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**Datasheet for the decision
of 23 January 2018**

Case Number: T 0586/16 - 3.3.09

Application Number: 02738145.8

Publication Number: 1401293

IPC: A23L1/29, A23L1/305, A23C9/20,
A61K38/00, A61K38/01

Language of the proceedings: EN

Title of invention:
CALORICALLY DENSE LIQUID ORAL SUPPLEMENT

Patent Proprietor:
Nestec S.A.

Opponents:
Fresenius Kabi Deutschland GmbH
N.V. Nutricia

Headword:

Relevant legal provisions:
EPC Art. 100 (c)

Keyword:

Grounds for opposition - subject-matter extends beyond content
of earlier application (yes)
Admissibility of late-filed documents

Decisions cited:

Catchword:



Beschwerdekammern

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Case Number: T 0586/16 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 23 January 2018

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 18 December
2015 revoking European patent No. 1401293
pursuant to Article 101(3) (b) EPC**

Composition of the Board:

Chairman W. Sieber
Members: M. O. Müller
 F. Blumer

Summary of Facts and Submissions

- I. This decision concerns the appeal filed by the proprietor of European patent No. 1 401 293 against the decision of the opposition division to revoke it.
- II. With their notices of opposition the two opponents had requested revocation of the patent in its entirety on the grounds under Article 100(a) (lack of novelty and inventive step), (b) and (c) EPC.

The documents submitted during the opposition proceedings included:

D2: US 5,904,948 A; and

D15: "Enteral Nutrition Formulas (Systemic)" in Drug Information Online from Drugs.com, revised on 8 March 1995, pages 1 to 35.

- III. The main request before the opposition division contained two independent claims 1 and 2 as follows:

"1. A liquid oral supplement comprising:

a protein source that provides 14% to 20% of the total caloric content of the product, the protein source consisting of caseinate and a soy protein isolate wherein the caseinate and soy protein isolate are present at a ratio of 75:25 to 50:50;

a fat source providing at least 40% of the caloric content;

a carbohydrate source providing at least 25% of the caloric content; and the product having a caloric

density of at least 9.42 kJ per ml (2.25 calories per ml),

which product is for use as a medicament for providing nutritional support to; *[sic]*

- (a) a stressed individual;
- (b) a malnourished individual; or
- (c) an elderly individual."

"2. Use of a liquid oral supplement comprising:

a protein source that provides 14% to 20% of the total caloric content of the product, the protein source consisting of caseinate and a soy protein isolate wherein the caseinate and soy protein isolate are present at a ratio of 75:25 to 50:50;

a fat source providing at least 40% of the caloric content;

a carbohydrate source providing at least 25% of the caloric content;

and the product having a caloric density of at least 9.42 kJ per ml (2.25 calories per ml), for the manufacture of a medicament for providing nutritional support to; *[sic]*

- (a) a stressed individual;
- (b) a malnourished individual; or
- (c) an elderly individual."

The opposition division rejected the main request, since the term "medicament" in claims 1 and 2 did not have a basis in the application as filed.

Auxiliary request 1 (not relevant to the present decision) was not admitted into the proceedings.

Claims 1 and 2 of auxiliary request 2 read as follows (amendments with respect to the corresponding claims of the main request highlighted):

"1. A liquid oral supplement comprising:

a protein source that provides 14% to 20% of the total caloric content of the product, the protein source consisting of caseinate and a soy protein isolate wherein the caseinate and soy protein isolate are present at a ratio of 75:25 to 50:50;

a fat source providing at least 40% of the caloric content;

a carbohydrate source providing at least 25% of the caloric content; and the product having a caloric density of at least 9.42 kJ per ml (2.25 calories per ml),

which product is for use as a medicament for providing nutritional support to; *[sic]*

~~(a) a stressed individual;~~

~~(b) a malnourished individual; or~~

~~(c) an elderly individual."~~

"2. Use of a liquid oral supplement comprising:

a protein source that provides 14% to 20% of the total caloric content of the product, the protein source consisting of caseinate and a soy protein

isolate wherein the caseinate and soy protein isolate are present at a ratio of 75:25 to 50:50;

a fat source providing at least 40% of the caloric content;

a carbohydrate source providing at least 25% of the caloric content;

and the product having a caloric density of at least 9.42 kJ per ml (2.25 calories per ml), for the manufacture of a medicament for providing nutritional support to; [sic]

~~(a) a stressed individual;~~
~~(b) a malnourished individual; or~~
~~(c) an elderly individual."~~

The opposition division did not admit auxiliary request 2 into the proceedings. The restriction to malnourished individuals did not overcome the objection under Article 123(2) EPC. Hence, the amendment in auxiliary request 2 was also not "*prima facie* relevant".

Claims 1 and 2 of auxiliary requests 3 to 6 (annexed to the opposition division's decision as auxiliary requests 1 to 4) all included the same formulation based on the term "medicament" as in the corresponding claims of the main request. Hence, for the same reasons as for the main request, these claims did not have a basis in the application as filed.

IV. This decision was appealed by the proprietor (hereinafter: the appellant). The statement setting out

the grounds of appeal contained a main request and auxiliary requests 1 to 5 as well as

D28: Excerpt from ICD 10-2016 "International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10)-WHO Version for ;2016" [sic], Chapter IV "Endocrine, nutritional and metabolic diseases (E00-E90) Malnutrition (E40-E46)", 3 pages.

V. A response was filed by opponents 1 and 2 (hereinafter: respondents 1 and 2), that of respondent 1 containing

D29: Excerpt from Wikipedia "Overnutrition", 1 page.

VI. In its communication dated 16 August 2017 the board communicated its preliminary opinion to the parties.

VII. With its letter dated 29 November 2017 respondent 2 submitted:

D30: Definition of "malnutrition" from the Cambridge Advanced Learner's Dictionary & Thesaurus, 1 page;

D31: Excerpts from The Free Dictionary, Free Thesaurus.com and Medical dictionary on the term "malnutrition", 14 pages;

D32a: Letter of Mr Rupp, dated 7 April 2017; and

D32b: Excerpt from Oxford Dictionaries on the term "malnutrition".

VIII. With its letter dated 13 December 2017 respondent 1 filed the following documents:

D28a/R1: "International statistical classification of diseases and related health problems", 10th revision, volume 2, 5th edition, 2016, World Health Organization, pages iii to vi and 1, 3 to 5 and 39; and

D28b/R1: Excerpt <http://apps.who.int/classification/icd10/browse/2016/en#/E86>, 1 page.

IX. With its letter dated 19 December 2017 the appellant withdrew auxiliary request 2 filed with the statement of grounds of appeal, renamed auxiliary request 3 filed with the same letter as auxiliary request 2 and filed a new auxiliary request 3 together with:

D28a: Excerpt <http://apps.who.int/classifications/apps/icd/icd10online2003/fr-icd.htm>, 1 page;

D28b: "Official Updates To ICD-10" from the Update Reference Committee of the World Health Organization, 30 November 2001, pages 1 to 7;

D28c: "Official Updates To ICD-10" from the Update Reference Committee of the World Health Organization, 30 November 2002, pages 1 to 7;

D28d: "Official Updates To ICD-10" from the Update Reference Committee of the World Health Organization, 11 February 2004, pages 1 to 11;

D33: "Nutritional Support", from Medline Plus, 5 pages;

D34a: "Guidelines On Artificial Nutrition

Support", 6 pages;

D34b: "Guidelines for Enteral Feeding in Adult Hospital Patients", 1 page;

D35: W. W. Souba, "Nutritional Support", The New England Journal of Medicine, volume 336, number 1, January 1997, pages 41 to 48;

D36: S. Klein et al., "Nutrition Support in Clinical Practice: Review of Published Data and Recommendations for Future Research Directions", Am. J. Clin. Nutr., volume 66, 1997, pages 683 to 706.

X. With its letter dated 9 January 2018 the appellant submitted

D37: The Merck Manual of Diagnosis and Therapy, M. H. Beers et al. (ed.), 17th edition, Merck Research Laboratories, Whitehouse Station N.J. 1999, pages 1 to 21.

XI. With its letter dated 12 January 2018 respondent 1 submitted:

D38: Excerpt from Wikipedia on the term "Food", 11 pages;

D39: L. Valentini et al., e-SPEN Journal, volume 9, 2014, pages e97 to e108;

D40: "Campbell's[®] Souper Soups - Give Your Residents More Than Just A Bowl Of Soup", 4 pages;

D41: EP 2 709 467 B1;

D42: WO 2013/102873 A2; and

D43: WO 2013/068425 A1.

XII. On 23 January 2018, oral proceedings were held before the board.

XIII. Claims 1 and 2 of the main request and auxiliary request 2 are identical to claims 1 and 2 of the main request and auxiliary request 2 before the opposition division (see point III above).

Claims 1 and 2 of auxiliary request 1 read as follows (amendments to the corresponding claims of the main request highlighted by the board):

"1. A liquid oral supplement comprising:

a protein source that provides 14% to 20% of the total caloric content of the product, the protein source consisting of caseinate and a soy protein isolate wherein the caseinate and soy protein isolate are present at a ratio of 75:25 to 50:50;

a fat source providing at least 40% of the caloric content;

a carbohydrate source providing at least 25% of the caloric content; and the product having a caloric density of at least 9.42 kJ per ml (2.25 calories per ml),

which product is for use as a medicament for providing nutritional support to ~~an~~ **an individual**

requiring nutritional support, whereby the individual is selected from:

- (a) a stressed individual;
- (b) a malnourished individual; or
- (c) an elderly individual."

"2. Use of a liquid oral supplement comprising:

a protein source that provides 14% to 20% of the total caloric content of the product, the protein source consisting of caseinate and a soy protein isolate wherein the caseinate and soy protein isolate are present at a ratio of 75:25 to 50:50;

a fat source providing at least 40% of the caloric content;

a carbohydrate source providing at least 25% of the caloric content;

and the product having a caloric density of at least 9.42 kJ per ml (2.25 calories per ml), for the manufacture of a medicament for providing nutritional support to ~~to~~ **an individual requiring nutritional support, whereby the individual is selected from; [sic]**

- (a) a stressed individual;
- (b) a malnourished individual; or
- (c) an elderly individual."

Claims 1 and 2 of auxiliary request 3 read as follows (amendments to the corresponding claims of the main request highlighted by the board):

"1. A liquid oral supplement comprising:

a protein source that provides 14% to 20% of the total caloric content of the product, the protein source consisting of caseinate and a soy protein isolate wherein the caseinate and soy protein isolate are present at a ratio of 75:25 to 50:50;

a fat source providing at least 40% of the caloric content;

a carbohydrate source providing at least 25% of the caloric content; and the product having a caloric density of at least 9.42 kJ per ml (2.25 calories per ml),

which product is for use as a medicament for providing nutritional support to; ~~[sic]~~ **an individual requiring nutritional support, whereby the individual is**

~~(a) a stressed individual;~~

~~(b) a malnourished individual; or~~

~~(c) an elderly individual."~~

"2. Use of a liquid oral supplement comprising:

a protein source that provides 14% to 20% of the total caloric content of the product, the protein source consisting of caseinate and a soy protein isolate wherein the caseinate and soy protein isolate are present at a ratio of 75:25 to 50:50;

a fat source providing at least 40% of the caloric content;

a carbohydrate source providing at least 25% of the caloric content;

and the product having a caloric density of at least 9.42 kJ per ml (2.25 calories per ml), for the manufacture of a medicament for providing nutritional support to; ~~[sic]~~ **an individual requiring nutritional support, whereby the individual is**

- ~~(a) a stressed individual;~~
- ~~(b) a malnourished individual; or~~
- ~~(c) an elderly individual."~~

Claims 1 and 2 of auxiliary request 4 read as follows (amendments to the corresponding claims of the main request highlighted by the board):

"1. A liquid oral supplement comprising:

a protein source that provides 14% to 20% of the total caloric content of the product, the protein source consisting of caseinate and a soy protein isolate wherein the caseinate and soy protein isolate are present at a ratio of 75:25 to 50:50;

a fat source providing at least 40% of the caloric content;

a carbohydrate source providing at least 25% of the caloric content; and the product having a caloric density of at least 9.42 kJ per ml (2.25 calories per ml) **and a sufficiently low viscosity to allow it to be administered by tube feeding,**

which product is for use as a medicament for providing nutritional support to; *[sic]*

- (a) a stressed individual;
- (b) a malnourished individual; or
- (c) an elderly individual."

"2. Use of a liquid oral supplement comprising:

a protein source that provides 14% to 20% of the total caloric content of the product, the protein source consisting of caseinate and a soy protein isolate wherein the caseinate and soy protein isolate are present at a ratio of 75:25 to 50:50;

a fat source providing at least 40% of the caloric content;

a carbohydrate source providing at least 25% of the caloric content;

and the product having a caloric density of at least 9.42 kJ per ml (2.25 calories per ml) **and a sufficiently low viscosity to allow it to be administered by tube feeding**, for the manufacture of a medicament for providing nutritional support to; *[sic]*

- (a) a stressed individual;
- (b) a malnourished individual; or
- (c) an elderly individual."

Claims 1 and 2 of auxiliary request 5 read as follows (amendments to the corresponding claims of the main request highlighted by the board):

"1. A liquid oral supplement comprising:

a protein source that provides ~~14% to 20%~~ **15% to 17%** of the total caloric content of the product, the protein source consisting of caseinate and a soy protein isolate wherein the caseinate and soy protein isolate are present at a ratio of 75:25 to 50:50;

a fat source providing at least 40% of the caloric content;

a carbohydrate source providing at least 25% of the caloric content; and the product having a caloric density of at least 9.42 kJ per ml (2.25 calories per ml),

which product is for use as a medicament for providing nutritional support to; *[sic]*

- (a) a stressed individual;
- (b) a malnourished individual; or
- (c) an elderly individual."

"2. Use of a liquid oral supplement comprising:

a protein source that provides ~~14% to 20%~~ **15 to 17%** of the total caloric content of the product, the protein source consisting of caseinate and a soy protein isolate wherein the caseinate and soy protein isolate are present at a ratio of 75:25 to 50:50;

a fat source providing at least 40% of the caloric content;

a carbohydrate source providing at least 25% of the caloric content;

and the product having a caloric density of at least 9.42 kJ per ml (2.25 calories per ml), for the manufacture of a medicament for providing nutritional support to; *[sic]*

- (a) a stressed individual;
- (b) a malnourished individual; or
- (c) an elderly individual."

XIV. The appellant's arguments which are relevant to the present decision may be summarised as follows:

Main request

D28 and D28a to D28d should be admitted into the proceedings, since D28 was a timely reaction to the opposition division's change of mind during the oral proceedings and D28a to D28d were a timely reaction to respondent 1's argument that D28 had been post-published. Furthermore D33, D34a, D34b and D35 to D37 should be admitted into the proceedings. They were not so complex that respondent 1 did not have enough time to react to them before the oral proceedings.

The application as filed disclosed the provision of nutritional support. The provision of nutritional support implied a therapeutic intervention to provide nutrition to individuals who were not able to feed themselves and so were at risk of or were suffering from malnutrition. Such therapeutic treatment implied that the liquid oral supplement was a medicament. In the context of the application as filed, even just eating ordinary food was a therapeutic treatment, since

it served to treat the clinical condition of malnutrition. If not treated, such a condition would lead to the death of the individual. The argument that providing nutritional support was a therapeutic treatment was supported by D2, D15, D33, D34a, D34b, D35, D36 and D37.

Auxiliary request 1

Auxiliary request 1 should be admitted into the proceedings since it was a timely reaction to the opposition division's change of mind during the oral proceedings as regards the compliance of the main request with Article 123(2) EPC.

Contrary to the respondents' assertion, the feature of an individual requiring nutritional support was clear. The skilled person would have been able to identify such individuals and would have known that they were not people who were just hungry.

The individuals in claims 1 and 2 were now restricted to those requiring nutritional support in order to treat or avoid the undesirable clinical condition of malnutrition. Hence individuals for whom the application as filed did not disclose any therapeutic treatment were no longer covered.

Auxiliary request 2

The opposition division's decision not to admit this request should be set aside. The opposition division should have admitted it, since it was a timely reaction to the opposition division's change of mind during the oral proceedings.

The use as a medicament in claim 1 and the manufacture of a medicament in claim 2 of auxiliary request 2 for providing nutritional support to a malnourished individual were based on the application as filed. As evidenced by D28, malnutrition was a specific entity in the International Statistical Classification of Diseases and Related Health Problems of the World Health Organization. Hence, the treatment of malnourished individuals as disclosed in the application as filed implied therapy and thus use as a medicament.

- XV. The respondents' arguments which are relevant to the present decision may be summarised as follows:

Main request

D28 and D28a to D28d should not be admitted into the proceedings, since D28 was post-published and thus not *prima facie* relevant. Furthermore, D33, D34a, D34b and D35 to D37 should not be admitted into the proceedings, since they were so complex that it had not been possible to properly react to them prior to the oral proceedings. In particular, D37 was an excerpt from a book of several hundred pages, and it would have been necessary to read the entire book, including its chapter 5 referred to on page 10 of D37, to understand what it was saying about providing nutritional support.

Contrary to the appellant's assertion, the disclosure of providing nutritional support in the application as filed did not provide a basis for the use as and manufacture of a medicament in claims 1 and 2 of the main request. As shown by D38 to D43, the provision of nutritional support covered eating ordinary food without any effect extending beyond that obtained with

ordinary food. Applying the appellant's understanding of the provision of nutritional support would mean that feeding a newborn baby with an infant formula was therapeutic, which did not make sense.

Auxiliary request 1

Auxiliary request 1 should not be admitted into the proceedings since it could have been filed before the opposition division and could not overcome the objection under Article 100(c) EPC raised against the main request.

The feature "an individual requiring nutritional support" inserted in claims 1 and 2 of auxiliary request 1 was unclear. Furthermore, it did not change the finding in respect of Article 100(c) EPC made with regard to the main request.

Auxiliary request 2

The opposition division's decision not to admit auxiliary request 2 was non-objectionable and thus should be maintained.

In the same way as for the main request, the provision of nutrition to malnourished individuals as disclosed in the application as filed did not extend beyond ordinary nutrition. Therefore, the ground under Article 100(c) EPC also prejudiced the maintenance of the patent on the basis of this auxiliary request.

Auxiliary requests 3 to 5

In the same way as for the main request and auxiliary requests 1 and 2, the ground under Article 100(c) EPC

also prejudiced the maintenance of the patent on the basis of these auxiliary requests.

XVI. The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for examination of the remaining grounds for opposition (i.e. Article 100(a) and (b) EPC) in respect of the claims of

- either the main request or auxiliary request 1 filed with letter dated 27 April 2016;
- auxiliary request 2 filed as "auxiliary request 3" with letter dated 27 April 2016;
- auxiliary request 3 filed with letter dated 19 December 2017; or
- either of auxiliary requests 4 and 5 filed with letter dated 27 April 2016.

XVII. The respondents requested that the appeal be dismissed.

Respondent 1 furthermore requested that D28, D28a to d, D33, D34a, D34b, D35, D36 and D37 as filed by the appellant not be admitted into the proceedings.

The respondents furthermore requested that

- auxiliary request 1 not be admitted into the proceedings;
- auxiliary request 2 not be admitted into the proceedings, implying that the opposition division's decision not to admit auxiliary request 2 be maintained.

Lastly the respondents requested that, should the board consider the amendments in any of the appellant's claim requests to meet the objections under Article 123(2) EPC as well as the further objections, the case be remitted to the opposition division for discussion of Articles 83, 54 and 56 EPC.

Reasons for the Decision

Main request

1. Admittance of documents
 - 1.1 Respondent 1 requested that D28, D28a to D28d, D33, D34a, D34b, D35, D36 and D37 not be admitted into the proceedings.
 - 1.2 D28 was filed by the appellant with its statement of grounds of appeal. Respondent 1 argued that D28 should not be admitted, since it was post-published and thus not relevant.

In its preliminary opinion the opposition division had stated that the main request was not in breach of Article 123(2) EPC. It was only during the oral proceedings that it changed its mind and rejected the main request for not being based on the application as filed. The appellant filed D28 to address the question of how the skilled person would understand the application as filed. Its filing with the statement of grounds of appeal is a timely reaction to the opposition division's change of mind. The board therefore decided to reject the request not to admit D28 into the proceedings.

1.3 D28a to D28d were submitted by the appellant with its letter dated 19 December 2017. They were filed in order to address the question of when the content of D28 had become public. They are thus a timely response to respondent 1's objection that D28 had been post-published. The board therefore decided to reject the request not to admit D28a to D28d into the proceedings.

1.4 D33, D34a, D34b, D35 and D36 were filed with the appellant's letter dated 19 December 2017. Respondent 1 argued that these documents should not be admitted into the proceedings, since they were rather complex and there had not been enough time before the opposition division to study and react to them.

Respondent 1 did not explain why the documents were so complex that the time remaining until the oral proceedings was not enough to study them. In fact these documents are fairly short and relatively easy to understand. The board therefore decided to reject the request not to admit these documents into the proceedings.

1.5 For D37, the admissibility of which was also contested by respondent 1, the situation is different. It was filed with the appellant's letter dated 9 January 2018, i.e. just two weeks prior to the oral proceedings, to address the question of what was meant by the provision of nutritional support. As acknowledged by the appellant, this document is an excerpt from a book of several hundred pages. In order to see what this book is saying as regards the provision of nutritional support, it is not enough to read only the few pages contained in D37. On the contrary, it would have been necessary to read the book in its entirety, and in particular chapter 5, explicitly referred to on page 10

of D37. Since the short time that remained until the oral proceedings was not enough to do so, the board decided not to admit D37 into the proceedings.

2. Amendments - Article 100(c) EPC

2.1 Claim 1 is directed to a liquid oral supplement for use as a medicament for providing nutritional support to a stressed individual, a malnourished individual or an elderly individual. Claim 2 is directed to the use of a liquid oral supplement for the manufacture of a medicament for providing nutritional support to a stressed individual, a malnourished individual or an elderly individual.

2.2 It was a matter of dispute between the parties whether the use as a medicament in claim 1 and the manufacture of a medicament in claim 2 of the main request were based on the application as filed.

2.3 The appellant acknowledged that the application as filed did not contain any explicit disclosure of the use or manufacture of a medicament. The appellant argued however that this use or manufacture was implicitly disclosed in the application as filed. More specifically, the application as filed disclosed the provision of nutritional support, and this implied a therapeutic intervention to provide nutrition to individuals who were not able to feed themselves and so were at risk of or were suffering from malnutrition. Such therapeutic treatment implied that the liquid oral supplement was a medicament.

2.4 The board acknowledges that the application as filed (e.g. page 2, lines 28 to 30) discloses the provision of nutritional support. The question with regard to

Article 100(c) EPC is therefore whether the skilled person using his common general knowledge would directly and unambiguously derive from the application as filed that this provision of nutritional support is a therapeutic treatment.

- 2.4.1 According to the Wikipedia excerpt D38, providing nutritional support merely means the consumption of food. According to the scientific article D39, which tries to give suggestions for terminology in the field of clinical nutrition (title), nutritional support is the provision of nutrition or nutrients either orally (regular diet, therapeutic diet, fortified food, oral nutritional supplements) or via enteral nutrition or parenteral nutrition to prevent or treat disease-related malnutrition (point 1.8 on page e100). Furthermore, D40 discloses soups for elderly individuals as nutritional support, defines the goal of nutritional support as nutritional repletion and improved quality of life and refers in this context to the process of eating as fulfilling a physiological and psychological need (second page of D40).

In view of the above, the provision of nutritional support at the very least covers ordinary nutrition.

This understanding in fact has been applied by the appellant itself in its patent D41 and patent applications D42 and D43. In paragraph [0003] of D41, it states that the goal of nutritional support is to provide nutritional products that can very efficiently provide individuals with a delicious, healthy and nutritious bite-sized snack, while at the same time providing a snack product that is easy to consume. In paragraph [0004] of D42, it states that one goal of nutritional support is to provide athletes with

appropriate nutritional compositions that meet their nutritional requirements for high-intensity workouts without causing negative side-effects or loss of active compounds. And on page 5, lines 12 to 13, of D43, providing nutritional support is mentioned in the context of the consumption of nutrients from food ingredients of natural origin.

- 2.4.2 The board acknowledges that ordinary nutrition is needed for nutritional repletion and thereby for maintaining the body's principal functions and that without eating one dies of starvation. The board is however convinced that this effect, which is intrinsically linked with eating, is not necessarily a therapeutic one. Otherwise every mother feeding her newborn baby with an infant formula would be carrying out a therapeutic step, which in the board's view would take the definition of therapeutic treatment too far. In the same way, the provision of nutritional support to malnourished individuals is not necessarily a therapeutic treatment, since it may merely include the normal process of eating in order to fulfill the individual's physiological and psychological needs.
- 2.4.3 This is not changed by D2, D15, D28, D34a, D34b, D35 and D36, referred to by the appellant. More specifically, none of these documents discloses any effect obtained by the provision of nutritional support that extends beyond that obtained by ordinary nutrition. Furthermore, D15, D34a, D34b, D35 and D36 do not refer to the provision of nutritional support as disclosed in the application as filed (D34a: artificial nutritional support; D15 and D34b: enteral nutrition; D35: feeding via the enteral or intravenous route; D36: feeding via the enteral, intravenous and parenteral route). These documents thus have no

relevance to what the skilled person would understand by the provision of nutritional support.

2.4.4 Therefore, the provision of nutritional support as disclosed in the application as filed includes ordinary nutrition, which is not a therapeutic treatment.

2.4.5 The board is aware in this respect that according to D33 providing nutritional support "is therapy for people who cannot get enough nourishment by eating and drinking" and that the nutritional support is provided through a needle or catheter placed in a patient's vein or a feeding tube which goes into the stomach. D33 is however in contradiction with e.g. D38 to D40, which, as set out above, define the provision of nutritional support simply as the provision of food (D38), a regular diet (D39) or soups (D40). So, at the very least there is no commonly accepted understanding that the provision of nutritional support as disclosed in the application as filed is a therapeutic treatment.

2.5 In view of the above, the skilled person, even taking his common general knowledge into account, would not directly and unambiguously derive from the application as filed that the provision of nutritional support disclosed therein was a therapeutic treatment. Consequently, the use as and manufacture of a medicament in claims 1 and 2 are not based on the application as filed. The ground under Article 100(c) EPC thus prejudices the maintenance of the patent in the form of the main request.

Auxiliary request 1

3. Admissibility

Both respondents requested that auxiliary request 1 not be admitted into the proceedings. The filing of auxiliary request 1 can be considered a timely reaction to the opposition division's change of mind during the oral proceedings (see point 1.2 above). Therefore, the board decided to admit auxiliary request 1 into the proceedings.

4. Amendments - Article 100(c) EPC

4.1 Auxiliary request 1 differs from the main request in that in claims 1 and 2 the individuals are defined as requiring nutritional support. As set out above in point 2.4.2 for the main request, even for individuals requiring nutritional support, such as newborn babies, the application as filed does not disclose anything which goes beyond ordinary nutrition. Therefore, for the same reasons as given above with regard to the main request, claims 1 and 2 of auxiliary request 1 are not based on the application as filed. Thus the ground under Article 100(c) EPC also prejudices the maintenance of the patent in the form of auxiliary request 1.

Auxiliary request 2

5. Admissibility

The opposition division decided not to admit this request ("auxiliary request 2" before the opposition division). The respondents requested that this decision be maintained.

The opposition division did not admit auxiliary request 2 since it was not *prima facie* allowable. The board acknowledges that *prima facie* allowability is normally the correct criterion to be applied when deciding on admittance of a late-filed claim request. However, in the present case the opposition division should have taken into account its change of mind during the oral proceedings (see point 1.2 above) and should have admitted the then auxiliary request 2, since it was a reaction thereto.

The board therefore decided to set aside the opposition division's decision as regards admittance of auxiliary request 2 and admitted this auxiliary request into the proceedings.

6. Amendments - Article 100(c) EPC

6.1 Claims 1 and 2 of auxiliary request 2 differ from claims 1 and 2 of the main request in that the two alternatives of a stressed and an elderly individual have been deleted. The individual is thus restricted to a malnourished individual.

As set out above in point 2.4.2 for the main request, even for malnourished individuals the application as filed does not disclose any therapeutic treatment. Therefore, for the same reasons as given above with regard to claims 1 and 2 of the main request, claims 1 and 2 of auxiliary request 2 are not based on the application as filed. Thus the ground under Article 100(c) EPC also prejudices the maintenance of the patent in the form of auxiliary request 2.

Auxiliary request 3

Auxiliary request 3 is a combination of auxiliary requests 1 and 2. As not disputed by the appellant during the oral proceedings, the board's finding with regard to auxiliary requests 1 and 2 equally applies to auxiliary request 3. Thus the ground under Article 100(c) EPC also prejudices the maintenance of the patent in the form of auxiliary request 3.

Auxiliary requests 4 and 5

7. Claims 1 and 2 of auxiliary request 4 differ from claims 1 and 2 of the main request in that the product defined in these claims must have a "sufficiently low viscosity to allow it to be administered by tube feeding".

Claims 1 and 2 of auxiliary request 5 differ from claims 1 and 2 of the main request by a more restricted range for the amount of protein source.

The appellant itself acknowledged that these auxiliary requests had only been filed to meet potential objections with regard to inventive step and that they did not overcome the objection under Article 100(c) EPC raised against the main request. Accordingly, the ground under Article 100(c) EPC also prejudices the maintenance of the patent in the form of auxiliary requests 4 and 5.

Request for remittal

In view of the above finding that none of the appellant's claim requests is allowable, the board did

not need to decide on the request for remitting the case to the opposition division.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



I. Aperribay

W. Sieber

Decision electronically authenticated