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Datasheet for the decision of 6 November 2012

Case Number: T 0934/10 - 3.2.02

Application Number: 04784163.0

Publication Number: 1667587

IPC: A61B 17/22

Language of the proceedings: EN

Title of invention:
Embolectomy device

Applicant:
Boston Scientific Limited

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0934/10 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 6 November 2012

Appellant: (Applicant)
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Decision under appeal:
Decision of the Examining Division of the European Patent Office posted 7 December 2009 refusing European patent application No. 04784163.0 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: E. Dufrasne
Members: P. L. P. Weber
M. Stern

Summary of Facts and Submissions

I. The appeal is against the decision of the Examining Division posted on 7 December 2009 to refuse European patent application No.04784163.0 because of lack of novelty over D1.

The notice of appeal was filed on 8 February 2010 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 15 April 2010.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the final main request filed on 13 November 2009, or as an alternative on the basis of the auxiliary request filed on the same date.

II. Claim 1 of the final main request reads as follows:

"A catheter for unclogging or fragmenting an embolus comprising:

a first elongate shaft (206) having a proximal end, a distal end and a lumen therethrough;

a second elongate shaft (208) at least partially disposed in the lumen of the first elongate shaft, the second shaft (208) having a proximal end, a distal end and a lumen therethrough;

a tip (210) disposed on the distal end of the second shaft (208) having a cavity fluidly connected to the lumen of the second shaft (208) and a distal opening,

the tip (210) movable between a first state and a second state wherein the distal opening has a greater cross-sectional area in the second state than in the first state; and

a vibratable wire for unclogging or fragmenting an embolus at least partially disposed within the lumen of the second elongate shaft (208)."

III. There is no need for the present decision to consider the subject-matter of the auxiliary request.

IV. The following documents are cited in the present decision:

D1: US-A-2002/0019590
D2: US-A-2003/0163158.

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

The apparatus disclosed in D1 is for biopsy and tumorectomy and for retrieving tissue specimens and not for unclogging or fragmenting an embolus as required by claim 1.

Several other features of claim 1 are also not known from D1. The Examining Division was mistaken in considering the mesh material to be a shaft, i.e. an elongate element having a proximal end, a distal end and a lumen therethrough. For this reason the mesh material also does not form a cavity fluidly connected to the lumen of the second shaft.

The device according to D1 is not suitable for unclogging or fragmenting an embolus, if only because it is not suitable to be inserted into small blood vessels due to its dimensions and due to its rigidity. Moreover, there is no disclosure in D1 of a vibratable wire for unclogging or fragmenting an embolus. The wire tissue cutter disclosed therein cannot be considered a vibratable wire within the meaning of the invention, it is for cutting a layer of tissue surrounding a target site. There is no indication in D1 that the cutter of D1 is suitable for fragmenting tissue.

For the above reasons, the subject-matter of claim 1 is novel over D1.

Also document D2 also does not disclose at least a vibratable wire for unclogging or fragmenting an embolus, so that the subject-matter of claim 1 is also novel over this document.

As none of the documents discloses a vibratable wire for unclogging or fragmenting an embolus, a combination of the documents cannot lead to the subject-matter of claim 1, which is therefore also inventive.

Reasons for the Decision

1. The appeal is admissible.

Final main request

2. Novelty

2.1 Novelty over D1

Document D1 discloses a device for diseased tissue removal, in particular in relation with cancer, typically breast cancer. Claim 1, instead, defines *A catheter for unclogging or fragmenting an embolus,* a purpose for which the device shown in D1 is not suitable. An embolus is mass, a detached blood clot or a foreign body, that travels through the bloodstream and lodges so as to obstruct or occlude a blood vessel. There is no indication in D1 that the device described there is suitable for such use. On the contrary, it is mentioned ([0015]) that the invention according to this document is directed to procedures including biopsy and tumorectomy. The mesh associated with the device shown in D1 (Figures 9, 11) is a cutting mesh, meant for cutting diseased tissue ([0060]).
Further, in D1, there is neither an explicit indication nor an implicit disclosure that the outer tubes 117 or 146 would have the necessary flexibility to render them suitable for entering a vessel and being guided along the said vessel to the location of an embolus. On the contrary, all the figures show straight outer tubes. There appears also to be no technical reason to use flexible catheters in order to cut a part of tissue from a breast, as exemplified in D1. It seems that in

the absence of any vessel walls helping to guide the catheter, as in a breast, a flexible catheter would actually be more difficult to handle than a rigid one.

Additionally, it is specifically mentioned in D1 that the severed tissue enclosed in the mesh for removal should remain substantially intact for examination by the physician (end of [0060]: *"This procedure helps to ensure tissue layer 100 is substantially intact for examination by the physician or other health-care professional."*). This teaching is clearly at odds with any fragmenting of the collected material as required by claim 1.

Hence, in the Board's opinion D1 discloses a different type of device which is not novelty-destroying for the subject-matter of claim 1 according to the final main request.

2.2 Novelty over D2

The device described in D2 comes closer to the subject-matter of claim 1, as it is a thromboembolectomy device for performing a thromboembolectomy procedure in a bodily vessel. This device mainly comprises three parts: a capture means 10 which can be deployed (or not) and is meant to be placed distally of the thrombus, a thromboembolectomy means 30 which is also meant to be placed distally of the thrombus (but proximally of the capture means 10) and finally an extractor means 20 which is meant to be placed proximally of the thrombus, this extractor means having an expandable distal end (e.g.[0013]). All the elements mentioned are within a percutaneous sheath 21 which

allows access to the vessel. When the thrombus is to be removed the capture means are deployed, the thromboembolectomy means is displaced proximally so as to remove the thrombus from the wall of the vessel and the removed part or parts are drawn into the extractor means, more precisely into the distal expanded end of it. The extractor means together with the thromboembolectomy means is then withdrawn, which brings the distal end into its unexpanded shape to encapsulate the removed thrombus ([0093]-[0094] and Figures 4a - 4d). The different steps of such a thromboembolectomy are described in paragraphs [0098] to [0109].

In other words, in the terms of claim 1, D2 discloses the following features:
a first elongate shaft (21) having a proximal end, a distal end and a lumen therethrough; a second elongate shaft (20) at least partially disposed in the lumen of the first elongate shaft, the second shaft (20) having a proximal end, a distal end and a lumen therethrough; a tip (18,19,99) disposed on the distal end of the second shaft (20) having a cavity fluidly connected to the lumen of the second shaft (20) and a distal opening, the tip movable between a first state and a second state wherein the distal opening has a greater cross-sectional area in the second state than in the first state ([0013],[0105]).

In D2 there is, however, no mention of any vibratable wire for unclogging or fragmenting an embolus at least partially disposed within the lumen of the second elongate shaft.

The guide wire 11, even if it were to be vibrated, could not have any fragmentation effect on an embolus captured in the tubular structure 17 of the device according to D2, because at that location this guide wire is surrounded by catheter 23.

Therefore, the subject-matter of claim 1 according to the final main request is also novel over D2.

2.3 The other document cited in the search report is less relevant.

2.4 In conclusion, the subject-matter of claim 1 according to the final main request is new within the meaning of Article 54 EPC.

3. Inventive step

3.1 From the documents cited in the search report, D2 is the closest prior art as it discloses a thromboembolectomy device for performing a thromboembolectomy procedure in a bodily vessel.

3.2 As mentioned above, D2 does not however disclose a vibratable wire for unclogging or fragmenting an embolus at least partially disposed within the lumen of the second elongate shaft.

3.3 The fundamental question when it comes to inventive step is whether it would have been obvious for the person skilled in the art to amend the device according to D2 in order to integrate the above-mentioned feature.

In the present case, it appears to make little technical sense to add a vibratable wire to the device according to D2 because in that device the detached thrombus is drawn into the extractor means by the thromboembolectomy means, and the detached thrombus together with the thromboembolectomy means and the extractor means are removed from the vessel ([0094],[0106]-[0109]). The device according to D2 does not use vacuum, so the fragmenting of the embolus would increase the risk of losing a fragment within the vessel.

3.4 Additionally, since none of the documents cited in the search report shows any such wire adapted for unclogging or fragmenting an embolus in an intraluminar surgical operation, there is no basis for a lack of inventive step objection based on a combination of the documents.

3.5 Finally, even if the person skilled in the art might wish, in order to solve whatever problem, to fragment the thrombus removed with the device according to D2, first, there is no reason why it would be obvious to use a vibrating wire, and second, if he wanted to use a vibrating wire, he would have to redesign completely the device according to D2 in order either to have enough space for an additional wire or to bring the guide wire somehow into contact with the embolus. None of these options can be said to be obvious.

3.6 Thus, the subject-matter of claim 1 of the final main request involves an inventive step within the meaning of Article 56 EPC.

4. The Board is satisfied that the other requirements for grant are fulfilled.

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 grant a patent on the basis of the final main request documents:

Claims:	1 to 15 as filed on 13 November 2009;
Description:	pages 1, 1b, 2, 3, 5 as filed on 13 November 2009; page 1a as filed on 13 October 2009; page 4 as published;
Drawings:	pages 1/3 to 3/3 as published.

The Registrar: The Chairman:

D. Hampe E. Dufrasne