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**Datasheet for the decision
of 21 July 2011**

Case Number: T 1118/08 - 3.2.02

Application Number: 02720759.6

Publication Number: 1351737

IPC: A61M 25/01

Language of the proceedings: EN

Title of invention:

Rapid exchange catheter sheath for deployment of medical devices

Patentee:

Boston Scientific Limited

Opponent:

EV3, Inc.

Headword:

-

Relevant legal provisions:

EPC Art. 123(2)

Relevant legal provisions (EPC 1973):

-

Keyword:

"Extended subject-matter (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 1118/08 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 21 July 2011

Appellant:
(Patent Proprietor) Boston Scientific Limited
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Respondent:
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 2 May 2008
revoking European patent No. 1351737 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: D. Valle
Members: P. L. P. Weber
A. Pignatelli

Summary of Facts and Submissions

- I. The appellant (patentee) lodged an appeal on 12 July 2008 against the decision of the Opposition Division posted on 2 Mai 2008 to revoke the patent. The fee for the appeal was paid the same day and the statement setting out the grounds for appeal was received on 4 September 2008.
- II. The patent was opposed on the basis of Article 100 (a) EPC (lack of novelty and inventive step) and 100 (b) EPC (insufficient disclosure) and 100 (c) EPC (extended subject-matter). The adverse decision was based on the grounds of lack of novelty and inventive step. In particular, the Opposition Division stated that the term "configured to facilitate backloading" was not used in the application as filed, but decided after discussion with the parties to interpret it as "to permit backloading" or "not to prevent backloading" and then considered that the so interpreted functional feature contained in the main claims: "to facilitate backloading" was already disclosed in the closest prior art.
- III. Oral proceedings were held on 21 July 2011.

At the end of the oral proceedings the appellant requested that the decision under appeal be set aside and that the patent be maintained as granted or according to the two auxiliary requests filed with the statement setting out the grounds of appeal of 4 September 2008 or according to auxiliary request 3 filed during the oral proceedings before the Board.

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

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

"A sheath for deployment of a medical device, comprising:

- an elongated tubular member (10) having a proximal end, a distal end (12), and an internal lumen (11) at least in part therebetween, said elongated tubular member (10) having a first opening (15) at the distal end (12) and a second opening (16) proximal to the distal end (12);

- a first elongated member (20) adapted to pass through the first opening (15), through the internal lumen (11) of the elongated tubular member (10), and through the second opening (16); and

- a second elongated member (25) positioned within the internal lumen (11) of the elongated tubular member (10), said second elongated member (25) having a proximal end and a distal end (26);

characterized in that:

- the elongated tubular member (10) further defines a third opening (17) proximal to the distal end (12) thereof; and

- wherein the elongated tubular member (10) is configured to facilitate backloading of the second elongated member (25) proximally through the first opening (15), through the internal lumen (11), and through the third opening (17)."

Claim 1 of the auxiliary request I reads as follows:

"A sheath for deployment of a medical device filter (50), comprising:

- an elongated tubular member (10) having a proximal end, a distal end (12), and an internal lumen (11) at least in part therebetween, said elongated tubular member (10) having a first opening (15) at the distal end (12) and a second opening (16) proximal to the distal end (12);
 - a first elongated member (20) adapted to pass through the first opening (15), through the internal lumen (11) of the elongated tubular member (10), and through the second opening (16); and
 - a second elongated member (25) positioned within the internal lumen (11) of the elongated tubular member (10), said second elongated member (25) having a proximal end and a distal end (26), the filter (59) disposed on the second elongated member (25);
- characterized in that:
- the elongated tubular member (10) further defines a third opening (17) proximal to the distal end (12) thereof; and
 - wherein the elongated tubular member (10) is configured to facilitate backloading of the second elongated member (25) proximally through the first opening (15), through the internal lumen (11), and through the third opening (17); and wherein the third opening (17) comprises a side-facing opening of the elongated tubular member (10)."

Claim 1 of the auxiliary request II reads as follows:

"A sheath for deployment of a medical device filter (50), comprising:

- an elongated tubular member (10) having a proximal end, a distal end (12), and an internal lumen (11) at least in part therebetween, said elongated tubular member (10) having a first opening (15) at the distal end (12) and a second opening (16) proximal to the distal end (12);
 - a first elongated member (20) adapted to pass through the first opening (15), through the internal lumen (11) of the elongated tubular member (10), and through the second opening (16); and
 - a second elongated member (25) positioned within the internal lumen (11) of the elongated tubular member (10), said second elongated member (25) having a proximal end and a distal end (26), the filter (59) disposed on the second elongated member (25);
- characterized in that:
- the elongated tubular member (10) further defines a third opening (17) proximal to the distal end (12) thereof; and
 - wherein the elongated tubular member (10) is configured to facilitate backloading of the second elongated member (25) proximally through the first opening (15), through the internal lumen (11), and through the third opening (17); and wherein the third opening (17) comprises a side-facing opening of the elongated tubular member (10); and wherein the internal lumen (11) is confined proximally by a slanted surface to facilitate backloading."

Claim 1 of the auxiliary request III reads as follows:

"A sheath for deployment of a filter (50), comprising:

- an elongated tubular member (10) having a proximal end, a distal end (12), and an internal lumen (11) at least in part therebetween, said elongated tubular member (10) having a first opening (15) at the distal end (12) and a second opening (16) proximal to the distal end (12);

- a first elongated member (20) adapted to pass through the first opening (15), through the internal lumen (11) of the elongated tubular member (10), and through the second opening (16); and

- a second elongated member (25) positioned within the internal lumen (11) of the elongated tubular member (10), said second elongated member (25) having a proximal end and a distal end (26), the filter (50) disposed on the second elongated member (25);

characterized in that:

- the elongated tubular member (10) further defines a third opening (17) disposed proximally of the second opening (16); and

- wherein the elongated tubular member (10) is configured to facilitate backloading of the second elongated member (25) proximally through the first opening (15), through the internal lumen (11), and through the third opening (17); and wherein the third opening (17) comprises a side-facing opening of the elongated tubular member (10); and wherein the internal lumen (11) is confined proximally by a slanted surface which is slanted towards and ends at the proximal end of the third opening (17) to facilitate backloading through the third opening."

V. The appellant argued in particular that the feature "facilitate backloading" was disclosed in the Figures 5A to 5C and in the corresponding passages of the description. The expression "to facilitate backloading" meant "to make backloading easy or easier". It was conceded that the feature was not literally disclosed in the application as originally filed, but the skilled person would immediately understand that Figures 5A through 5C of the application as originally filed disclosed means for facilitating backloading. In Figures 5A and 5B an interior ramp guided the proximal end of support wire 25 to exit third opening 17 of lumen 11. In Figure 5C, the "facilitating" feature was the increased angular window available for allowing the wire 25 to be guided toward an aperture 17. The skilled person of the art would compare the tube illustrated in the figures with the same tube but with the above illustrated features omitted (see letter of 21 June 2011, page 2, second and third full paragraph) and would immediately understand that such features would facilitate backloading.

Claim 1 of the second auxiliary request contained the further feature specifying that backloading was facilitated by a slanted surface.

The third auxiliary request represented a serious attempt to overcome the objections raised, since it further specified the measures for facilitating backloading by a slanted surface "through the third opening", whereby the surface was slanted towards and ended at the proximal end of the third opening. The request was not late since it was caused by the objections during the oral proceedings.

VI. The respondent contested the statements of the appellant and argued essentially that the feature "facilitate backloading" was not disclosed originally. Also the third auxiliary request was not suitable for overcoming the above objection since it contained also the contested feature.

Reasons for the Decision

1. The appeal is admissible.
2. Extended subject-matter

Claim 1 of the main and of auxiliary requests one and two contains the feature:

"the elongated tubular member (10) is configured to facilitate backloading of the second elongated member (25)".

In the opinion of the Board, "to facilitate backloading" means "to make backloading easy or easier" and not simply to make backloading possible, as stated by the decision under appeal. The former is also the meaning given to the clause by the appellant.

The feature is not disclosed in the originally filed application. The original disclosure concerns a rapid exchange sheath for deployment of medical devices and methods of use. The sheath consists of an elongate tubular member designed to accommodate a guidewire and a further support wire with an expandable filter. In

order to facilitate exchange operations the sheath is provided with a lateral opening proximal to its distal end in order to insert the guidewire. In some embodiments, see in particular Figures 5 and 6, a further lateral opening adjacent to the first one is provided on the sheath in order to laterally insert the support wire backward or forward. This latter opening is designed either as a side-facing opening distally limited by a slanted surface (Figure 5A), or as a side opening at the end of a tubular extension inclined with respect to the sheath direction (Figure 5B) or parallel to it (Figure 5C). In the parts of the description related to these figures it is mentioned that backloading (as well as forward loading) is possible, but throughout the application no indication can be found that backloading was difficult nor that some special features could facilitate it. Therefore the feature "to facilitate backloading" contained in claim 1 of the main and of the auxiliary requests 1 and 2 is not originally disclosed.

The argument of the appellant that the feature was disclosed in the drawings can not be accepted. Drawings disclose structural features in combination. The feature "facilitate backloading" is a purposive feature. Purposive features are - as a rule - not disclosed by drawings. Furthermore, it is not allowed to pick and choose from a drawing a single feature which was possibly disclosed there in combination with all the further features of the drawing itself. In this context it is to be noted that Figures 5A, 5B and 5C are rather schematically drawn and not precise technical drawings. This also leads to assume that the structural features summarily hinted at in the drawings

but not specifically addressed to in the description do not have any relevance or were not intended to be of relevance at the filing date. There is thus no disclosure in the original application that backloading could be difficult and that some measure specifically intended to facilitate backloading could be beneficial. The original disclosure does not even give hints to it.

Regarding auxiliary request two, it has to be noted that no special meaning or purpose was given to the interior ramp of Figures 5A and 5B in the original disclosure; this interior ramp has not even been mentioned in the original disclosure.

In addition the slanted surface as claimed could be anywhere in the lumen 11, which was not originally disclosed either.

Accordingly, claim 1 of the main and of the auxiliary requests one and two does not comply with Article 123 (2) EPC.

3. Third Auxiliary request

The third auxiliary request has been submitted at the end of the oral proceedings. The Board considers this request not admissible because too late and because it does not appear prima facie to be clearly allowable, see Article 114 (2) EPC and Articles 12 and 13 RPBA.

The request was too late because no new facts or arguments could justify it at so late stage. The objection against the feature "facilitate backloading" has been already considered in the decision under appeal and in the letters of the parties during the

appeal proceedings and has been mentioned in the communication of the Board attached to the summons for oral proceedings. It was also clear right from the beginning of the procedure that the appellant considered that the support for claim 1 was to be found in the drawings.

Furthermore claim 1 of the third auxiliary request does not appear prima facie to overcome the objection above since it still contains the term "facilitate". As said above this term defines a purpose. There are no hints at all throughout the original disclosure that backloading could be difficult and that it would be advantageous to suggest measure in order to facilitate it.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

The Registrar:

The Chairman:

D. Sauter

D. Valle