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D E C I S I O N
of 21 March 1996

Case Number: T 1058/93 - 3.3.2

Application Number: 85100461.4

Publication Number: 0150053

IPC: A61K 31/195

Language of the proceedings: EN

Title of invention:
Hypocaloric low osmotic aqueous preparation for infusion

Patentee:
Oehmke, Martin, Dr.

Opponent:
B. Braun Melsungen Aktiengesellschaft
BASF Aktiengesellschaft, Ludwigshafen
Fresenius AG

Headword:
Preparation for infusion/OEHMKE

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step - no - obvious preparation for infusion - adaptation to critically ill patients no distinguishing feature"

Decisions cited:
G 0005/83

Catchword:
-

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Case Number: T 1058/93 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 21 March 1996

Appellant: (Opponent)
B. Braun Melsungen Aktiengesellschaft
Karl-Bruan-Strasse 1, Postfach 1 20
D-34209 Melsungen (DE)

Representative:
von Kreisler, Alek, Dipl.-Chem.
Patentanwälte
von Kreisler-Selting-Werner
Postfach 10 22 41
D-50462 Köln (DE)

Appellant: (Opponent)
BASF Aktiengesellschaft, Ludwigshafen
-Patentabteilung - C6-
Carl-Bosch-Strasse 38
D-67056 Ludwigshafen (DE)

Representative:
-

Appellant: (Opponent)
Fresenius AG
D-61343 Bad Homburg v.d. Höhe (DE)

Representative:
Fuchs, Luderschmidt & Partner
Patentanwälte
Postfach 46 60
D-65036 Wiesbaden (DE)

Respondent: (Proprietor of the patent)
Oehmke, Martin, Dr.
Wiesenweg 52
D-91088 Bubenreuth (DE)

Representative:
Freiherr von Pechmann, Eckehart, Dr. Dipl.-Chem.
Wuesthoff & Wuesthoff
Patent- und Rechtsanwälte
Schweigerstrasse 2
D-81541 München (DE)

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 4 November 1993 concerning maintenance of European patent No. 0 150 053 in amended form.**

Composition of the Board:

Chairman: P. A. M. Lançon
Members: U. Oswald
C. Holtz

Summary of Facts and Submissions

I. European patent No. 0 150 053 concerning a hypocaloric low osmotic aqueous preparation for infusion was granted on the basis of eight claims contained in European patent application No. 85 100 461.4

II. Three oppositions under Article 100(a) and (b) EPC were filed against the granted patent.

Of the numerous documents cited, the following remain relevant to the present decision:

(1) WO-A-82/03552
(2) "Infusionstherapie", 2:69-76(2/1981)
(8) booklet "PE 900 pfrimmer", J. Pfrimmer + Co. Erlangen, Pharmazeutische Werke, 1978, (100678 ft)
(10) booklet "Nutrifundin® ", B. Braun company, Melsungen (G 10.03 71)

III. According to the interlocutory decision under Article 106(3) EPC of the Opposition Division the patent was maintained in amended form on the basis of four claims.

Claim 1 reads as follows:

"1. A hypocaloric low osmotic aqueous preparation for infusion in critically ill patients containing dietary amino acids, xylitol as sole source of the carbohydrate energy and electrolytes in a dosage of physiological requirements, this preparation comprising:

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	g/l
Xylitol	30 - 80
L-Isoleucine	1 - 6
L-Leucine	1 - 6
L-Valine	0.85 - 5
L-Tryptophan	0.11 - 0.70
L-Phenylalanine	0.3 - 2
L-Lysine acetate	1 - 6
L-Threonine	0.5 - 3.0
L-Arginine	0.67 - 4
L-Alanine	0.67 - 4
L-Histidine	0.25 - 1.5
L-Proline	0.82 - 5.0
L-Serine	0.5 - 3.0
L-Cysteine·HCl·H_2O	0.003 - 0.02
L-Methionine	0.15 - 0.80
Glycine	0.67 - 4

wherein the total amino acid concentration is between 25 and 50 g/l."

The decision under appeal held that none of the cited documents disclosed the preparation for infusion according to the amended claim 1 showing the low contents of the cysteine and methionine components in combination with the narrow range of content of xylitol as the only energy substrate.

In the light of document (1) representing the closest prior art, the technical problem underlying the patent-in-suit was to provide a hypocaloric infusion preparation, specifically suitable for critically ill patients. Since document (1) concerned a totally different problem, namely how to obtain infusion solutions which do not contain precipitated calcium

phosphate, the claimed subject-matter involved an inventive step. When deciding on the question of inventive step, it was necessary to take into account the fact that document (1) did not state that each of the compounds xylitol, glycerol and sorbitol could be regarded as individually representing an equivalent energy substrate. The worked examples showed exclusively glycerol for this purpose. On the basis of a fair analysis of the prior art, document (1), even in combination with document (2), which showed much higher contents of amino acids, could not be interpreted as proposing an upper concentration value of 100 g/l when using xylitol as the only energy source for critically ill patients. Accordingly, it was not obvious for a person skilled in the art that in the case of critically ill patients with high losses of protein less xylitol could be administered than in the case of less ill patients.

IV. The two Appellants (Opponent 01 and Opponent 03) lodged an appeal against this decision and argued that the amended claim 1 according to the main request as well as that of the auxiliary request were related to an aqueous preparation per se and therefore any additional reference to the specific use of this preparation for critically ill patients could not influence the decision whether or not the claimed subject-matter was novel and/or involved an inventive step. It was particularly to be noted that each infusion preparation according to the cited prior art represented a composition of amino acids and energy substrates suitable for critically ill patients.

It was not possible to distinguish the critically ill patients according to the patent-in-suit from the group of patients described in the prior art. Moreover, since the quantity of infusion preparation to be administered

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and the group of patients to be treated, e.g. small children or adults, represented essential parameters when defining if an infusion preparation was hypocaloric or hypercaloric, it was not possible to distinguish the claimed subject-matter, not containing said parameters, by the term hypocaloric from the prior art. Contrary to the Respondent's assertion and the decision of the Opposition Division, document (1) disclosed on the basis of e.g. claims 11, 12, 13 and 15 an upper limit of the xylitol concentration of 100 g/l. Taking into account the contents of the other components of the infusion preparation according to document (1), there was no doubt that this prior art also related to a hypocaloric low osmotic aqueous preparation. As regards the additional feature in claim 1 according to the auxiliary request, namely that the osmolarity of the preparation is between 300 and 900 mOsm, it was to be noted that none of the worked examples of the patent-in-suit contained a reference to this parameter. Moreover, there was no evidence that the low osmolarity was related to any particular unexpected effect when using the preparation for infusion. Document (1) did not expressly mention the osmolarity of the infusion solution but it was common practice in the art and for example disclosed in document (8) on page 10, to provide for peripheral intravenous infusions solutions having an osmolarity in the range claimed. Consequently, it could not be accepted that the preparation according to the patent-in-suit represented a selection invention with respect to the caloric and/or osmotic effect on the treated people. Furthermore, there was a clear teaching in document (1), in particular having regard to the worked examples that glycerol sorbitol and xylitol individually represented equivalent energy substrates. In the absence of any particular effect related to the difference of the amino acid content, it was not possible to establish an inventive step on the corresponding lower amino acid

concentrations of methionine and cysteine since the adjustment of the content of each amino acid in the infusion preparation depending on the patients requirement was common general knowledge.

To demonstrate lack of inventiveness, it was furthermore to be noted that document (2) and a further publication,

document (21) "Influence of Posttraumatic Nutrition on Patient Outcome", pages 128 to 135 in "New Aspects of Clinical Nutrition", (Karger, Basel 1983),

by one of the inventors of the patent-in-suit as well as a plurality of other pre-published literature emphasised the fact that xylitol played an important role as an energy substrate.

Finally, it was to be noted that claim 1 did not contain a definition of the electrolytes used and thus, claim 1 could also comprise calcium phosphate.

V. The Respondent (patentee) took the view that the only problem to be solved by the inventors of document (1) was to prevent calcium phosphate precipitations. Document (1) clearly contained the teaching that glycerol sorbitol and/or xylitol could be used for this purpose. As regards the question of nutrition, this prior art put emphasis only on glycerol. Since the disadvantage when using glycerol in high dosages was well known in the art, it was clear that the low amounts of 20-100 g/l of polyol exclusively were related to glycerol as the only energy substrate. None of the worked examples disclosed xylitol as the only energy substrate in such low amounts as presently claimed and there was no indication that the solutions according to document (1) could be regarded as having an hypocaloric

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and low osmotic effect. Taking into account the amount of up to 300 g/l for the three polyol compounds used document (1) disclosed hypercaloric and high osmotic solutions. The dosage of up to 100 g/l was only valid for each polyol when using the three polyols in combination. Without hindsight, there was no indication that xylitol in the low amounts and amino acids in the claimed concentration ranges not only provided sufficient energy for critically ill patients but also influenced the regeneration phase in a positive way. This was proven by a publication in 1992 describing an pharmacological effect of the xylitol component on the DNA substance. The definition of critically ill according to the patent-in-suit was to be understood such that the treatment of the patients, in particular those who require ventilatory support was started before the occurrence of high nitrogen losses and consequently before a severe loss of energy. Consequently, the prior art according to document (10), referring to values of nitrogen losses of patients not treated with the claimed preparation was in no way relevant. Since the prior art did not destroy the novelty of the claimed composition, there was no need to discuss further to which extent the term critically ill could be regarded as a delimiting feature in the sense of Article 54 EPC. The inventors of the patent-in-suit suggested for the very first time, and in contrast to the usual practice, the treatment of a special group of critically ill patients by peripheral intravenous infusion techniques with xylitol as the only energy substrate in combination with amino acids before a stabilization of the circulatory system of these patients took place. Moreover, before the priority date of the patent-in-suit a person skilled in the art only took into account the administration of the preparation according to document (21) into the central vein. Although this prior art disclosed 3 g xylitol per kg body weight and day, it was clear that the clinical

tests according to this prior art were carried out by using commercially available solutions of amino acids, carbohydrates and electrolytes not suitable for peripheral intravenous infusion techniques. Furthermore, it was to be noted that a person skilled in the art never would have taken into account the administration of such high amounts of the claimed preparation to provide a hypercaloric nutrition since, in practice, this involved the administration of a dangerous high amount of water. Attention was drawn to the Appellant's argumentation presented before the Opposition Division in another case, which argument was based on a contraindication when using xylitol and thus clearly supported an inventive step in the present case. The same applied to the Appellants statement that in the light of the facts on file it would only have been possible to base an inventive step on the amino acid composition. The inventiveness of the claimed subject-matter was also proven by the commercial success of the claimed preparation now distributed by one of the well known companies in the field of infusion solutions. As regards the relevance of the other documents cited against the features of claim 1, it was to be noted that document (8) disclosed a low osmolarity only for a preparation comprising xylitol and sorbitol in combination.

The auxiliary request limiting the claimed subject-matter to a defined osmolarity was presented for commercial reasons, in particular having regard to a document not published before the priority date of the patent-in-suit but describing a plurality of commercially distributed preparations for infusion.

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Although claim 1 according to the main request as well as the auxiliary request related to a preparation for infusion per se, when assessing inventive step it was necessary in the light of the decisions of the Enlarged Board of Appeal of the EPO to take into account the medical indication and the therapeutic effect respectively of the preparation as an essential feature.

VI. In response to a question by the Board as to what the patent in suit really achieved when compared with the closest prior art according to document (1), one of the Respondent's Representatives declared that the claimed subject-matter provided an alternative preparation for infusion.

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 (main request) or that the patent be maintained on the basis of claims 1 to 3 as submitted in the oral proceedings (auxiliary request).

Reasons for the Decision

1. The appeal is admissible.

2. Claim 1 according to the main request corresponds to claims 1, 3 and 4 originally filed and claims 1 and 3 as granted; claim 2 of the main request is based on claim 2 originally filed in combination with page 13, lines 14 to 17 of the original description and claim 2 as granted; claim 3 of the main request corresponds to claim 5 originally filed and claim 4 as granted; claim 4

of the main request is based on page 15, lines 22/23 and page 18, line 34 up to page 19, lines 1/2 of the original description and claim 8 as granted.

Claim 1 of the auxiliary request is limited to an osmolarity between 300 and 900 mOsm, which is derived from claim 2 according to the main request. Claims 2 and 3 of the auxiliary request correspond to claims 3 and 4 of the main request.

The requirements of Articles 123(2) and 123(3) are accordingly satisfied.

3. None of the documents cited during the proceedings discloses a preparation for infusion having all the features set out in claim 1 of the main request. Since novelty is no longer in dispute, it is not necessary further to investigate the matter.

4. Document (1) was accepted by the Opposition Division and each of the parties as representing the closest state of the art. The Board sees no reason to deviate from this point of view.

4.1 This document relates to solutions suitable for peripheral intravenous infusion techniques for the treatment of patients who require parenteral nutrition. According to the so-called "Background of the Invention" the group of patients envisaged by document (1) shows inter alia severe losses of nitrogen accompanied by severe weight loss during trauma sepsis etc. It has been found that the use of a polyhydric alcohol such as glycerol, xylitol or sorbitol, or combinations thereof, as the energy source in the parenteral solutions containing amino acids, electrolytes, calcium and phosphate, provides a solution which can be steam sterilized without the precipitation of calcium

phosphate and without a browning effect. The solutions preferably contain 2.5 to 13 percent weight/volume of L-amino acids and/or their organic and inorganic salt equivalents, the major intra- and extracellular electrolytes in concentrations sufficient for maintenance of normal values, and 2 to 10 per cent glycerol as a metabolizable antiketotic energy substrate chemically compatible with amino acid solutions and acting as a stabilizing agent for the chemically incompatible calcium and phosphate ions. In addition to stabilizing amino acid solutions, glycerol is unique in that it prevents patients from becoming ketotic when metabolizing amino acids alone or amino acids and fat. It is then indicated that antiketotic compounds other than glycerol which stabilize calcium and phosphate and prevent metabolic ketoacidosis are the polyhydric alcohols sorbitol and xylitol, which may be used in place of or in combination with glycerol. The concentrations of the ingredients of the solution may vary depending on the purpose for which the solution is administered (see page 1, first paragraph; page 2, lines 11 to 16; page 2, line 17 up to page 3, line 23; page 7, lines 9 to 25 and page 11, lines 4/5).

According to a preferred embodiment the solution has the following composition:

Compound	g/l
L-Methionine	1.28 - 1.92
L-Isoleucine	1.68 - 2.52
L-Leucine	2.16 - 3.24
L-Phenylalanine	1.36 - 2.04
L-Valine	1.60 - 2.40
L-Threonine	0.96 - 1.44
L-Lysine	1.87 - 2.53
L-Alanine	1.70 - 2.54
L-Arginine	2.32 - 3.48
L-Histidine	0.68 - 1.02
L-Proline	2.72 - 4.08
L-Serine	1.44 - 2.16
Amino Acetic Acid	3.00 - 5.04
L-Tryptophan	0.37 - 0.55
L-Cysteine·HCl·H_2O	0.03 - 0.30
Sodium Acetate 3 H_2O	1.94 - 2.14
Magnesium Acetate 4 H_2O	0.5 - 0.58
Calcium Acetate	0.244 - 0.284
Sodium Chloride	1.11 - 1.23
Potassium Chloride	1.42 - 1.56
Potassium Metabisulfite	0.55
Glycerol	20 - 100
Phosphoric Acid 85%	0.216 - 0.264 ml
Glacial Acetic Acid	pH Adjustment
Water for Injection	q.s.

In a particularly preferred embodiment the concentration of glycerol in the above solution is 30 - 90 g/l (see page 8, line 27 to page 9, line 21). The preparation may contain from 2 to 14 weight percent of total amino acids based on the solution. For total parenteral nutrition the use of an optimum concentration of total amino acids from 2.5 to 4.5 weight per cent is proposed based on the

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solution as prepared for protein conservation of mildly stressed surgical patients. Full protein nutrition can be provided by administration from about 1 to 3 litres of solution per patient during each 24 hours (see page 11, lines 11 to 23). Each of the worked examples 1 to 3 as well as the set of claims, in particular claims 11 and 33 in the claimed combination with claim 29 indicate in the same form of a listing to use glycerol or sorbitol or xylitol or combinations thereof as the energy substrates in an amount of 20 to 300 g/l. The listing reads as follows:

"

Energy Substrates	20 - 300
Glycerol or Sorbitol or Xylitol or combinations thereof, provided that the concentration of any one energy substrate does not exceed 100 g/l	

."

4.2 In spite of some attempts by the Respondent to define the problem as the provision of a preparation for infusion adapted to critically ill patients, the Board had to conclude that in the light of document (1) and as confirmed by one of the Representatives of the Respondent, the problem to be solved could only be to provide an alternative (see 5.4 and 5.5 hereunder).

4.3 The problem is solved by the preparation for infusion according to claim 1 of the main request (see paragraph III above) comprising L-Cysteine·HCl·H_2O in the range of 0.003 to 0.02 g/l and L-Methionine in the range of 0.15 to 0.8 g/l. Having regard to the examples of the patent in suit, the Board is satisfied that the problem has indeed been solved.

5. It remains to be investigated whether or not claim 1 of the main request satisfies the requirements of Article 56 EPC in respect of inventive step.

5.1 Contrary to the Respondent's argumentation, in the Board's opinion, not only persons skilled in the art faced with the problem of avoiding precipitation of calcium phosphate in solutions for parenteral nutrition but also those searching in general for information concerning the composition of such solutions for practical applications, would take notice of document (1).

5.2 The essential difference between the composition of **the preparation** according to claim 1 of the main request and that of document (1) lies in the quantitative proportion of the amino acids.

5.3 The reference to a hypocaloric, low osmotic aqueous preparation for infusion in critically ill patients according to claim 1 of the main request cannot be accepted as a distinguishing feature in the present case.

The teaching of document (1) is neither restricted to hypercaloric high osmotic solutions nor is there an indication that hypocaloric low osmotic solutions would show any disadvantage. In fact, document (1) unambiguously teaches with reference to the preferred

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embodiment according to page 8, line 26 up to page 9, line 21 (see paragraph 4.1 above), the use of an infusion solution with a defined content of the amino acids, electrolytes and one component as a carbohydrate energy substrate. Peripheral intravenous infusion techniques which require a low osmotic preparation are mentioned expressly on page 11. The Respondent did not contest that the preferred embodiment on page 9, comprising 30 g/l to 90 g/l of one component as the energy substrate, represents a hypocaloric low osmotic preparation. In this respect it is to be noted that the concentration range of the energy substrate in g/l and that of the amino acids in g/l according to the said preferred embodiment of document (1) in comparison with claim 1 of the main request do indeed overlap to a large degree and that claim 1 according to the main request contains neither a definition of the electrolytes used nor a reference to the absolute amount of electrolyte content. Even the worked examples of the patent in suit do not contain a reference to the adjusted value of osmolarity.

5.4 It remains therefore to be considered whether the mere reference to the **use for** critically ill patients in combination with the claimed features could imply an additional characteristic of the preparation in such a way as to make the claimed preparation distinguishable and non obvious over preparations as envisaged by document (1). In this respect the only information contained in the patent in suit, and on which a **quantitative comparison** with the prior art could be based, refers on page 6, lines 62 to 64 to patients showing nitrogen losses **greater than** 4 grams per day or a blood glucose level greater than 120 mg/dl. Taking into account, however, the common general knowledge about the metabolism of patients after a trauma or surgical treatment, e.g. according to document (10),

page 13 last paragraph and page 14 second paragraph, indicating that nitrogen losses of 10 g per day do not represent an unusual value, it is not possible to derive any quantitative difference from the values specifying the patients according to the patent in suit over **patients usually envisaged for parenteral nutrition.**

5.5 Even if one were to assume a group of patients showing after a certain period of time a highly dangerous pattern of metabolism data, in view of the fact that **it is not possible to distinguish the patients by the metabolic status as defined in the patent in suit namely at the beginning of the treatment with the preparation for infusion immediately after a trauma or surgical treatment**, the term critically ill is in the present case in no way suitable to imply either a quantitative or functional difference to the low osmotic and hypocaloric solution described in document (1). The same reasoning would apply to a further characterisation of critically ill patients requiring ventilatory support.

5.6 In the light of the prior art, likewise, the use of xylitol as the sole source of carbohydrate energy for critically ill patients could not support an inventive step. The Board agrees with the Respondent's statement that document (1) taken singly does not contain any preference as to the use of xylitol in place of glycerol or sorbitol. However, document (21) (see in particular page 130, last two paragraphs and page 131 as well as figures 2 and 3 on pages 132/133) and document (2) (see in particular page 74, right column "Schlußfolgerungen"), both documents also relating to post-operative and post-traumatic nutrition respectively, clearly teach with reference to the metabolism of the liver the advantage of using xylitol and amino acids within the scope of a short-term hypocaloric parenteral nutrition therapy.

Taking into account in addition the numerous cross references in documents (2) and (21) relating to further publications the advantageous of use of xylitol, the whole prior art appears to point in the direction of using xylitol as the sole energy source during the first days after trauma or a surgical treatment. Accordingly, in the light of the further cited prior art a skilled person reading document (1), would not regard either glycerol or sorbitol as an alternative energy source having the same effect on the metabolism of critically ill patients as xylitol. In other words, the use of xylitol in place of either glycerol or sorbitol in a preparation for infusion adapted to critically ill patients cannot be regarded as being based on an inventive choice.

5.7 Although there is indeed no hint in document (1) itself which might have given an incentive to the skilled person to modify the ratio of particular amino acid components, this prior art clearly states that the concentrations of the ingredients may vary depending on the purpose for which the solution is administered. Document (21) additionally gives the clear teaching on page 133 that there is no "significant advantage for protein metabolism between the various amino acid solutions available" and that the only difference lies in the dose of amino acids to be administered. Neither on the basis of the description of the patent in suit nor taking into account the written and oral submissions by the Respondent, is there any evidence illustrating a particular effect of the modified ratio of amino acids on the patients envisaged by the patent in suit. In the absence of such evidence, the Board can only conclude that the amino acid composition according to the patent in suit represents an obvious alternative to the amino

acid composition known from document (1). It follows from the preceding paragraphs that the preparation for infusion according to claim 1 of the main request lacks the required inventive step (Article 56 EPC).

6. The Board notes that an osmolarity between 300 and 900 mOsm referred to in the auxiliary request is well known in the art to provide preparations for infusion suitable to be infused in a peripheral vein (see for example document (8), pages 10/11, "Abbildung 2" and general explanations relating to the physical background of the phenomena of osmolarity). According to this document a range of 300 to 600 mosmol/l is suggested to avoid irritation of the veins. It is furthermore clear from the explanations in document (8) and well known in the art that the absolute value of osmolarity only depends on the total amount (number) of dissolved particles and not on the chemical composition of the solution. When discussing the matter of obviousness of the osmolarity according to the auxiliary request, in contrast to the Respondent's argumentation, it is irrelevant whether or not document (8) relates to the same composition of the preparation as presently claimed. The restriction to the range of osmolarity is the only difference between claim 1 of the main request and the respective claim 1 of the auxiliary request. Such a restriction leaves the reasoning above set out in relation to claim 1 of the main request equally applicable to claim 1 of the auxiliary request, which thus also lacks the required inventive step.

7. Finally, the Board draws attention to the fact that in the present case, in which **a preparation** for an infusion, whose composition **per se** is regarded as **obvious** within the light of the prior art, the mere possibility of using this preparation in a new infusion therapy cannot of itself render the claimed subject-

matter relating to the product inventive per se within the meaning of Article 56 EPC. It was therefore not necessary to discuss further the Respondent's argumentation concerning specific infusion therapies using a product which was obvious for other reasons. Decision G 5/83 (OJ EPO 1985, 64) clearly relates to subject matter only concerning the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application. However, taking into account the reasoning as set out under paragraph 5.5 above, illustrating the impossibility of distinguishing **in the present case** between the so-called critically ill patients and groups of other patients, it is also clear that even a claim relating to a second medical indication would have failed to meet the requirements of Article 56 EPC.

8. As each of the requests put forward by the Appellant contains a claim which fails to comply with the patentability requirements of the EPC, the patent must be revoked.

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 P. A. M. Lançon