3.1.1 The application as filed (WO-A-02/060520) describes on page 5, lines 14 to 15 and 29 to 31 in conjunction with Figure 1 that the stent delivery system is inserted into a body vessel with a stent 128 received about the stent receiving region 124. Also original claim 1 referred to "a medical device receiving region ... for receiving a medical device thereabout", and original claim 3 specified that "the medical device is a stent". Thus, by defining the stent as a stent "to be received", the subject-matter of claim 1 of the granted patent contains no additional subject-matter.

3.1.2 The application as filed describes moreover that the stent sheath 132 provides a stent chamber 134 in which the stent 128 resides (page 5, lines 17 to 18), and that for deploying the stent the stent sheath 132 is retracted in proximal direction so that it no longer

covers the stent 128; desirably, the stent sheath is retracted until the stent sheath 132 abuts the distal end 144 of the outer sheath 140 (page 5, line 31 to page 6, line 3).

As this passage provides an explicit disclosure of a final *retracted* position of the stent sheath (allowing deployment of the stent), the initial position of the stent sheath (covering the stent) may be termed an "extended position" without any addition of information with respect to the original disclosure.

Page 5, lines 27 to 28 of the application as filed discloses for the embodiment of Figure 1 that the distal end 144 of the outer sheath 140 is separated from the proximal end of the stent sheath 132 by "at least the length of the (received) stent". Although the schematic nature of Figure 1 may give the impression that not the entire length of the stent is covered by the stent sheath, the skilled person would nevertheless realise that the stent sheath is capable of fully extending and enclosing a stent having the length of the stent chamber 134. This specific situation is depicted in Figure 8 (even if other features of this embodiment do not fall under the terms of claim 1 of the patent as granted). The separation of "at least the length of the (received) stent" disclosed on page 5, lines 27 to 28 thus applies when the stent sheath is in its (fully) extended position.

The Board therefore comes to the conclusion that no subject-matter has been added by defining in claim 1 of the contested patent that "the distal end (144) of outer sheath (140) is separated from the proximal end of the stent sheath (132) by at least the length of the

stent **to be received**, when the stent sheath (132) is in **its extended position**" (emphasis added).

- 3.1.3 The respondent requested the Board not to consider the appellant's objection under Article 100(c) EPC against dependent claim 14 of the granted patent, since it had not been raised in the first-instance proceedings.

The Board notes, however, that the objection had been brought forward in the statement of grounds of appeal and that it is very similar and related to the objections (against claim 1) under the same ground of Article 100(c) EPC which had already been raised in the first-instance proceedings. Thus, the Board considers that the objection against dependent claim 14 is part of the appellant's case and is hence to be examined in the present appeal proceedings.

- 3.1.4 From page 5, lines 24 to 30 of the application as filed, in conjunction with Figures 1 and 3, it is clearly and unambiguously derivable that, when the stent sheath is extended, there is a section of the inner tube 104 between the distal end of the outer sheath 140 and the proximal end of the stent sheath 132 which is not covered by a further device (Figure 3), and which thus remains exposed to the body lumen in which it is inserted (page 5, lines 29 to 30). The fact that the figures also show the hypotube 136 to be exposed over that length, as argued by the appellant, cannot be seen as being of importance for attaining the advantage of reducing friction when the stent sheath is slid back, as explained on page 8, lines 14 to 20 of the application as filed.

Hence, the Board takes the view that the features of dependent claim 14 do not introduce subject-matter

extending beyond the content of the application as filed.

3.1.5 It follows that the maintenance of the patent as granted is not prejudiced by the ground for opposition under Article 100(c) EPC.

3.2 *Article 100(b) EPC*

3.2.1 The appellant argued that the stents to be received could have a multitude of lengths and that therefore a stent delivery system according to claim 1 of the opposed patent, which referred to such a stent, could not be built by a person skilled in the art.

3.2.2 The Board does not follow the respondent's request not to admit the objection under Article 100(b) EPC which had not been raised in the first-instance proceedings. In analogy to point 3.1.3 above, the Board considers that the objection was brought forward in the statement of grounds of appeal and is very similar and related to the objections under the same ground of Article 100(b) EPC which had already been raised in the first-instance proceedings. Thus, the Board considers that the objection is part of the appellant's case and is to be examined in the present appeal proceedings.

3.2.3 As to the merit of the objection, the Board follows the respondent's view. The drawings of the opposed patent, for example Figures 1 to 3 in conjunction with the specification, for example paragraphs [0021] to [0028], clearly disclose an embodiment of the stent delivery system according to claim 1 which can easily be carried out by the person skilled in the art. In particular, paragraphs [0025] and [0026] of the patent explain that the distal end of the outer sheath is separated from

the proximal end of the stent sheath by at least the length of the stent which is to be deployed.

Hence, the maintenance of the patent as granted is not prejudiced by the ground for opposition under Article 100(b) EPC.

### 3.3 *Article 100(a) EPC - novelty*

3.3.1 The invention of the opposed patent relates to a stent delivery system in which, in essence, a stent is carried by an inner member and surrounded by a retractable stent sheath. Once in place, the stent sheath is retracted by pulling it in the proximal direction by pull back means attached to the stent sheath.

3.3.2 Both the application as originally filed and the opposed patent cite document D1 as relevant prior art, explaining that it discloses a catheter having a proximal outer shaft, a retractable distal sheath arranged around a stent receiving portion of the catheter and a pull back means operatively connected to the retractable distal sheath for freeing the loaded stent (page 2, lines 18 to 24 of the original application and paragraph [0008] of the opposed patent).

3.3.3 More specifically, the stent delivery system disclosed in Figures 1 to 4 of D1 comprises an inner member (inner shaft 15) for receiving a stent (35) thereabout (column 4, lines 10 to 12), a stent sheath (retractable sheath 40) with a pull back wire (45) as a stent sheath retraction device (column 4, lines 16 to 20), and an outer sheath (proximal slide sheath 49 and shaft 10; column 3, lines 46 to 49) about a portion of the stent

sheath retraction device (45). As can be seen in Figure 1 of D1, where the stent sheath (40) is in its extended position, "the distal end of the outer sheath (at position 50 in Figure 1) is separated from the proximal end of the stent sheath (40) by at least the length of the stent (35) to be received", as defined in claim 1.

3.3.4 It may be noted in this respect that the Board interprets the definition of two points on the device "separated" by a certain length in accordance with its normal meaning of a distance between the two points. The Board sees no justification in the present case for interpreting the expression in the more restricted sense of a gap between the outer sheath and the stent sheath, as was argued by the respondent and was held by the Opposition Division in the impugned decision. Moreover, the mentioning of the advantage of reducing frictional forces when retracting the stent sheath in paragraph [0043] of the patent does not limit the claimed "separation" between the outer sheath and the stent sheath.

3.3.5 Also at variance with the position taken by the respondent and the Opposition Division, the Board considers that it is permissible to equate the "stent sheath" of claim 1 of the patent with the retractable sheath 40 of D1. In fact, the retractable sheath 40 has the same function, i.e. of covering the underlying stent during the introduction of the stent to the deployment site, as the "stent sheath" of claim 1 of the patent (D1, column 4, lines 65 to column 5, line 3). The fact that the retractable sheath 40 is affixed to something else, in particular to the tubular member 48, does not necessarily mean that the assembled component of retractable sheath 40 and tubular member



48 is the equivalent of the "stent sheath" of claim 1 of the patent. In fact, also in the opposed patent the stent sheath 132 is identified as a "stent sheath" although it is attached to hypotube 136 (paragraph [0023]; Figure 1).

3.3.6 The Board thus concludes that the subject-matter of claim 1 of the main request lacks novelty within the meaning of Article 54(1), (2) EPC, precluding the maintenance of the patent as granted.

4. Auxiliary request I

In the written proceedings, the appellant did not present any specific objection against this request, and it explicitly confirmed at oral proceedings that it did indeed not have any. The Board moreover sees no compelling reason in the present case to raise any objection itself following Article 114(1) EPC. Furthermore, the objections raised under Article 100(b) and (c) EPC which were considered above (and which also apply to auxiliary request I) do not prejudice the maintenance of the patent.

The Board therefore concludes that the patent is to be maintained on the basis of auxiliary request I. There is consequently no need for the Board to examine the further auxiliary requests II to VII.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of:
  - claims 1 to 12 of auxiliary request I filed with letter dated 25 January 2011; and
  - description and figures of the patent as granted.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated