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D E C I S I O N
of 27 November 2002

Case Number: T 1081/00 - 3.2.2

Application Number: 91920110.3

Publication Number: 0582570

IPC: A61M 16/00

Language of the proceedings: EN

Title of invention:
Perfluorocarbon Associated Gas Exchange

Applicant:
University of Pittsburgh of the Commonwealth System of Higher
Education

Opponent:

-

Headword:

-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (no)"

Decisions cited:

-

Catchword:

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Boards of Appeal

Chambres de recours

Case Number: T 1081/00 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 27 November 2002

Appellant: University of Pittsburgh of the Commonwealth
System of Higher Education
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PA 15260 (US)

Representative: VOSSIUS & PARTNER
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 8 June 2000
refusing European patent application
No. 91 920 110.3 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: W. D. Weiß
Members: M. G. Noël
R. T. Menapace

Summary of Facts of Submissions

- I. The Examining Division refused European application No. 91 920 110.3 (International publication No. WO 92/19300) on the grounds of lack of novelty (first two requests) vis-à-vis a document (referred to as document D4 or Fuhrman abstract) presumably made available to the public by the inventor before the filing date of the present application and of lack of inventive step (further auxiliary requests) with respect to this prior art document, having regard to the general knowledge of a person skilled in the art.
- II. The appellant (applicant) lodged an appeal against this decision on 18 August 2000 and filed a statement of grounds on 18 October 2000 along with several sets of claims according to a main and five auxiliary requests, these being identical in substance to the requests as refused, respectively.
- It submitted that the disclosure of document D4 was the consequence of an evident abuse in relation to the applicant. Therefore, it should have been disregarded as being a non-prejudicial disclosure under Article 55(1)(a) EPC. Further, this document was, contrary to all expectations, considered by the Examining Division as the closest prior art at the late stage of oral proceedings, so that the applicant was not given sufficient time and opportunity to comment in particular about the third auxiliary request. This constituted a substantial procedural violation.
- III. The appellant requested the grant of a patent on the basis of the main request or one of the first to the fifth auxiliary requests; failing that, remittal of the case back to a different Examining Division for further prosecution. On a further auxiliary basis, the

appointment of an oral proceedings was requested as well as the reimbursement of the appeal fee because a procedural violation was seen to have occurred.

IV. In a communication of the Board dated 2 July 2002 sent together with a summons to attend oral proceedings, the appellant was informed of the preliminary view of the Board that the subject-matter of the claims according to the various requests seemed to lack an inventive step vis-à-vis the teachings of documents D1 to D3 and the common general knowledge of a person skilled in the art:

D1: WO-A-91/03267

D2: "Physiological effects of ventilation with liquid fluorocarbon at controlled temperatures", by T.H. Shaffer et al., Undersea Biomedical Research, vol. 11, No. 3, September 1984, pages 287-298.

D3: FR-A-2 214 467.

If, in addition, document D4 was considered as state of the art (i.e. its publication not qualifying as an evident abuse within the meaning of Article 55(1)(a) EPC), this document could even affect the novelty of the claimed subject-matter.

V. Oral proceedings were held on 27 November 2002 in the absence of the appellant's representative who had withdrawn its respective request by letter dated 30 October 2002. After deliberation of the Board, the appeal was dismissed.

VI. Claims 1 according to the various requests read as follows:

Main request:

"Use of a perfluorocarbon liquid in the manufacture of a medicament for use in a treatment of disorders and diseases of the pulmonary air passages comprising the steps of

- introducing into the pulmonary air passages of a mammalian host a volume of perfluorocarbon liquid substantially equivalent to or less than the pulmonary functional residual capacity of the host;
 - maintaining respiratory gas exchange in said perfluorocarbon liquid-laden pulmonary air passages by means of a gas ventilator for a treatment period;
- and
- thereafter removing the perfluorocarbon liquid from the pulmonary air passages."

First auxiliary request:

"Use of a perfluorocarbon liquid in the manufacture of a medicament for use in a method comprising the steps of

- introducing into the pulmonary air passages of a mammalian host a volume of perfluorocarbon liquid substantially equivalent to or less than the pulmonary functional residual capacity of the host;
- maintaining respiratory gas exchange in said perfluorocarbon liquid-laden pulmonary air passages by means of a gas ventilator for a treatment period;

and

- thereafter removing the perfluorocarbon liquid from the pulmonary air passages."

Second auxiliary request:

"Use of a perfluorocarbon liquid in the manufacture of a medicament for use in a method comprising the steps of

- introducing into the pulmonary air passages of a mammalian host a volume of perfluorocarbon liquid substantially equivalent to or less than the pulmonary functional residual capacity of the host;
- maintaining respiratory gas exchange in said perfluorocarbon liquid-laden pulmonary air passages by means of a gas ventilator for the treatment period of more than one hour; and
- thereafter removing the perfluorocarbon liquid from the pulmonary air passages."

Third auxiliary request:

"Use of a perfluorocarbon liquid in the manufacture of a medicament for use in a method comprising the steps of

- introducing into the pulmonary air passages of a mammalian host a volume of perfluorocarbon liquid less than the pulmonary functional residual capacity of the host;
- maintaining respiratory gas exchange in said perfluorocarbon liquid-laden pulmonary air passages by means of a gas ventilator for the treatment period or more than one hour, and
- thereafter removing the perfluorocarbon liquid from the pulmonary air passages."

Fourth auxiliary request:

"Use of a perfluorocarbon liquid in the manufacture of a medicament for use in a method comprising the steps of

- introducing into the pulmonary air passages of a mammalian host a volume of perfluorocarbon liquid that is $\frac{1}{2}$ to $\frac{3}{4}$ of the normal pulmonary functional residual capacity of the host;
- maintaining respiratory gas exchange in said perfluorocarbon liquid-laden pulmonary air passages by means of a gas ventilator for the treatment period of more than one hour; and
- thereafter removing the perfluorocarbon liquid from the pulmonary air passages."

Fifth auxiliary request:

"Use of a perfluorocarbon liquid in the manufacture of a medicament for use in a method comprising the steps of

- introducing into the pulmonary air passages of a mammalian host a volume of perfluorocarbon liquid that is $\frac{1}{2}$ or $\frac{3}{4}$ of the normal pulmonary functional residual capacity of the host;
- maintaining respiratory gas exchange in said perfluorocarbon liquid-laden pulmonary air passages by means of a gas ventilator for the treatment period of more than one hour, and
- thereafter removing the perfluorocarbon liquid from the pulmonary air passages."

Reasons for the Decision

1. The appeal is admissible.

2. *Formal aspects*

The question of whether there are any formal objections to the current version of the claims need not be answered since all the main claims (main and auxiliary requests) are anyway unallowable on other grounds, as set out hereinafter.

3. *Novelty and inventive step (main request)*

3.1 Document D1 is considered by the Board as the closest prior art. Following the same terminology as that used in claim 1 in suit, D1 discloses the use of a perfluorocarbon (PFC) liquid in the manufacture of a medicament for use in a treatment of disorders and diseases of the pulmonary air passages (cf. page 9A, lines 20 to 29 and page 10, lines 26 to 27). The expression "in the manufacture of a medicament" incorporated to claim 1 at the very beginning of the examining procedure is not supported by the (international) application as originally filed. It was introduced into claim 1 by the appellant with the purpose of presenting the invention as a second medical use of a substance for the preparation of a medicament, thus casting it into a form which is not excluded from the protection under Article 52(4) EPC. Because document D1 relates to a similar use of PFC liquid, such a use is, however, implicitly disclosed in that document.

Further, document D1 discloses the steps of, successively:

- introducing into the pulmonary air passages of a mammalian host a volume of PFC liquid (cf. page 9A, lines 21 to 29),
- maintaining respiratory gas exchange in said PFC liquid-laden pulmonary air passages by means of a gas ventilator of a treatment period (cf. claim 1 and page 9A, lines 26 to 29; page 15, lines 13 to 19 and page 16, lines 8 to 15),
- and thereafter removing the PFC liquid from the pulmonary air passages (cf. claim 1 and page 16, lines 15 to 18).

With respect to the disclosure of D1, the subject-matter of claim 1 in suit only differs by introducing a volume of PFC liquid which is "substantially equivalent to or less than the pulmonary functional residual capacity (FRC) of the host". This wording FRC stands for the volume of space in the pulmonary air passages at the end of expiration (cf. international application, page 7, lines 20 to 24). Therefore, the subject-matter of claim 1 is novel over document D1.

- 3.2 Starting from the closest prior art the major advantage provided by the differentiating feature (cf. international application, page 7, lines 25 to 35), consists in that the barotrauma associated with prior liquid breathing techniques is avoided, and adequate gas exchange via bubble-oxygenation is assured. The achievement of this advantage represents the problem underlying the invention.

The introduction of a volume of PFC liquid substantially equivalent to the FRC with the aim of assuring adequate physiological gas exchange and tissue oxygenation and avoiding any residual gas is, however, disclosed by document D2 (cf. page 289: "liquid ventilation procedure"). Since the documents D2 and D1 stem from the same authors (Schaffer and Wolfson) and D2 is referred to in document D1 under the reference [30] (cf. pages 5 and 39), the combination of these two documents is obvious and leads the skilled person immediately to the claimed subject-matter.

It results therefrom that the subject-matter of claim 1 according to the main request does not involve an inventive step within the meaning of Article 56 EPC.

4. *Auxiliary requests 1 to 5*

- 4.1 Claim 1 according to the first auxiliary request only differs from the main request in that the terms "for use in a treatment of disorders and diseases of the pulmonary air passages" have been replaced by the terms "for use in a method".

The so amended wording is still wider than the previous one, so that the above considerations and the conclusion of the Board concerning the obviousness of claim 1 according to the main request are equally valid for the first auxiliary request.

- 4.2 Claim 1 according to the second auxiliary request differs from the first auxiliary request by the addition of the terms "of more than one hour" for specifying the treatment period in the second step of the method. This trivial feature is known *per se* from document D3 which relates to the washing of a respiratory system with PFC liquid and in which a treatment period of up to eight hours or more is

recommended (cf. page 6, lines 27 to 31). Moreover, document D3 refers to general knowledge based on studies by L.C. Clark (cf. page 1, line 38 and page 3, line 31), see in particular Science, vol. 152, 1966. The same references, also, are referred to in the application in suit (cf. citation [22] on pages 4 and 35).

Therefore, the mere specification of a treatment period of more than one hour in claim 1 is well within the customary practice of a person skilled in the art, which can be readily determined by the physician according to the patient's need, as also mentioned in document D1 (cf. page 10, lines 4 to 8). It results therefrom that the added feature in question does not involve any inventive step.

- 4.3 The main claims according to the third, fourth and fifth auxiliary requests differ from the second auxiliary request in that the expression "substantially equivalent to or less than" has been replaced by the terms "less than", "that is $\frac{1}{2}$ to $\frac{3}{4}$ of", and "that is $\frac{1}{2}$ or $\frac{3}{4}$ of", respectively, for specifying the volume ratio between the introduced volume of PFC liquid and the normal pulmonary functional residual capacity (FRC) of the host.

The selection of the most appropriate ratio is, however, an obvious matter of optimization in relation to the patient's requirements, which is given in the application in suit only by way of example (cf. page 7, lines 35 to 36) without any particular effect. Further, said volumetric ratios are indeterminate since the FRC volume itself is variable and may change as the lung expands (cf. page 7, lines 24 to 25). Also in document D2 (page 289) is the functional residual capacity said to be "estimated" and, therefore, indefinite. Consequently, the specific ratios

successively introduced in the claims according to the remaining auxiliary requests fail to add any inventive step to the subject-matter thereof.

5. *Remittal and reimbursement*

The appellant further requested that the case be remitted to the first instance for further prosecution and that reimbursement of the appeal fee be ordered by reason of substantial procedural violation. It was argued, in particular, that at the oral proceedings before the Examining Division, the appellant had no opportunity to comment about the inventive step of the third auxiliary request.

As already submitted by the Board in its communication of 2 July 2002, the appellant's arguments are not well founded in view of the fact that the auxiliary requests are normally discussed in the order indicated by the party submitting them and fourth and fifth auxiliary requests were duly and undisputedly discussed at the oral proceedings before the Examining Division. Therefore, the Board does not see any misleading conduct nor any violation of Article 113(1) EPC by the first instance. The Board therefore decided to exercise its power conferred by Article 111(1) EPC by not remitting the case to the first instance.

Reimbursement of the appeal fee is already excluded under (Rule 67 EPC) because the present appeal was not deemed to be allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß