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Datasheet for the decision of 15 January 2021

Case Number: T 0070/16 - 3.2.02

Application Number: 08151320.2

Publication Number: 1915943

IPC: A61B5/00, A61M25/00, A61F7/12

Language of the proceedings: EN

Title of invention:
Central venous catheter with heat exchange properties

Patent Proprietor:
Zoll Circulation, Inc.

Opponent:
IPMED GmbH

Headword:

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
Amendments

Decisions cited:

Catchword:

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Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0070/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 15 January 2021

Appellant: (Opponent)	IPMED GmbH Am Rathausplatz 6460 Altdorf (CH)
Representative:	Meissner Bolte Partnerschaft mbB Widenmayerstrasse 47 80538 München (DE)
Respondent: (Patent Proprietor)	Zoll Circulation, Inc. 650 Almanor Avenue Sunnyvale, CA 94085 (US)
Representative:	Potter Clarkson The Belgrave Centre Talbot Street Nottingham NG1 5GG (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 5 November 2015 concerning maintenance of the European Patent No. 1915943 in amended form.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	A. Martinez Möller
	L. Bühler

Summary of Facts and Submissions

I. In the interlocutory decision despatched on 5 November 2015, the Opposition Division decided that, account being taken of the amendments made by the patent proprietor during the opposition proceedings according to auxiliary request 2 then on file, European patent No. 1 915 943 and the invention to which it related met the requirements of the EPC.

II. The opponent lodged an appeal against this decision in the prescribed form and time limits. The opponent requested that the contested decision be set aside and that the patent be revoked. The proprietor also appealed but subsequently withdrew its appeal with a submission dated 23 October 2020.

III. In the reply to the grounds of appeal, the patent proprietor requested that the appeal be dismissed and the patent be maintained in the form as set out in the interlocutory decision of the Opposition Division. The patent proprietor submitted two auxiliary requests with corresponding sets of claims.

IV. Claim 1 of the main request, with added feature numbering in bold, reads as follows:

"**M** A central venous access system, comprising:
M1 a multi-lumen catheter (18);
M2 at least one heat exchange membrane or balloon (22) located distally on the catheter and
M2.1 communicating with a coolant supply lumen and a coolant return lumen of the catheter, wherein

M2.2 coolant circulates in a closed circuit coolant path that includes the supply lumen, heat exchange membrane or balloon, and return lumen;
M3 a heat exchange system (12) communicating with at least one of the coolant lumens,
M3.1 coolant being circulated between the heat exchange system and the heat exchange membrane or balloon to effect heat exchange with a patient;
M4 a central venous monitoring system comprising a blood gas monitoring system; and
M5 at least one through lumen of the catheter in fluid communication with the bloodstream of the patient and the central venous system."

V. Claim 1 of auxiliary request 1 corresponds to claim 1 of the main request except for features M4 and M5, which read as follows:

"a central venous monitoring system, wherein the central venous monitoring system is a blood gas monitoring system; and
at least one through lumen of the catheter in fluid communication with the bloodstream of the patient and the central venous monitoring system."

VI. Claim 1 of auxiliary request 2 corresponds to claim 1 of auxiliary request 1 except for feature M5, which reads as follows:

"at least one through lumen of the catheter in fluid communication with the bloodstream of the patient and wherein the central venous monitoring system communicates with the through lumen of the catheter via a tube."

VII. The arguments of the appellant/opponent, where relevant to the present decision, may be summarised as follows.

Claim 1 of the main request included subject-matter extending beyond the content of the application as filed (Article 123(2) EPC). In particular, feature M5 mentioned a "through lumen", a term which was not present in the application as filed. The term "blood gas monitoring system" was not further defined but included oxygen measurement in blood by means of pulse oximetry. Common measurement methods for this do not require fluid communication with the bloodstream; rather they involve optical measurements.

VIII. The arguments of the respondent/proprietor, where relevant to the present decision, may be summarised as follows.

The application as filed unambiguously disclosed features M4 and M5 on page 5, lines 5-6 and page 7, line 23 to page 8, line 6. The skilled person would appreciate that, since the central venous system can allow infusion into the blood or extraction of blood from a patient, there must be direct access to the patient's bloodstream. Hence, the lumen of the catheter with which the central venous system communicates would be a through lumen and the communication would be a fluid communication. The limitation to a central venous system comprising a blood gas monitoring system did not alter that, irrespective of whether it is possible to perform blood gas monitoring without direct access to the blood.

Reasons for the Decision

1. Invention

The invention relates generally to an apparatus for cooling patients for therapeutic purposes, and in particular to a central venous access system comprising a multi-lumen catheter, a heat exchange membrane or balloon located distally on the catheter, a heat exchange system, a central venous system and a lumen of the catheter which communicates with the bloodstream of the patient and with the central venous system.

2. Main request - extension of subject-matter

It is uncontested that there is no literal disclosure in the application as filed of a "through lumen" of the catheter in fluid communication with the bloodstream of the patient and the central venous system as defined by feature M5 of claim 1.

It is true that some of the alternatives for the central venous system indicated on page 8, lines 2-6 of the application as filed require a through lumen of the catheter as defined by feature M5. Such through lumen may thus be regarded as inherent when the central venous system is, for example, a source of medicament to be infused into a patient's central venous system (page 8, lines 3-4). However, such through lumen in fluid communication with the bloodstream of the patient is not inherent to any central venous system, in particular not to a blood gas monitoring system (feature M4 of claim 1).

As brought forward by the appellant, several techniques are known for blood gas monitoring which do not require

fluid communication with the bloodstream, e.g. by means of an optical measurement. An example of that is provided in the application as filed, namely within the jugular vein catheter system of Figs. 4-5 (see also pages 11, lines 11-21) which employs an oxygen measuring system 110 connected to a sensor lumen 113 of the catheter by means of an optical connection (optical connection 108, optical fiber 106 and oxygen sensor 104). The example does not disclose the sensor lumen 113 as being a through lumen in fluid communication with the bloodstream of the patient. Moreover, in the example the blood gas monitoring system 110 is connected with that lumen via an optical connection and is thus not in fluid communication with that lumen.

It is thus clear that a blood gas monitoring system does not require 1) the lumen of the catheter with which the central venous system communicates to be a through lumen in fluid communication with the bloodstream of the patient, or 2) the lumen to be in fluid communication with the central venous system.

Feature M5 is thus neither explicitly nor implicitly disclosed in the application as filed in combination with the central venous system comprising or being a blood gas monitoring system.

It follows that claim 1 of the main request contains subject-matter extending beyond the content of the application as filed (Article 123(2) EPC).

3. First auxiliary request - extension of subject-matter

In claim 1 of the first auxiliary request, it has been specified that the central venous monitoring system is a blood gas monitoring system (feature M4). Feature M5

has been merely amended to recite that the central venous system is a central venous "monitoring" system. The extension of subject-matter related to feature M5 as indicated above is thus still present.

4. Second auxiliary request - extension of subject-matter

In claim 1 of the second auxiliary request, feature M5 has been amended to indicate that the central venous monitoring system communicates with the through lumen of the catheter via a tube. This does not change the fact that there is no disclosure in the application as filed for this lumen of the catheter being in fluid communication with the bloodstream of the patient. Therefore, claim 1 contains subject-matter which extends beyond the content of the application as filed.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated