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D E C I S I O N
of 3 December 2004

Case Number: W 0032/04 - 3.2.2

Application Number: PCT/NL 03/00615

Publication Number:

IPC:

Language of the proceedings: EN

Title of invention:

Catheter pump, catheter and fittings therefore and methods of
using a catheter pump

Applicant:

Intra-Vasc. NL B.V.

Opponent:

-

Headword:

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Relevant legal provisions:

PCT Art. 17(3) a

PCT R. 40.1, 40.2(c)

Keyword:

"Non-unity a posteriori (no)"

Decisions cited:

-

Catchword:

-



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International Application No. PCT/NL 03/00615

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 3 December 2004

Applicant: Intra-Vasc. NL B.V.
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Decision under appeal: Protest according to Rule 40.2(c) of the Patent
Cooperation Treaty made by the applicants
against the invitation (payment of additional
fees) of the European Patent Office
(International Searching Authority) dated
23 April 2004.

Composition of the Board:

Chairman: T. Kriner
Members: R. Ries
B. J. Schachenmann

Summary of Facts and Submissions

I. The applicant filed an international application PCT/NL 03/00615 with 25 claims. Independent product claims 1, 16, 17 and 18 read as follows:

"1. A catheter pump comprising:
a catheter (20) comprising:
- a catheter wall bounding a channel (36) inside said catheter (20);
- a distal end portion (24);
- a proximal end portion, said channel (36) communicating with said distal end portion (24) for alternately leading fluid in said channel (36) in a direction away from said distal end portion towards said proximal end portion and in a direction away from said proximal end portion towards said distal end portion;
- at least one inlet passage (25) in said wall; and
- at least one outlet passage (26) distally spaced from said inlet passage (25); and
a displacement structure (16) communicating with said proximal end portion for alternately applying suction and pressure for driving said fluid displacement;
wherein, at least in operating condition, said at least one inlet passage (25) is continuously open."

"16. A catheter for a catheter pump comprising:
- a catheter wall bounding a channel (36) inside said catheter;
- a distal end portion (24);
- a proximal end portion for connection to a displacement structure (16) for alternately applying suction and pressure for driving a fluid displacement,

said channel (36) communicating with said distal end portion (24) for alternately leading fluid in said channel (36) in a direction away from said distal end portion (24) towards said proximal end portion and in a direction away from said proximal end portion towards said distal end portion (24);

- at least one inlet passage (25) in said wall; and
- at least one outlet passage (26) distally spaced from said inlet passage (25);

wherein, at least in operating condition, said at least one inlet passage (25) is continuously open."

"17. A fitting for a catheter pump, comprising a tubular section having a wall bounding a channel (36), at least one inlet passage (25) in said wall, wherein, at least in operating condition, said at least one inlet passage (25) is continuously open."

"18. A fitting for a catheter pump, comprising a tubular section bounding a channel (36), a valve located in said channel (36), said valve comprising a valve body (45) pivotably suspended for rotation about an axis (46) extending across said channel (36), between a closed position, substantially closing off said channel (36) and an open position allowing fluid to pass past said valve, wherein said valve body (45) in open position extends along a plane parallel to said channel (36), in axial view, has a central portion (47) spaced from said pivoting axis (46) and, in side view, projects from said pivoting axis (46) further in distal direction than in proximal direction."

Independent claims 19 and 23 relate to a method for generating pulsations in the blood flow towards the organs of a patient comprising, i.a., inserting a catheter (20) into the aorta (2) of a patient.

Claims 2 to 15 which were directly or indirectly dependent on claim 1 relate to preferred embodiments of the catheter pump according to claim 1.

II. On 23 April 2004 the EPO, acting as International Search Authority (ISA), sent to the applicant an invitation to pay two (2) additional search fees pursuant to Article 17(3)(a) and Rule 40.1 PCT.

In the invitation, the ISA identified three (3) groups of inventions:

1. group (claims 1, 2 to 6, 9, 14 to 16):

a catheter pump comprising catheter wall bounding a channel and at least one inlet passage in said wall; a catheter therefor

2. group (claims 1, 7, 8, 17):

a fitting for a catheter pump comprising a section having a wall bounding a channel and at least one inlet passage in said wall; a catheter pump as in claim 1 where the catheter includes at least one fitting.

3. group (claims 1, 10 to 13, 18):

a fitting for a catheter pump comprising a valve; a catheter pump as in claim 1, further comprising a valve.

The ISA specifically referred to the documents D1:

US 4 754 752 A and D2: US 4 173 981 A. These documents

disclosed, in the ISA's view, all the features of claim 1 including a displacement structure communicating with a the proximal end portion of a catheter for alternately applying suction and pressure for driving the fluid displacement well suited for pulsatile flow pumping, thus anticipating the subject matter of claim 1.

With respect to the remaining claims of the first group (claims 2 to 6, 9, 14), the second group (claims 7, 8) and the third group (claims 10 to 13) all being dependent on claim 1 and the technical features distinguishing these claims from the prior art D1 and D2, the ISA found that these technical features had nothing in common and solved different problems. Hence the inventions defined by these groups were not considered to be linked by a common general inventive concept and, consequently, the requirement of unity pursuant to Rule 13.1 PCT was not met.

III. On 7 June 2004 the applicant paid one (1) additional fee under protest pursuant to Rule 40.2(c) PCT and requested that the fee should be refunded. The additional search fee was paid for the search of claims 7 and 8.

In support of the protest, the applicant submitted the following arguments:

As to the objection of lack of novelty vis-à-vis D1 and D2, the ISA failed to take into account the displacement structure stipulated in claim 1 and communicating with the proximal end portion of the claimed catheter for alternately applying suction and

pressure and driving the fluid. None of documents D1 and D2, however, disclosed the claimed displacement structure or made it obvious to use it. D1 related to a balloon catheter comprising a central channel for supplying perfusate (e.g. saline), and D2 was concerned with a catheter distribution structure (cannula) either for blood intake from or for blood delivery to several positions in a vein or artery. In view of their different purpose, a person skilled in the art had no incentive to provide the known catheters with a displacement structure of the type claimed in the application. The subject matter of claim 1 was, therefore, novel and involved an inventive step over D1 and D2.

Given this situation, there has been no reason for not searching the subject matter of claims 7, 8 and 10 which are all dependent upon claim 1 and relate to preferred embodiments of the claimed catheter pump and thus satisfied the requirement of unity of invention.

- IV. On 8 July 2004, the Review Panel of the ISA confirmed that the finding of lack of unity was justified and invited the applicant to pay a protest fee.

- V. On 27 July 2004, the applicant paid the required protest fee.

Reasons for the Decision

- 1. As all formal requirements of PCT Rule 40.2 (protest fee, reasoned statement) were met in due time, the protest is admissible.

2. In the present case the applicant paid one additional search fee only for the second group of inventions (claims 7 and 8) and did not comment on the independent claims 17 and 18 relating both to a fitting for a catheter pump. Likewise, the applicant did not comment on either of independent claims 19 and 23 which relate to **an invasive surgical method** for inserting a catheter into the aorta of a patient and withdrawing blood in a first area and feeding blood towards a second area and by generating pressure pulsations in the aorta.

Following the provisions of PCT Rule 39.1(iv) in combination with PCT Article 17(2)(a)(i), the ISA correctly decided not to search the subject matter claimed in the claims 19 and 23. The Board, therefore, has only to consider the question of whether the ISA's reasoning with respect to the second group of inventions is sufficient to substantiate a finding of lack of unity.

3. A lack of unity may become evident after having taken prior art into consideration, for instance a document showing that there is a lack of novelty of the subject matter of independent claim 1, and leaving two or more dependent claims without a single general inventive concept. This situation appears to apply to the present case, since the ISA argued in its invitation referred to above that the documents D1 and D2 anticipated the catheter pump set out in claim 1. It is thus apparent that the ISA made an "*a posteriori*" non-unity objection. However, decision G 1/89 of the Enlarged Board of Appeal makes it clear that an objection of this kind can only be based **on a provisional opinion** on novelty

and inventive step which is in no way binding upon the authorities subsequently responsible for the substantive examination (cf. G 1/89, point 8.1 of the reasons). The Enlarged Board also held that charging of additional fees under Article 17.(3)(a) PCT should be made only in clear cases (see also PCT International Search Guidelines, S06/1998(E) VII-12).

4. The Board has provisionally verified the novelty objection in particular with respect to the technical teaching given in documents D1 and D2 and comes to the following conclusion:
 - 4.1 Document D1 is concerned with a balloon-tipped catheter which includes (i) means for convectively heating the inflation medium within the balloon promoting the restoration and healing of the arterial wall in the region of a stenosis and (ii) a central lumen to supply and pump perfusate to the plurality of oblique perfusion ports and the distal port located in the distal tip. Document D1, therefore, appears to relate to a totally different type of catheter compared to the one of the present application.

Document D2 discloses a cannula (a sort of catheter) which is suitable for total bypass procedures in arterial and venous cannulation for the extracorporeal perfusion of blood and for pulsatile flow pumping. In a first single-directional flow embodiment, blood can be withdrawn from the body or, alternatively, introduced into the vein or artery through various intra-corporeal openings to accomplish the appropriate fluid transfer. A second embodiment of the cannula that is described in column 5, line 67 to column 6, line 10 and depicted in

Figure 2 is capable to provide a bidirectional flow to maintain a sufficient blood flow to the extremities located along the direction of the flow from the short segment opening 28 that is continuously open. Therefore, the ISA's view that the technical features of the catheter pump set out in claim 1 of the application and those described in D2 are the same might be pertinent.

4.2 The claimed catheter pump is, however, not restricted to the technical features set out in independent claim 1 but comprises further preferred embodiments which are stipulated in 15 dependent claims. After the demise of independent claim 1 on the account of the subject matter's lack of novelty, the question, therefore, arises whether the subject matter of the remaining claims 2 to 15 and any new independent claim in particular formed by combining independent claim 1 with dependent claims 7 or 8 are so linked to form a single general inventive concept. To this end, the technical problem to be solved by the claimed catheter in relation to the prior art, specifically represented by the documents D1 and D2, has to be considered.

4.3 The present application relates to a catheter for pumping blood. One important problem associated with the pumping of blood is thrombosis that is promoted by blood cell damage. This harm is caused by the presence of mechanical valves and by abrupt changes in either the rate or direction of the blood flow under the influence of mechanical forces. The problem underlying the present application, therefore, resides in providing a simple and reliable catheter pump for displacing blood from an inlet passage to a distal outlet port whereby the risk of blood cell damage and

thrombosis is reduced (cf. the application page 2, lines 24 to 28).

This problem is not addressed in document D1 which relates to the provision of an apparatus for promoting the healing and restoration of the interior wall of a blood vessel damaged by balloon angioplasty. Document D2 appears to be essentially concerned with a cannula for partial emplacement in communication with arterial branches of a patient's circulatory system to effect extracorporeal fluid transfer rather than with the pumping of blood and the problems associated therewith.

According to the present application, the identified problem is solved by a valve-free catheter pump (page 4, first paragraph) comprising a displacement structure (pump 16, Figure 5) which communicates with the proximal end portion of the catheter and provides alternately suction and pressure for driving the blood displacement from an inlet opening to an outlet opening. Despite the absence of a valve at the inlet passage and the fact that the inlet passage therefore remains continuously open when the displacement device urges blood through the channel in a distal and proximal direction, over a complete cycle, a net displacement of blood from the inlet to the outlet is achieved (cf. the application page 3, lines 17 to 36). The inlet passage can be provided in a simple manner directly in the catheter tubing wall or, more conveniently, in an appropriate inlet fitting tube which allows a more accurate finish of the opening (cf. the application page 11, lines 30 to 33). In a more preferred embodiment, the inlet section of the tubing wall or fitting comprises narrower and wider distal and

proximal sections (claim 2 to 6; claims 7, 8). The restriction of the tube diameter in one section causes a venturi effect counteracting the backflow or outflow of blood via the inlet passage, and thereby contributes to effectively increasing the throughput of blood by the catheter pump (cf. page 12, lines 1 to 17).

- 4.4 It is, therefore, concluded that the technical features set out in claim 1 and those stipulated in at least the dependent claims 7 and 8 all contribute to the same general inventive concept of providing a catheter pump of claim 1 having a valve-free inlet passage. Hence, there was no reason to disregard the technical features set out in dependent claims 7 and 8 when searching claim 1.

The Board, therefore, concludes that for the two groups of inventions referred to above, the requirement of Rule 13.1 PCT is satisfied. Given that there is no basis for a non-unity objection as regards claims 1, 7 and 8, one (1) search fee and the protest fee should be reimbursed.

5. It is, however, noted that the Board's present assessment of unity of invention does not exclude the possibility that - in the later International Preliminary Examination under PCT Chapter II and based on other grounds - the issue of unity of invention may arise again with respect to parts of the application.

Order

For these reasons it is decided that:

Reimbursement of the additional search fee and of the protest fee is ordered.

The Registrar:

The Chairman:

R. Schumacher

T. Kriner