BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [ ] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 16 April 2009

Case Number: T 0626/07 - 3.2.02

Application Number: 99912477.9

Publication Number: 1061846

IPC: A61M 29/00

Language of the proceedings: EN

Title of invention:
Protective device and method against embolization in carotid angioplasty

Applicant:
Gore Enterprise Holdings, Inc.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 52, 56

Relevant legal provisions (EPC 1973):
-

Keyword:
"Inventive step (yes, after amendments)"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0626/07 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 16 April 2009

Appellant: Gore Enterprise Holdings, Inc.
551 Paper Mill Road
P.O. Box 9206
Newark, DE 19714-9206 (US)

Representative: Shanks, Andrew
Marks & Clerk LLP
19 Royal Exchange Square
Glasgow G1 3AE (GB)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 19 October 2006 refusing European application No. 99912477.9 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: M. Noël
Members: D. Valle
A. Pignatelli

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal on 14 December 2006 against the decision of the examining division posted on 19 October 2006 to refuse the European patent application No. 99912477.9 for lack of inventive step. The fee for the appeal was paid on 15 December 2006 and the statement setting out the grounds for appeal was received on 28 February 2007, along with amended claims.

II. The following documents are relevant for the present decision:

D1 = US - A - 5 011 488
D2 = US - A - 5 102 415.

III. Oral proceedings were held on 16 April 2009, at the end of the oral proceedings the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 7 filed during the oral proceedings.

IV. Claim 1 reads as follows:

"A device (b) for removing emboli generated during carotid angioplasty comprising:
a guide catheter (9) having proximal and distal ends (10, 11), and a lumen extending therebetween;
a tubular member (12) slidably disposed within the lumen of the guide catheter (9) and an occluder (14) at a distal end (13) of the tubular member (12), the tubular member (12) having two proximal branches, the branches including an outlet port and an access port

(16, 17), the distal end (13) having an opening communicating with a drainage port (15) of the occluder (14), and a lumen (90) extending between the outlet and access ports (16, 17) and the distal opening, the tubular member (12) having a retracted position wherein the occluder (14) is disposed within the guide catheter (9) and has a retracted diameter suitable for endoluminal insertion, and an extended position, wherein the occluder (14) extends beyond the distal end (11) of the guide catheter (9) and has an expanded diameter adapted to occlude anterograde blood flow in a vessel; and
a hemostatic valve (160) disposed on the outlet port (16) for controlling the flow of blood therethrough in a reverse retrograde direction and suction out emboli generated during an angioplasty procedure."

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

The amendments to the claims are based on page 4, first full paragraph, page 12, first paragraph, page 16, lines 10 to 14; Figures 1A and 1B and the corresponding passages of the description of the original disclosure. They do not extend beyond the content of the application as originally filed and are therefore allowable under Article 123(2) EPC.

3. *Novelty and inventive step*

3.1 Using the words of claim 1 in suit, D1 (see Figures 1, 2 and 5) discloses a device 10 for removing emboli comprising a guide catheter 12 having proximal and distal ends 22, 20, and a lumen extending therebetween, a tubular member 14 slidably disposed within the lumen of the guide catheter 12 and an occluder 30 at a distal end 20 of the tubular member 14, the distal end 20 having an opening communicating with a drainage port of the occluder 30. The tubular member 14 can take a retracted position (see Figure 2C) wherein the occluder 30 is disposed within the guide catheter and has a retracted diameter suitable for endoluminal insertion, and an extended position, wherein the occluder extends beyond the distal end of the guide catheter and has an expanded diameter (see Figure 2A).

Further, D1 discloses that in the expanded configuration, the occluder is adapted to occlude anterograde blood-flow in the vessel (see Figures 5C and column 6, lines 54 - 60).

Moreover, the proximal end of the tube is in flow communication with an aspiration outlet port 48 (Figure 1) for aspirating the blood in a reverse retrograde direction and suctioning out emboli generated during an angioplasty procedure (see column 5, lines 54 - 57 and column 7, lines 4 - 7).

However, D1 which is considered as the closest state of the art does not disclose that the tubular member has two proximal branches including an outlet port and an access port and a lumen extending between the outlet

and access ports, and that a hemostatic valve is disposed on the outlet port for controlling the flow of blood therethrough. Moreover the device according to D1 is not specifically designed for directly removing emboli generated during carotid angioplasty but for removing clot or thrombus by first dislodging them from the blood vessel and then collecting them in the distal end of the intravascular catheter (see column 1, lines 9 to 14).

Since the claimed features are not disclosed as a whole in any other prior art document, the claimed subject-matter is novel under Article 54 EPC 1973.

3.2 D1 provides a sealing box 44 attached to the proximal end of the tubular member 14 and having a first aspiration port 48 and a second port for introducing an elongate member 18. However this construction is more complicated than that of the invention and may give rise to sucted material being trapped within the sealing box, resulting in blockage of the aspiration port or obstruction of the elongate member.

With respect to the disclosure of D1, this problem is solved in the present invention by the distinguishing features mentioned in point 3.1 above, in particular by the provision of a branched tube which directs removed emboli along a separate branch to that provided for an elongate member such as an interventional instrument. Moreover, this simpler construction allows for a smoother flow of blood out of the tube.

D2 discloses (see Figure 2 and column 3, lines 62 - 66) a catheter having its proximal end connected to a

suction means 7 through a control valve 8, for extracting or sluicing out a blood clot from arteries and veins. However, even if a hemostatic valve and a suction means are known per se, from D2, their incorporation in the device disclosed in D1 would still be insufficient to arrive at the combination of features as claimed. The present invention resides primarily in the provision of a branched tube in combination with a hemostatic valve especially designed for inducing a retrograde blood flow in the vessel.

Accordingly, the subject-matter of claim 1 involves an inventive step within the meaning of Article 56 EPC.

Dependent claims 2 to 7 disclose further embodiments of the invention and are also allowable.

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 grant a patent with the claims 1 to 7 filed during the oral proceedings, a description to be adapted and drawings as originally filed.

The Registrar: The Chairman:

D. Sauter M. Noël