

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 11 December 2023**

Case Number: T 2015/16 - 3.3.04

Application Number: 06006408.6

Publication Number: 1721606

IPC: A61K31/194, A61K33/14,
A61P13/12

Language of the proceedings: EN

Title of invention:

Buffered compositions for dialysis

Patent Proprietor:

Advanced Renal Technologies

Opponents:

GAMBRO LUNDIA AB
Fresenius Medical Care AG & Co. KGaA
INTERMEDT Medizin & Technik GmbH
D_MED Consulting A

Headword:

Compositions for dialysis / ADVANCED RENAL TECHNOLOGIES

Relevant legal provisions:

EPC Art. 123(2), 54

Keyword:

Main request - amendments - added subject-matter (yes)

Auxiliary request 1 - novelty - (yes)

Decisions cited:

G 0002/10, T 2020/07, T 0245/19



Beschwerdekammern
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 2015/16 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 11 December 2023

Appellant: Advanced Renal Technologies
(Patent Proprietor) 40 Lake Bellevue
Suite 100
Bellevue, WA 98005 (US)

Representative: Forresters IP LLP
Skygarden
Erika-Mann-Straße 11
80636 München (DE)

Former opponent : INTERMEDT Medizin & Technik GmbH
(Opponent 3) Gewerbestrasse Süd 13
26842 Ostrhauderfehn (DE)

Respondent: D_MED Consulting AG
(Opponent 4) Wilhelmshofallee 79-81
47800 Krefeld (DE)

Representative: terpatent Patentanwälte ter Smitten
Eberlein-Van Hoof Rütten Daubert
Partnerschaftsgesellschaft mbB
Burgunderstraße 29
40549 Düsseldorf (DE)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 3 August 2016
revoking European patent No. 1721606 pursuant to
Article 101(3) (b) EPC**

Composition of the Board:

Chair	M. Pregetter
Members:	S. Albrecht
	A. Bacchin

Summary of Facts and Submissions

- I. European patent No. 1 721 606 ("the patent") is based on European patent application No. 06006408.6 ("the application as filed"). The patent was granted with six claims.

Claims 1 and 3 read as follows:

"1. An aqueous acid-concentrate composition comprising water, chloride at a concentration of 1,000 to 7,000 mEq/L; citrate at a concentration ranging from 20 to 900 mEq/L; and sufficient physiologically-acceptable cations comprising calcium to provide for a neutral composition, where the composition has a pH of less than 4, and does not contain any of acetate, bicarbonate or lactate."

"3. The aqueous acid-concentrate composition of any one of Claims 1 and 2 wherein the physiologically-acceptable cations comprise a combination of calcium and magnesium."

- II. The patent was opposed by four opponents. The grounds for opposition relied on were Article 100(a) EPC for lack of novelty and lack of inventive step and Article 100(b) and (c) EPC.
- III. Opponents 1 and 2 withdrew their oppositions in the course of the opposition proceedings.
- IV. The documents filed during the opposition proceedings included:

R1: EP 0457 960 A2

V. The opposition division's decision to revoke the patent was based on the patent as granted as the main request and a set of five claims filed as a first auxiliary request during the oral proceedings before the opposition division.

In the impugned decision, the opposition division found, *inter alia*, that:

(a) the subject-matter of claim 3 of the main request comprised added subject-matter (Article 100(c) EPC),

(b) document R1 anticipated the subject-matter of claim 1 of auxiliary request 1.

VI. The patent proprietor ("appellant") lodged an appeal against the opposition division's decision.

VII. In the statement of grounds of appeal, the appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims of the main request underlying the impugned decision (i.e. the claims as granted) or, alternatively, on the basis of the set of claims of the first auxiliary request underlying the impugned decision, or on the basis of one of the sets of claims filed as the second and third auxiliary requests with the statement of grounds of appeal.

What is more, the appellant raised a substantial procedural violation in relation to a violation of its right to be heard under Article 113(1) EPC on the ground that the opposition division at the oral proceedings had refused to let its technical expert,

Dr Mitra, make oral submissions relating to novelty over document R1 (see points 118 to 123 of the statement of grounds of appeal).

- VIII. By letter dated 7 March 2017, opponent 3 withdrew its opposition and thereby ceased to be a party to the appeal proceedings in respect of the substantive issues. Opponent 4 ("respondent") remained the sole respondent.
- IX. The board issued a summons to oral proceedings to be held on 13 April 2022.
- X. In a letter dated 11 February 2022, the appellant informed the board that it would not be attending the oral proceedings.
- XI. Subsequently, the board cancelled the oral proceedings.
- XII. With further letter dated 23 October 2023, the parties were informed that, taking into account the requests and submissions on file, the board considered the case ready for decision. A preliminary opinion on the validity of the patent was not envisaged.
- XIII. The appellant's written submissions, in so far as they are relevant to the present decision, may be summarised as follows.

Main request - amendments (Article 100(c) EPC) - claim 3 (when dependent upon claim 1)

The amendments made consisted in importing the definition of "physiologically-acceptable cations" given on page 10, lines 14 to 23 of the application as filed into claim 5 as filed (or page 4, lines 22 to 27,

or page 39, clause 40 of the application as filed) and selecting calcium and magnesium as sufficient physiologically-acceptable cations to include in the dialysate from the single list of given physiologically-acceptable cations.

The notion that calcium and magnesium could be combined with citrate in the context of the claimed compositions was further supported by page 7, lines 9 to 10, page 8, lines 7 to 9, and page 19, lines 18 to 30 of the application as filed.

Auxiliary request 1 - novelty over document R1

All the acid concentrates shown in the examples of document R1 used hydrochloric acid instead of citric acid. The latter was mentioned in a long, generic laundry list of acids on page 3, lines 43 to 45 of this document. However, in view of the common general knowledge at the publication date of document R1, the skilled person would not simply substitute hydrochloric acid used in all example formulations of document R1 for citric acid.

XIV. The respondent did not file any requests or make any submissions on substance in the appeal proceedings.

Reasons for the Decision

1. The appeal is admissible.

Decision in written proceedings

2. The present decision is taken in written proceedings without holding oral proceedings.

- 2.1 The appellant requested oral proceedings on condition that the board did not intend to maintain the patent as granted.
- 2.2 By letter of 11 February 2022, the appellant, even before receiving the board's preliminary opinion, announced that it would not be attending the oral proceedings scheduled for 13 April 2022 and furthermore stated that it was not necessary to re-schedule oral proceedings on their behalf. The oral proceedings were therefore cancelled.
- 2.3 The announcement of a party that it will not be appearing at the hearing results in its request for oral proceedings becoming ineffective (see T 245/19, Reasons 1). The board may dispense with oral proceedings if no other reason makes it necessary or desirable to hold them.
- 2.4 In the present case, there is no such reason, because the board, despite not allowing the appellant's main request, has decided to allow their appeal, i.e. to maintain the patent in amended form on the basis of auxiliary request 1, and also because the respondent has not requested oral proceedings.
- 2.5 In view of the fact that the case is ready for decision on the basis of the written submissions, which have been fully taken into account by the board, the board issues this decision by written procedure in accordance with Article 12(8) RPBA and Article 15(3) RPBA (see Case Law of the Boards of Appeal, 10th edition 2022, III.B.2.7.3), while respecting the right to be heard.

Main request

3. Amendments (Article 100(c) EPC) - claim 3 (when dependent upon claim 1)
 - 3.1 The subject-matter of the European patent must not extend beyond the content of the application as filed (see Article 100(c) EPC). In accordance with established case law of the boards of appeal, the relevant question to be decided in this context is whether the skilled person would have derived the subject-matter of the patent directly and unambiguously from the application as filed, meaning that it must not have resulted in the addition of technical information which a skilled person would not have objectively derived from the application as filed (see Case Law of the Boards of Appeal of the EPO, 10th edition 2022, II.E.1.1, in particular G 2/10, OJ EPO 2012, 376).
 - 3.2 In the case at issue, the board finds that the passages of the application as filed relied on by the appellant (see point XIII. above, first paragraph) do not directly and unambiguously disclose the subject-matter of claim 3 (when dependent upon claim 1). The reasons are as follows.
 - 3.2.1 It is undisputed that claim 5 as filed, which is identical in content to page 4, lines 22 to 27 and page 39, clause 40 of the application as filed, differs from the subject-matter of claim 3 (when dependent upon claim 1) in that it fails to specify that the physiologically-acceptable cations sufficient to provide for a neutral composition comprise a combination of calcium and magnesium.

- 3.2.2 It is equally undisputed that in a preferred embodiment of the invention of the application as filed (see page 10, lines 14 to 23), the physiologically-acceptable cation is selected from hydrogen, sodium, potassium, calcium, magnesium and combinations thereof.
- 3.2.3 However, this list does not constitute a direct and unambiguous disclosure of a specific combination of calcium and magnesium.
- 3.2.4 The same holds true for page 7, lines 9 to 10 of the application as filed, which merely states that "[a] composition containing citrate anion may contain a mixture of physiologically-acceptable cations."
- 3.2.5 As a consequence, this passage does not support the notion that calcium and magnesium can be combined with citrate in the context of the claimed compositions.
- 3.2.6 The same holds true for page 8, lines 8 to 9 and page 19, lines 18 to 30 of the application as filed. Page 8, lines 8 to 9 of the application as filed states that the magnesium and/or calcium concentrations of the aqueous acid-concentrate compositions acting as dialysate precursor compositions must be increased when citrate concentrations of 200 to 900 mEq/L are employed. Likewise, page 19, lines 18 to 30 of the application as filed explains that acid-concentrate compositions with citrate concentrations within the range of 200 to 900 mEq/L preferably have elevated levels of calcium and/or magnesium to compensate for the extent to which citrate will bind serum calcium and magnesium.
- 3.2.7 Hence page 8, lines 8 to 9 and page 19, lines 18 to 30 of the application as filed explicitly define the

calcium and magnesium concentrations of the aqueous acid-concentrate compositions in relation to their citrate concentration. This stands in contrast with claim 5 as filed, which requires that the physiologically-acceptable cations be present in an amount sufficient to provide for a neutral composition (see point 3.2.1 above).

3.3 In view of the preceding considerations, the board does not see any reason to deviate from the opposition division's finding that the subject-matter of claim 3 (when dependent upon claim 1) comprises added subject-matter (Article 100(c) EPC).

3.4 As a consequence, the ground for opposition under Article 100(c) EPC prejudices maintenance of the patent on the basis of the main request.

Auxiliary request 1

4. Novelty of the claimed subject-matter over document R1

4.1 In the impugned decision (see point 5 of the Reasons), the opposition division found that the subject-matter of claims 1 to 5 of auxiliary request 1 lacked novelty over the disclosure of preparations 2, 5 or 6 of document R1 (see pages 7 to 9) taken in combination with section (ii) of claims 4 or 18 of this document.

4.2 Preparations 2, 5 and 6 of document R1 are aqueous acid concentrates comprising hydrochloric acid (preparations 2, 5) or a mixture of hydrochloric acid and glacial acetic acid (preparation 6).

4.3 Section (ii) of claims 4 and 18 of document R1 refers to an acid concentrate comprising an acid selected from

the group consisting of hydrochloric acid, acetic acid, citric acid, lactic acid, pyruvic acid, formic acid, fumaric acid, succinic acids and mixtures thereof.

4.4 In the opposition division's view, the skilled person would understand all the acids listed in this section as "equally suitable" or as "pure alternatives" and conclude therefrom that the acid(s) used in preparations 2, 5 and 6 could be replaced by any of the other acids listed in this section, including citric acid. In support of its position, the opposition division referred to decision T 2020/07, section 3.2.2 (see point 5 of the impugned decision).

4.5 However, as convincingly argued by the appellant, the skilled person reading document R1 in the light of their common general knowledge would understand that:

(a) hydrochloric acid is a very strong, monoprotic acid, whilst citric acid is a triprotic acid,

(b) hydrochloric acid contributes to the overall chloride amount of preparations 2, 5 and 6, whilst citric acid does not,

(c) citrate is a strong chelator of calcium, and hence may interact with the calcium ions contained in preparations 2, 5 and 6.

4.6 In view of these differences, the skilled person would not consider citric acid as an alternative to the acid(s) contained in preparations 2, 5 and 6, i.e. hydrochloric acid alone or in combination with glacial acetic acid.

4.7 It follows that the passages of document R1 referred to by the opposition division do not anticipate the claimed subject-matter.

5. Amendments (Article 123(2) EPC) and sufficiency of disclosure

5.1 In the decision under appeal (see points 2.1 and 3 of the Reasons), the opposition division considered that the claimed subject-matter complied with the requirements of Article 123(2) EPC and that the claimed invention was sufficiently disclosed.

5.2 The board, absent any objections in this regard in appeal proceedings, does not see any reason to take a different view.

Procedural issues

6. Alleged substantial procedural violation by the opposition division (see point VII. above)

Given that the claimed subject-matter of auxiliary request 1 is found to be novel over document R1, it is not necessary for the board to give further consideration to the appellant's allegation of a substantial procedural violation in relation to a violation of its right to be heard under Article 113(1) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent in amended form on the basis of the following documents:
 - (a) claims 1 to 5 filed as auxiliary request 1 with the statement of grounds of appeal;
 - (b) a description possibly adapted thereto;
 - (c) drawings: the single Figure of the patent specification.

The Registrar:

The Chair:



I. Aperribay

M. Pregetter

Decision electronically authenticated