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**Datasheet for the decision
of 7 May 2020**

Case Number: T 1703/16 - 3.2.08

Application Number: 08769222.4

Publication Number: 2142070

IPC: A61B1/00

Language of the proceedings: EN

Title of invention:

APPARATUS AND METHOD FOR POSITIONING AND RETENTION OF CATHETER

Applicant:

St. Jude Medical,
Atrial Fibrillation Division, Inc.

Relevant legal provisions:

EPC Art. 54(2), 56

Keyword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

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Case Number: T 1703/16 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 7 May 2020

Appellant: St. Jude Medical,
(Applicant) Atrial Fibrillation Division, Inc.
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Representative: Kramer Barske Schmidtchen
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 8 March 2016
refusing European patent application No.
08769222.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairwoman P. Acton
Members: G. Buchmann
Y. Podbielski

Summary of Facts and Submissions

I. In its decision to refuse European patent application No. 08 769 222.4, the examining division held that the subject-matter of claim 1 of the then valid main request and of auxiliary requests I and II lacked novelty (Article 54 EPC) with respect to

D2: EP1180380 A

II. The applicant (appellant) lodged an appeal against that decision.

III. The appellant requests that the decision under appeal be set aside and a patent be granted on the basis of claims 1-6 filed with the letter of 31 March 2020 (main request).

IV. The following additional documents were cited in the European Search Report and have been considered for the present decision:

D1: US2004215186 A

D3: US5593405 A

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

"A catheter (60) for positioning and anchoring an electrode in a coronary sinus for use in a localization or ablation system, the catheter comprising:

an elongate catheter body (64) adapted to be inserted into a coronary sinus, the elongate catheter body (64) including an anchor section (66) having an expandable

axial cross-section;

at least one electrode (62) on the catheter body (64);

and an actuation mechanism (70) operably coupled to the anchor section (66) to actuate the anchor section (66) between an undeployed configuration, wherein the expandable axial cross section of the anchor section (66) is in a collapsed state, and a deployed configuration, wherein the expandable axial cross-section of the anchor section (66) is in an expanded state,

wherein, when the anchor section (66) is in the deployed configuration, the expandable axial cross-section engages a tissue surface of the coronary sinus to inhibit movement between the catheter body (64) and the coronary sinus without completely occluding the coronary sinus, and

wherein the catheter body includes at least one perfusion passage through the interior of the catheter body having a first opening positioned distally of the anchor section and a second opening positioned proximally of the anchor section to preserve a perfusion pathway through the coronary sinus."

VI. The appellant's arguments can be summarised as follows.

The novelty objection raised by the examining division was not correct, because the catheter of D2 was used for a completely different purpose, and a perfusion blood flow was not needed in D2. The passage and openings of D2 were used for delivering a fluid. Therefore, the passage was not a blood perfusion passage and the openings were all outlets, not an inlet

and an outlet.

D2 did not disclose the specific location of the openings, i.e. an opening on each side of the anchor section. In this respect, the examining division had combined different embodiments of Figures 1, 2 and 3. Furthermore, since the catheter of D2 did not have an inlet which is inside the patient's body when in use, no blood could enter the catheter. Due to the fact that the coronary sinus was not completely occluded by the catheter of D2, the blood would flow along the catheter and not into the catheter.

Therefore, the subject-matter of claim 1 was novel over D2. It was also inventive, because the catheter of D2 was for a completely different use compared to the claimed catheter.

Reasons for the Decision

1. Amendments (Article 123(2) EPC)

Claim 1 of the main request is based on claims 1 and 5 as originally filed. The added feature according to which the catheter is "for use in a localization or ablation system", is based on paragraph [0094] of the description. The features according to which the perfusion passage is "through the interior of the catheter body" and it is "to preserve a perfusion pathway through the coronary sinus", is based on paragraph [0090] of the description.

The dependent claims 2-5 are based on original dependent claims 2, 3, 4, 6, 7 and 9.

The feature of dependent claim 6 can be derived from Figures 5 and 32 of the original application.

Therefore, the claims of the main request fulfill the requirements of Article 123(2) EPC.

2. Novelty over D2 (Article 54(2) EPC)

The examining division held that the subject-matter of claim 1 lacked novelty over D2.

Document D2 discloses (paragraphs [0004] and [0005]) a catheter which is designed for use in a method of repairing a bone or cartilage percutaneously. This method includes positioning the catheter adjacent to bone or cartilage to be repaired and dispensing a fluid (e.g. an adhesive) through the catheter. An example is given wherein the catheter is percutaneously introduced adjacent a vertebra in order to stabilise the vertebral column. From the intended use and the dimensions given in paragraph [0032] of D2, it can be concluded that the length of the catheter of D2 is in the order of magnitude of 20 cm. In contrast to that, a catheter which is suitable to be inserted into the coronary sinus typically has a length of at least 100 cm, because it is introduced via the venous system of the patient.

Therefore, it can not unambiguously be derived from D2 that the catheter disclosed there is suitable for positioning and anchoring an electrode in a coronary sinus.

2.1 Embodiment of Figure 1

With reference to Figure 1, document D2 discloses (paragraph [0025])

a catheter (50) comprising:

an elongate catheter body (52) including an anchor section (balloon 63) having an expandable axial cross-section;

at least one electrode (54) on the catheter body (52);

and an actuation mechanism (implicitly necessary for inflating the balloon 63) operably coupled to the anchor section to actuate the anchor section (63) between an undeployed configuration, wherein the expandable axial cross section of the anchor section (63) is in a collapsed state, and a deployed configuration, wherein the expandable axial cross-section of the anchor section (63) is in an expanded state.

The catheter of D2 comprises openings (62, see also paragraph [0010]) and a passage (60) in the catheter, which are regarded as suitable for blood perfusion, because a simple opening or passage is not restricting the flow to only one direction, but allows a flow in both directions. The disclosure of D2, in particular paragraph [0010], comprises the case that the openings are located proximal and distal of the anchor section (balloon 63). Therefore, the catheter body of D2 also includes at least one perfusion passage (60) through the interior of the catheter body having a first opening positioned distally of the anchor section (62) and a second opening (see paragraph [0010]) positioned

proximally of the anchor section to preserve a perfusion pathway.

The feature "wherein, when the anchor section is in the deployed configuration, the expandable axial cross-section engages a tissue surface of the coronary sinus to inhibit movement between the catheter body and the coronary sinus without completely occluding the coronary sinus" is not disclosed in D2, Figure 1, for the following reasons. A balloon (63) as shown in Figure 1 of D2 normally has a spherical or cylindrical shape. D2 does not give any indication to the contrary. If such a balloon is inflated inside a blood vessel for anchoring the catheter inside the vessel, then the balloon necessarily occludes the vessel. Again, D2 gives no indication that this would not be the case.

The examining division held that the embodiment of Figure 1 was novelty destroying for the second alternative of the claim which is a catheter "for use in an ablation system". This decision was based on the fact that paragraph [0091] of the description mentions that it may be desirable in an ablation procedure that the catheter completely occludes the coronary sinus. It is noted, however, that claim 1 clearly defines that "when the anchor section is in the deployed configuration, the expandable cross section engages a tissue surface... without completely occluding the coronary sinus". Thus, the example described in paragraphs [0091] and [0092] clearly does not fall under the scope of claim 1, whilst the balloon shown in Figure 1 of D2 does not fulfill the definition of the claim that it shall not completely occlude the coronary sinus when deployed.

For the reasons given above, the subject-matter of

claim 1 differs from the embodiment shown in Figure 1 of D2 in that:

- the catheter is adapted for positioning and anchoring an electrode in a coronary sinus for use in a localization or ablation system and in that,
- when the anchor section is in the deployed configuration, the expandable axial cross-section engages a tissue surface of the coronary sinus to inhibit movement between the catheter body and the coronary sinus without completely occluding the coronary sinus.

2.2 Embodiments of Figures 2 and 3

Figures 2 and 3 of D2 disclose two similar embodiments. Instead of the balloon (63) shown in Figure 1, they comprise fixation devices (nitinol fixation device 65, tine fixation device 67). When deployed for anchoring in a blood vessel, these fixation devices allow blood flow along the body of the catheter. Therefore, the feature "wherein, when the anchor section is in the deployed configuration, the expandable axial cross-section engages a tissue surface of the coronary sinus to inhibit movement between the catheter body and the coronary sinus without completely occluding the coronary sinus", is disclosed for the embodiments of Figures 2 and 3. However, contrary to the interpretation of the examining division, the nitinol fixation device 65 and the tines 67 do not form part of the catheter body, as it is required for the anchor section according to claim 1. The fixation device 65 and the tines 67 are separate parts which are attached to the catheter body or extend through the catheter body, but they do not form part of it.

Therefore, the subject-matter of claim 1 differs from the disclosure of D2, Figures 2 and 3, in that

- the catheter is adapted for positioning and anchoring an electrode in a coronary sinus for use in a localization or ablation system and in that
- the elongate catheter body includes an anchor section having an expandable axial cross-section.

Therefore, the subject-matter of claim 1 is novel over D2.

3. Inventive step

3.1 Document D2

The catheter according to D2 is conceived for drug delivery and tissue stimulation, in particular in a method for cartilage and bone treatment, which is a purpose completely different from the purpose of the present invention. Consequently, the catheter of D2 is also structurally completely different from a catheter apparatus for positioning and anchoring an electrode in a coronary sinus and faces different problems in its use and realisation/implementation. Therefore, it cannot be considered as representing the closest prior art for a catheter apparatus for positioning and anchoring an electrode in a coronary sinus. The skilled person would not even take D2 into consideration when trying to design such a catheter.

3.2 Document D1

D1 discloses (para. 85-106) an anchoring cage catheter 230, 250 which is positioned at the ostium of the pulmonary vein by an anchoring cage 236, an expandable mesh section 252 or a balloon having a blood perfusion lumen (para. 106). An ablation catheter 256 (having electrodes) is advanced over this anchoring catheter.

Since the device described in D1 comprises two separate catheters instead of only one this document is less relevant than D2 in view of novelty and inventive step.

3.3 Document D3

D3 discloses an endoscope for mapping or ablation in a heart chamber. It comprises a transparent inflatable balloon at its end for preventing the contact of electrodes and the wall of the heart chamber and a guide forming a loop for steering the endoscope to different positions. Moreover, the endoscope of D3 is not suitable for insertion into the coronary sinus. Therefore, D3 is less relevant than D2 in view of novelty and inventive step.

3.4 Combinations of documents

Regarding possible combinations of the cited documents in view of inventive step, it is noted that D1 and D3 describe catheters which are used for purposes which are completely different from that of D2. The problem of blood perfusion is mentioned in D1, but there is no incentive for the skilled person to combine any of the cited documents, or selected features thereof, with each other.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the examining division with order to grant a patent in the following version:

Description:

Pages 12	as published
1, 2, 3-11, 14, 15, 18	filed with the letter of 31 March 2020
2a, 13, 16, 17	filed with the letter of 28 April 2020.

Claims:

No. 1-6	filed with the letter of 31 March 2020.
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Drawings:

Sheets 1/26-26/26	as published.
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The Registrar:

The Chairwoman:



M. Kiehl

P. Acton

Decision electronically authenticated