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Datasheet for the decision of 6 August 2015

Case Number: T 2406/11 - 3.2.02

Application Number: 98926204.3

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Language of the proceedings: EN

Title of invention:
SPLITTABLE MULTIPLE CATHETER ASSEMBLY AND METHODS OF INSERTING THE SAME

Patent Proprietor:
Medical Components, Inc.

Opponent:
Pourchez, Thierry

Headword:

Relevant legal provisions:
EPC Art. 100(a)

Keyword:
inventive step (yes)

Decisions cited:

Catchword:

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Case Number: T 2406/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 6 August 2015

Appellant: (Patent Proprietor)	Medical Components, Inc. 1499 Delp Drive Harleysville, PA 19438 (US)
Representative:	Molnia, David Df-mp Dörries Frank-Molnia & Pohlman Patentanwälte Rechtsanwälte PartG mbB Theatinerstrasse 16 80333 München (DE)
Appellant: (Opponent)	Pourchez, Thierry 172 Boulevard Jean Moulin 62400 Béthune (FR)
Representative:	Demulsant, Xavier Dejade & Biset 35, rue de Châteaudun 75009 Paris (FR)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 29 September 2011 concerning maintenance of the European Patent No. 1009315 in amended form.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	C. Körber
	D. Ceccarelli

Summary of Facts and Submissions

I. On 29 September 2011 the Opposition Division posted its interlocutory decision concerning maintenance of European patent 1009315 in amended form.

II. Appeals were lodged against this decision by both the patent proprietor and the opponent, by notices received on 17 November and 8 December 2011 respectively, with the appeal fees being paid on the same days. The statements setting out the grounds of appeal were received on 7 and 8 February 2012, respectively.

III. By communication of 22 April 2015, the Board forwarded its provisional opinion to the parties and summoned them to oral proceedings.

IV. Oral proceedings were held on 6 August 2015.

The final requests of the parties were as follows:

The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, on the basis of one of the auxiliary requests 1 to 12, all filed with letter dated 7 February 2012.

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

V. The following documents are of importance for the present decision:

D1: WO-A-97/09086
D2: WO-A-93/05730

D3: US-A-4 925 452.

VI. Claim 1 of the patent as granted reads:

"A multiple catheter assembly (10, 10',10'' ,10''' , 10'''' ,10''''') having a distal portion of generally rounded cross section for insertion into the vasculature of a patient, comprising:
(a) a first catheter (26, 26' ,26'' ,26''' ,26'''' , 26''''') having a proximal tip (62), a distal end region (48) terminating in a distal tip (64), and an outer surface (34) defining at least a first lumen (28) extending longitudinally therethrough between a distal and a proximal opening (76, 78);
(b) a second catheter (30, 30', 30'' ,30''' ,30'''' , 30''''') having a proximal tip (66), a distal end region (52) terminating in a distal tip (68), and an outer surface (40) defining at least a second lumen (32) extending longitudinally therethrough between a distal and a proximal opening (80, 82),
wherein the first lumen (28) and the second lumen (32) are independent from each other for facilitating simultaneous flow in opposite directions; and
(c) a single splittable membrane (46) joining the outer surfaces (34, 40) of both the first and second catheters (26, 30) for allowing the first and second catheters to be at least partially longitudinally split from each other from the distal end region (48, 52) toward the proximal tip (62, 66);"

Claims 2 to 15 are dependent claims.

The claims of auxiliary requests 1 to 12 are of no relevance for the present decision.

VII. The appellant opponent's arguments are summarised as follows:

D1 was the closest prior art. It was questionable whether the distinguishing feature of the splittable membrane had any technical effects at all, since it had to be destroyed in order to achieve the desired freely flexible distal ends. Since in D1 the division point (12) was located at a certain distance from the distal ends of the conduits, the device of D1 was not easy to manipulate prior to its insertion. Such manipulation, however, did not relate to the actual intended use of the catheter assembly and took only a few minutes. Also, any adaptation to the specific circumstances of the individual patient had to take place before the actual insertion of the device. Moreover, no technical advantages related to the manipulation of the claimed catheter were indicated in the description as filed.

D2 disclosed a medical device with multiple flexible conduits for blood. It thus belonged to the same technical field as the invention and would be taken into consideration by the skilled person. The splittable tubes (410, 410') depicted in Figures 23, 26 and 26A could also be regarded as catheters. The divisible wall (416) permitted manual adjustment of the point of separation as disclosed at page 76, lines 6 to 9. With this teaching the skilled person would immediately recognise that a splittable membrane could advantageously be used instead of the fixed division point of D1. The subject-matter of claim 1 of the main request was therefore obvious in view of D2.

D3 also disclosed a medical device with multiple flexible conduits. Its intended use, the drainage of bodily fluids from wounds, was among the applications

of the claimed catheter assembly as mentioned in paragraph [0019] of the patent in suit. D3 thus also belonged to the same technical field as the invention and would be taken into consideration by the skilled person. In column 2, lines 47 to 56, it was disclosed that the conduits (18, 20) were joined by one or more frangible membranes which allowed the conduits to be separated from each other. Even though multiple membranes were disclosed as more advantageous, it was clear from this passage that a single membrane would be sufficient. Before being separated, the multiple conduits represented a unitary device in which individual conduits could readily be parted, as stated in column 1, lines 45 to 47. With this teaching the skilled person would immediately recognise that a splittable membrane could advantageously be used instead of the fixed division point of D1. The subject-matter of claim 1 of the main request was therefore also obvious in view of D3.

VIII. The appellant patent proprietor's arguments are essentially those on which the following reasons for the present decision are based. It was further argued that the appellant opponent's appeal was inadmissible because it was not sufficiently reasoned.

Reasons for the Decision

1. The appellant patent proprietor's appeal is admissible. In view of the fact that its main request is allowable as detailed below, it is not necessary for the Board to decide on the admissibility of the appellant opponent's appeal.

2. Inventive step – main request

Among the cited documents, D1 represents the closest prior art. D1 fails to disclose a splittable membrane as defined in feature (c) of claim 1. This was not disputed by the parties.

The technical effects achievable by feature (c) are to facilitate manipulation and handling of the catheter assembly prior to its insertion into the vasculature (by virtue of the membrane which, before being split, keeps the two catheters together, thus forming one single compact entity), and to provide adjustability of the length of the freely movable distal ends for their proper positioning within the vasculature (by splitting the membrane from the distal end region towards the proximal tips up to a certain length and thus obtaining two separate catheters of a length which can be chosen in accordance with their intended position within the vasculature of a given anatomy). These technical effects, which are partly addressed in feature (c) itself, are plausible and derivable from what is described in paragraphs [0056] to [0060] and [0065] of the patent in suit. The appellant opponent's arguments that the membrane is at least partially destroyed when used in this way and that the procedure might take only a few minutes and is carried out before insertion into the patient do not imply that the stated technical advantages are not achieved by virtue of the claimed splittable membrane. Nor is it necessary that the technical effects be explicitly indicated in the patent application as filed.

The objective technical problem is to provide a catheter assembly which allows improved handling prior to insertion into the vasculature and adaptability to the

desired placement of the catheters in the specific anatomical circumstances of the individual patient.

Document D1 itself does not address the above-mentioned problem. On the contrary, throughout D1 it is emphasised that the distances D1, L1 and L2 are **predetermined** (claim 1, page 1, lines 26 to 35, page 3, lines 11 to 20), which implies that the division point (12) should be fixed. This teaches away from providing adaptability to specific circumstances.

The embodiment in Figures 22 to 26A of document D2 cited by the appellant opponent relates to vascular prostheses, as mentioned in the first paragraph of page 69. It is doubtful whether the skilled person starting from document D1, which deals with a catheter for insertion into the vasculature, would consider this teaching when attempting to solve the above-mentioned problem. The divisible wall (416) which allows separation of the two tubes (410, 410'), as stated in the last paragraphs of pages 73 and 75, constitutes a "single splittable membrane" as mentioned in feature (c), joining the outer surface of both tubes and allowing them to be split from each other. However, D2 does not give any hint that the divisible wall serves to improve handling prior to insertion of the tubes into the body. Moreover, after their partial separation, the ends of the tubes are sutured to the desired locations (first paragraph of page 76), i.e. they remain fixed. This would result in a loss of the advantageous feature of the freely movable distal ends which is explicitly desired in D1 (page 3, lines 27 to 33). For these reasons, the skilled person would not combine the teaching of D1 with that of D2.

Document D3 relates to a drainage device, in particular for surgical wounds (column 3, lines 4 to 8). Again it is doubtful whether this teaching would be taken into consideration by the skilled person when starting from D1. In any case, D3 fails to disclose a **single** splittable membrane as required by feature (c). The aim of D3 is rather to overcome the disadvantages of a single membrane as used in the prior art (column 1, lines 37 to 42; column 1, line 65 to column 2, line 2). It is therefore required that (at least) two membranes are provided (column 2, lines 50 to 52; claim 1). The fact that a single membrane is mentioned in line 56 of column 2 must be understood in this context, i.e. what it is meant there is the single membrane used in the prior art. The sentence in lines 53 to 56 of column 2 does not imply that multiple membranes are merely advantageous and that a single membrane may also be suitable, as argued by the appellant opponent. Accordingly, even if the skilled person took the teaching of D3 into account, he would not arrive at the subject-matter of claim 1.

Since the provision of feature (c) in a multiple catheter assembly as disclosed in D1 is not rendered obvious by D2 or D3, it is not necessary for the Board to take into consideration possible further distinguishing features of claim 1 over D1.

It follows that the ground of opposition of lack of inventive step under Article 100(a) EPC does not prejudice maintenance of the patent as granted.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated