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D E C I S I O N
of 17 October 1996

Case Number: T 0617/94 - 3.3.2

Application Number: 85116532.4

Publication Number: 0190459

IPC: A61K 31/70

Language of the proceedings: EN

Title of invention:
Method of providing total energy requirements to a human who has to be intravenously fed because of illness

Patentee:
Pharmacia GmbH

Opponent:
01: B. Braun Melsungen AG
02: Fresenius AG

Headword:
Intravenous feeding/PFRIMMER

Relevant legal provisions:
EPC Art. 54(1)

Keyword:
"Late filed request - inadmissible - not clearly allowable"
"Novelty - no improvement of protein preservation - no distinguishing feature"

Decisions cited:
T 0095/83; T 0153/85; T 0772/92

Catchword:
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Case Number: T 0617/94 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 17 October 1996

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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 8 June 1994 concerning maintenance of the European Patent No. 0 190 459 in amended form.**

Composition of the Board:

Chairman: F. Antony
Members: U. Oswald
R. E. Teschemacher

Summary of Facts and Submissions

I. European patent No. 0 190 459 relating to a method of providing total energy requirements to a human who has to be intravenously fed because of illness was granted with effect from 14 March 1990, with 6 claims, in response to European patent application No. 85 116 532.4 filed on 23 December 1985 and claiming priorities from United States of America applications US 686 719 filed on 27 December 1984 and US 707 457 filed on 1 March 1985.

II. Two oppositions were filed on 10 December 1990 by B. Braun Melsungen AG (Opponent 01) and by Fresenius AG (Opponent 02). Revocation of the patent was requested on the grounds of lack of novelty and lack of inventive step (Article 100(a) EPC).

Of the numerous documents cited during the Opposition, only the following remains relevant for the present decision:

(1) "Zeitschrift für Ernährungswissenschaft", vol. 12, issue number 2, pages 159-174, June 1973.

This document was referred to as (D8) at the appeal stage.

III. According to the interlocutory decision under Article 106(3) EPC of the Opposition Division, dispatched 8 June 1994, the patent could be maintained in amended form on the basis of two claims filed on 25 May 1993.

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Those claims read as follows:

"1. Use of glucose and xylitol as the only carbohydrates in an amount of 20 to 200 g each per liter for the manufacture of an aqueous solution for the improvement of protein preservation with intravenous nutrition for patients suffering from severe trauma, injury, burn or infection in which body nitrogen loss is greater than 4 g/day or blood glucose concentration is greater than 120 mg/dl.

2. Use of glucose and xylitol as claimed in claim 1 for the manufacture of the preparation for the treatment of cancer cachexia."

More particularly, the decision under appeal held that the cited documents neither disclosed the use of glucose and xylitol as the only carbohydrates in infusion solutions for the specific medical indications as claimed, nor did they render the claimed subject matter obvious to a person skilled in the art.

For the assessment of inventive step, the Opposition Division considered document (1) to be the closest prior art and took the view that this document described, inter alia, "a combination of xylitol and glucose administered to seriously ill patients in amounts which could/would fall under the terms of the amended claim 1." In the light of the disclosure of this document, the technical problem underlying the patent in suit was "to provide a nutritive solution which covers the energy requirements of a seriously ill human suffering from severe trauma, injury, burn or infection in which body nitrogen loss is greater than 4 g/day or blood glucose concentration is greater than 120 mg/dl." In the Opposition Division's opinion, there was no teaching in document (1) alone, nor a suggestion by (1) in combination with the other then cited

documents, that a combination of xylitol and glucose would be suitable for "the improvement of protein preservation with intravenous nutrition for patients as specified in claim 1."

IV. On 26 July 1994 Opponent 02, now Appellant 02, and on 2 August 1994 Opponent 01, now Appellant 01, lodged appeals against that decision, followed by statements of grounds of appeal on 7 October 1994 and 18 October 1994, respectively. In their statements of grounds of appeal the Appellants made reference to several new documents. Oral proceedings took place on 17 October 1996. At the end of these oral proceedings, after intermediary deliberations of the Board leading to the conclusion that the claims upheld by the first instance lacked novelty, the Respondent submitted a further set of claims as auxiliary request.

These claims read as follows:

"1. Use of glucose and xylitol as the only carbohydrates in an amount of 20 to 200 g each per liter for the manufacture of an aqueous solution for the improvement of protein preservation with intravenous nutrition for patients suffering from severe trauma, injury, burn or infection in which body nitrogen loss is greater than 4 g/day or blood glucose concentration is grater than 120 mg/dl, such that the infusion rate of glucose is up to 200 g/70 kg bodyweight/24 hours but greater than 100.0 g/day with xylitol no higher than 210 g/70 kg bodyweight/24 hours but greater than 62.0 g/day.

2. Use of glucose and xylitol as claimed in claim 1 for the manufacture of the preparation for the treatment of cancer cachexia."

V. Concerning Article 54(1) EPC, the Appellants argued that the claims held allowable by the decision under appeal lacked novelty in the light of the disclosure of document (1). Having regard to the different groups of patients tested during an intensive care unit stay, the method and time of treatment, the infusion rates of glucose and xylitol mixtures, the absolute amounts of carbohydrates administered to the patients and the diagnoses of the collectives of patients as set out on page 159, and tables "1a" and "1b" on pages 160/161, it was clear that this prior art comprised each of the features presently claimed. It was particularly pointed out that table "1a" made reference to patients suffering from Hodgkin's disease, ovarian carcinoma, pancreatitis and peritonitis infection. Furthermore, a person skilled in the art reading document (1) would inevitably take into account the fact that, according to well known clinical practice, up to three liters of aqueous infusion solution were administered per day and patient. Moreover, claim 1 considered by the decision under appeal did not comprise any dosage figures for the carbohydrates to be administered and thus, the claimed subject-matter was not restricted to either a hypo- or a hyperalimentation of the patients.

VI. The Respondent contested these arguments and took the view that document (1) could at best be regarded as an accidental anticipation. The experimental studies presented in this document were based on nothing else but an arbitrary mixture of 231 patients treated over a period of three years. The teaching according to this prior art was neither related to the problem underlying the patent in suit, nor to its solution, i.e. in the case of patients suffering from severe trauma which was otherwise correlated with a high body nitrogen loss occurring after the acute-phase to start with the intravenous nutrition at a very early stage of the acute-phase. In other words, the solution was to

commence with the treatment of patients at a time at which the nitrogen loss was not yet dramatic, but was still low (such as 4g/day and more), resulting in an improved protein preservation during the later, critical phase. It was therefore irrelevant that document (1) already mentioned diagnoses which might overlap with the medical indications referred to in claim 1. The essential point of the present invention was the purpose of the medical treatment, namely the treatment of a defined subgroup of patients at a well defined time, which treatment was accompanied by a defined effect on the nitrogen metabolism of the body. Document (1) clearly related to studies on long lasting parenteral nutrition with glucose and xylitol, at a time at which the nitrogen metabolism was no longer out of balance and the patients were in a normal conditions. Moreover, at the priority date of the patent in suit, hyperalimentation of patients was common practice for those skilled in the art, and there was clearly no preference for a hypoalimentation as now taught by the invention.

In the present case, the claimed subject matter needed interpretation within the meaning of Article 69 EPC, i.e. the claims had to be read in the light of the description and the examples.

VII. The Appellants requested that the decision under appeal be set aside and that the European patent be revoked.

The Respondent requested that the appeal be dismissed. Alternatively he requested that the decision under appeal be set aside and the patent be maintained on the basis of Claims 1 and 2 as submitted during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. In appeal proceedings claims forming the basis of auxiliary requests should normally be filed with the statement of grounds or soon thereafter. A number of decisions by the Boards of Appeal have made it clear that claims filed at a late stage of proceedings may be rejected as inadmissible. In particular, if the late filed claims are not clearly allowable, then the Board, in exercise of its discretion, may refuse to admit such (see for example, T 95/83, OJ 1985, 75; T 153/85, OJ 1988, 1; and unpublished decision T 772/92 of 21 June 1995, point 2 of the reasons).

In the present case, the auxiliary request was submitted after the Board had deliberated upon the allowability of the previous sole request. Taking into account the objections under Article 54(1) EPC put forward by the Appellants in their written submissions during the appeal procedure, there was reason enough to submit such a request much earlier or at the very latest when the oral proceedings began.

In any event, the Board fails to see how the proposed amendments to claim 1 could possibly have rendered the claimed subject matter inventive. It was not before the oral proceedings that the Respondent emphasised that for the assessment of novelty and inventive step it was necessary to take into account that the inventor had developed a new therapy for critically ill patients suffering from severe trauma, namely to start with intravenous nutrition of these patients at a very early

stage of the acute-phase. Even more important, the amended claims do not contain any additional feature relating to a **concrete realisation** of such new approach (cf. point 4 below).

Consequently, the auxiliary request submitted by the Respondent is not admitted into the proceedings, because it has been filed at a very late stage and is not clearly allowable. Below, this decision deals only with the claims which formed the basis for the decision under appeal.

3. Claims 1 and 2 are based on claims 1 to 3 and 6 as originally filed (corresponding to claims 1 to 3 and 6 as granted) and find further support on page 1, first paragraph of the description originally filed (page 2, lines 6 to 10 of the patent specification). The claims are of narrower scope than the granted claims. The requirements of Article 123(2) and (3) EPC are accordingly satisfied.

4. Document (1) discloses clinical studies on 231 patients from an intensive care unit which patients underwent a long lasting infusion therapy with the carbohydrates glucose, fructose or xylitol and combinations thereof. The course of treatment lasted between 1 and 30 days with an infusion time of 4 to 24 hours/day. The total amount of carbohydrates infused amounted to between 50 and a maximum of 7800 g and the mean infusion velocity was estimated at 15-20 g/h (cf. page 159, paragraph "Patienten und Methodik"). According to table "1b" an average total dose of 47 g/day (first day), 60,8 g/day (third day) and 62 g/day (sixth day) of xylitol and 79,0 g/day (first day), 87,0 g/day (third day) and 100 g/day (sixth day) of glucose as the only carbohydrates was administered to a group of 31 patients. The diagnoses of these patients according to table "1a"

included one patient suffering from malignant Hodgkin disease, one patient suffering from ovarian carcinoma, one patient suffering from pancreatitis and one patient suffering from peritonitis.

Taking into account that a dosage of up to about three liters of aqueous infusion solution per day and patient forms the basis for the clinical practice, which amount of liquid was not contested by the Respondent, document (1) discloses the use of glucose and xylitol in amounts falling within the range of claim 1. This is in line with the teaching of the complete specification, in particular with the clinical tests on page 4, lines 4 to 20 (page 7 of the original application documents) leading in the light of common general knowledge to the same daily dosage.

The so-called nitrogen saving effect of carbohydrates, in particular that of xylitol, intravenously administered to critically ill patients was undisputedly well-known for a long time before the priority date of the patent in suit. As a consequence, parenteral nutrition was always carried out with the general aim of influencing the nitrogen balance in a positive way. Accordingly, the mere reference in claim 1 to an **improvement** of protein preservation cannot be accepted as a new technical feature in comparison with what document (1) actually teaches when referring to intravenous nutrition with glucose and xylitol in amounts per liter falling within the range as required by claim 1.

Equally, the reference in claim 1 to disorders defined in broad terms, such as injury or infection accompanied by a body nitrogen loss **greater** than 4 g/day or a blood glucose concentration **greater** than 120 mg/dl, does not represent a distinguishing technical feature over the

disclosure of document (1). Such an open-ended definition of the metabolism status comprises virtually all situations in which parenteral nutrition may be used, in other words a clinical picture ranging from an almost normal up to an extremely critical status of the nitrogen metabolism; it therefore clearly covers the diagnoses set out in table 1a of document (1). The Respondent has not contested that the lower limits of the nitrogen loss and glucose concentration values as set out in claim 1 represent the border-line between a normal and a pathologic status of a patient.

Accordingly, novelty of the subject matter of claim 1 and that of claim 2 directed to the treatment of cancer cachexia cannot be recognised.

5. In deciding on the question of novelty, the Board has not overlooked the Respondent's argument that document (1) does not disclose starting intravenous nutrition purposely and exclusively at a very early stage of the acute-phase of patients suffering from severe trauma which, without the treatment of the invention, would be correlated with a high body nitrogen loss occurring after the acute-phase. However, having regard to the disclosure of the patent in suit as a whole, taking into account the description, the clinical tests and the claims singly or in combination, there is clearly no teaching that the use of glucose and xylitol should be limited to a certain time immediately after the beginning of the acute phase. In other words, the Board fails to see any congruence between the arguments put forward by the Respondent at the oral proceedings and the actual teaching of the patent in suit.

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:

P. Martorana F. Antony