

Internal distribution code:

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

**Datasheet for the decision
of 17 June 2019**

Case Number: T 0235/15 - 3.3.01

Application Number: 07821451.7

Publication Number: 2081597

IPC: A61K45/06, A23L1/29, A61P3/02,
A23L1/303, A23L1/304, A23L1/305

Language of the proceedings: EN

Title of invention:
LONG-TERM ENTERAL FEED FOR MAINTENANCE

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponent:
Fresenius Kabi Deutschland GmbH

Headword:
Tube feeding/NESTLÉ

Relevant legal provisions:
EPC Art. 53(c), 112(1)(a)
RPBA Art. 13(1)

Keyword:

Main request, auxiliary requests 1 to 7 - Method for treatment
by therapy - (yes)

Referral to the Enlarged Board of Appeal - (no)

Auxiliary request 8 - admitted (no)

Decisions cited:

G 0001/07, T 1599/09



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 0235/15 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 17 June 2019

Appellant: Société des Produits Nestlé S.A.
(Patent Proprietor) Entre-deux-Villes
1800 Vevey (CH)

Representative: Rupp, Christian
Mitscherlich PartmbB
Patent- und Rechtsanwälte
Postfach 33 06 09
80066 München (DE)

Respondent: Fresenius Kabi Deutschland GmbH
(Opponent) Else-Kröner-Strasse 1
61352 Bad Homburg (DE)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 5 December 2014
revoking European patent No. 2081597 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman A. Lindner
Members: J. Molina de Alba
L. Bühler

Summary of Facts and Submissions

I. European patent No. 2 081 597, based on European patent application No. 07 821 451.7, was granted with ten claims. Claim 1 as granted reads as follows:

"1. A method for providing long-term tube-fed nutrition to an adult patient under the age of sixty-five who cannot receive nutrition through a normal diet but who is normometabolic comprising the steps of:

providing to the patient, at least once a day, for a long term, an enteral nutrition product through a tube comprising per 100 kcal of product:

a source of protein;
a source of carbohydrates;
a source of lipids;
sodium 100 to 200 mg;
potassium 25 to 250 mg;
calcium above 50 mg;
phosphorus less than 150 mg;
magnesium at least 15 mg;
chloride at least 100 mg;
iron 0.4 to 1.5 mg;
zinc 0.4 to 2.0 mg;
copper 0.08 to 0.4 mg;
fluoride 0 to 0.15 mg;
chromium 2.0 to 10.0 micrograms;
molybdenum 2.0 to 14.0 micrograms;
selenium 3.0 to 9.0 micrograms;
manganese 0.1 to 0.4 mg;
iodine 7.0 to 15.0 micrograms;
Vit A 100 to 500 IU;
Vit D 0.5 to 2.5 micrograms;

Vit E 1.5 to 4.0 mg;
Vit K greater than 4.0 micrograms;
Vit C greater than 4.0 mg;
Vit B1 greater than 0.06 mg;
Vit B2 greater than 0.07 mg;
Vit B3 0.7 to 3.5 mg;
Vit B5 0.2 to 2.0 mg;
Vit B6 0.1 to 0.7 mg;
Vit B8 at least 1.0 micrograms;
Vit B9 at least 12.0 micrograms;
Vit B12 0.1 to 1.0 micrograms;
at least 30 mg of choline;
at least 4.0 mg of taurine; and
at least 3.0 mg of carnitine."

II. The present appeal lies from the decision of the opposition division revoking the patent. The decision was based on the claims of one main request and five auxiliary requests.

In the decision, the opposition division concluded that the methods in claim 1 of each of the requests then on file were excluded from patentability under Article 53(c) EPC because they were methods for treatment of the human body by therapy.

III. The patent proprietor (appellant) lodged an appeal against this decision. With the statement of grounds of appeal, the appellant filed six claim sets, as main request and auxiliary requests 1 to 5; they were identical to the main request and auxiliary requests 1 to 5 on which the appealed decision was based. Auxiliary request 5 was subsequently replaced (see appellant's letter dated 22 March 2016).

Claim 1 of the main request is identical to claim 1 as granted.

Claim 1 of auxiliary request 1 differs from claim 1 as granted in that the enteral nutrition product additionally comprises at least one of tomato lycopene and spinach lutein.

Claim 1 of auxiliary request 2 differs from claim 1 as granted in that it specifies that the source of protein provides 10 to 18% by caloric content of the product.

Claim 1 of auxiliary request 3 differs from claim 1 as granted in that the enteral nutrition product additionally comprises tomato lycopene.

Claim 1 of auxiliary request 4 differs from claim 1 as granted in that the enteral nutrition product additionally comprises at least one of tomato lycopene and carrot β -carotene.

In addition, the appellant requested that questions be referred to the Enlarged Board of Appeal (see point X below).

IV. With a letter dated 22 March 2016, the appellant filed further claim sets as auxiliary requests 5 to 8.

Claim 1 of auxiliary request 5 differs from claim 1 as granted in that the enteral nutrition product additionally comprises:

- at least 0.2 mg of lycopene;
- at least 0.1 mg of beta-carotene; and
- at least 10 g/l of a source of dietary fiber;

and in that it is characterised by the following features:

- the source of protein provides 10 to 18% by caloric content of the product;
- the source of carbohydrate provides 40 to 65% by caloric content of the product; and
- the source of lipids provides 25 to 40% by caloric content of the product.

Claim 1 of auxiliary request 6 differs from claim 1 as granted in that the normometabolic patient is specified to be a normometabolic healthy patient.

Claim 1 of auxiliary request 7 differs from claim 1 as granted in that the tube through which the enteral nutrition product is provided is specified to be a nasogastric feed tube.

Claim 1 of auxiliary request 8 differs from claim 1 as granted in that it has been reformulated as a purpose-related product claim by amending its first clause in the following way:

"An enteral nutrition product for use in the treatment of method for providing long-term tube-fed malnutrition ~~to~~in an adult patient..."

- V. The opponent (respondent) replied to the statement of grounds of appeal and to the appellant's letter of 22 March 2016 with letters dated 14 July 2015 and 15 April 2016, respectively.
- VI. In its preliminary opinion dated 21 February 2019, the board considered, *inter alia*, that the method in claim 1 of each of the main request and auxiliary requests 1 to 7 was therapeutic. The board also noted that it was minded not to admit auxiliary request 8.

VII. Oral proceedings were held before the board on 17 June 2019.

VIII. The appellant's arguments, where relevant to the present decision, may be summarised as follows:

The method of claim 1 of the main request is not therapeutic because it involves only the provision of a nutrition product to a healthy (normometabolic) patient; the claim does not mention any specific disease, disorder or pathological condition, and the nutrition product does not produce any effect going beyond that of regular food. There is no link between the provision of the nutrition product of claim 1 and the disease at the origin of the patient's incapacity to receive nutrition through a normal diet.

In particular, the nutrition product of claim 1 does not produce any pharmacological effect: the patient's inability to eat is not reversed or ameliorated by its provision. The only effect that might possibly be assigned to the nutrition product is the prevention of malnutrition. However, this cannot be seen as a method of treatment by therapy since malnutrition is neither a symptom nor a pathological condition. Otherwise, the normal eating of food or drinking of beverages should be also considered as being therapeutic.

The conclusions of the decision T 1599/09 in relation to Article 53(c) EPC are not applicable to the method of claim 1 since the case underlying T 1599/09 does not relate to the provision of a nutrition product but to the operation of a feeding pump and, unlike the present case, it includes the administration of therapeutic agents.

The same reasoning is valid for the methods in claim 1 of each of auxiliary requests 1 to 7.

The board is requested to refer the questions posed by the appellant to the Enlarged Board of Appeal, to decide on a point of law of general interest on which there is diverging case law. Particularly, decision T 1599/09 does not entirely follow G 1/07.

Regarding auxiliary request 8, it should be admitted into the proceedings as an attempt to address the objection in the appealed decision that the claimed method is therapeutic because it covers the treatment of malnutrition. Contrary to the respondent's opinion, the reformulation of claim 1 from a method claim to a purpose-related product claim does not open a new case; the product claim complies with Article 123(3) EPC because Article 64(2) EPC establishes that the protection conferred by a process claim extends to the products directly obtained by that process.

IX. The respondent's arguments, where relevant to the present decision, may be summarised as follows:

The method in claim 1 of the main request is therapeutic. A patient who cannot eat normally, and is therefore dependent on the administration of nutrition artificially, has a medical condition; the fact that the patient is normometabolic does not change this circumstance. Such a patient has only two options to receive nutrition: either by intravenous administration of nutrients or, as in the present case, tube feeding. If nutrients are not provided by either of these ways, the patient ends up dying of starvation. Hence, the method of claim 1 is necessarily therapeutic because it involves the use of a tube as an essential element to

overcome or alleviate the patient's incapacity to eat normally, which would otherwise lead to the patient's death.

For the same reasons, the methods in claim 1 of each of auxiliary requests 1 to 7 are also therapeutic.

The board should not refer questions to the Enlarged Board of Appeal because there is no divergent case law in relation to the therapeutic character of tube feeding. In particular, decision T 1599/09 confirms that tube feeding is therapeutic (see pages 10/11).

Auxiliary request 8 should not be admitted because it has been filed late in the appeal proceedings in order to overcome an objection under Article 53(c) EPC that was already present in the notice of opposition (see point 5.1) and which has not changed during the whole opposition and appeal proceedings. Furthermore, the subject-matter of claim 1 of auxiliary request 8 extends the protection conferred by the claims as granted within the meaning of Article 123(3) EPC.

X. The final requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of any of the claim sets filed with the statement of grounds of appeal as main request and auxiliary requests 1 to 4.

Alternatively, the appellant requested that the claim sets filed with the letter dated 22 March 2016 as auxiliary requests 5 to 8 be admitted into the appeal proceedings and that the patent be maintained on the basis of any of these claim sets.

Alternatively, the appellant requested that the case be remitted to the opposition division, should the board decide that the claims of any of the requests on file comply with Article 53(c) EPC.

In addition, the appellant requested that the following questions be referred to the Enlarged Board of Appeal:

"(i) Does the term `therapy` cover any treatment of a symptom in terms of a perceptible body reaction, even if this symptom is not caused by or associated with a specific disease?

(ii) If the enlarged Board of Appeal answers Question 1 to the affirmative, is then malnutrition as a consequence of not eating considered a symptom of a disease or disorder?

(iii) If the enlarged Board of Appeal also answers Question 2 to the affirmative, is then every kind of provision of nutrition considered therapeutic?"

The respondent requested that the appeal be dismissed and that the appellant's request to refer questions to the Enlarged Board of Appeal be rejected.

It further requested that auxiliary requests 5 to 8 filed with the letter dated 22 March 2016 not be admitted into the appeal proceedings.

Reasons for the Decision

1. Exceptions to patentability - Article 53(c) EPC
- 1.1 Main request

Claim 1 of the main request is directed to a method of tube feeding an adult normometabolic patient under the age of sixty-five who cannot receive nutrition through a normal diet. Thus, although the patients treated according to the method of claim 1 are explicitly defined as not having any metabolic diseases, it is clear that they suffer from a serious condition, namely that they cannot receive nutrition through a normal diet. If this condition were not overcome or at least alleviated, it would inevitably lead to the patient's death. In consequence, the fact that the patient has no metabolic diseases or that the method does not involve the administration of a medicament is not sufficient to say that the method of claim 1 is non-therapeutic; the patient suffers from a serious condition that needs to be treated in order to prevent fatal consequences.

As noted by the respondent, the patient may be treated in two possible ways, either by tube feeding or by intravenous provision of nutrients. However, independently of the method used, the artificial administration of nutrition to patients who are unable to eat normally has to be seen as therapeutic since, in its absence, the patient would inevitably die of starvation.

In this context, contrary to the appellant's view, tube feeding cannot be equated with normal eating since it is not a natural way of providing nutrition and the subject who receives it is a patient with a serious condition. Particularly relevant is the fact that tube feeding requires the use of a tube as an essential element for overcoming the patient's incapacity to eat normally. It is precisely the use of this tube which allows the administration of nutrition and which prevents the patient's death by starvation. Consequently, the method of claim 1 is a method for treatment of the human body by therapy and is therefore excluded from patentability by Article 53(c) EPC.

1.2 Auxiliary requests 1 to 4

As conceded by the appellant at the oral proceedings before the board, the amendments included in auxiliary requests 1 to 4 are not directed to addressing the objection that the claimed methods are therapeutic.

Claim 1 of auxiliary request 2 is identical to claim 1 of the main request, and claim 1 of each of auxiliary requests 1, 3 and 4 contains only restrictions with regard to the composition of the enteral nutrition product. Thus, the circumstance that the patient has an incapacity to eat and that this is overcome by the use of a tube which facilitates the administration of nutrition remains in the methods of claim 1 of each of auxiliary requests 1 to 4. Hence, those methods are also therapeutic within the meaning of Article 53(c) EPC.

1.3 Auxiliary requests 5 to 7

Without prejudice of the issue of their admission, the methods in claim 1 of each of auxiliary requests 5 to 7 are excluded by Article 53(c) EPC for the same reasons as the method of claim 1 of the main request:

Claim 1 of auxiliary request 5 differs from the main request in that the enteral nutrition product used in the claimed method of tube feeding is more restricted. As in the case of auxiliary requests 1, 3 and 4, this does not change the situation with regard to the method of treatment by therapy.

Claim 1 of auxiliary request 6 specifies that the patient who cannot receive nutrition through a normal diet is healthy. Considering that the patient still has an incapacity to receive nutrition through a normal diet and that this is overcome by tube feeding, the method of auxiliary request 6 is also therapeutic.

Claim 1 of auxiliary request 7 specifies that the tube is a nasogastric feed tube. This situation is identical to that of claim 1 of the main request since the nasogastric tube is the essential element that overcomes the patient's inability to eat.

2. Admission of auxiliary requests 5 to 7 - Article 13(1) RPBA

For the sake of completeness, the board notes that these requests were admitted during the oral proceedings of 17 June 2019 because they were filed to address objections of lack of clarity, added subject-matter and exclusion of a method of treatment by

surgery raised by the respondent in its reply to the statement of grounds of appeal.

Taking into consideration that the methods in claim 1 of each of auxiliary requests 5 to 7 are considered to be therapeutic (see point 1.3), the board sees no need to further specify the reasons for their admission.

3. Referral of questions to the Enlarged Board of Appeal

The appellant requested that the board refer the questions it posed with the statement of grounds of appeal to the Enlarged Board of Appeal, in order to give an answer to an important point of law on which there is diverging case law, namely whether or not the treatment of a symptom which is not caused by or associated with a specific disease may be therapeutic, particularly in the context of the treatment of malnutrition as a consequence of not eating.

The board does not, however, see any need to refer the posed questions to the Enlarged Board of Appeal, since the appellant has not proved that there is indeed diverging case law on whether the alleviation of symptoms is considered to be therapeutic, especially in the case of tube feeding to alleviate a patient's inability to receive nutrition through a normal diet. In fact, the board's judgement in the present decision is in line with the main decision discussed during the present appeal proceedings, namely T 1599/09. In case T 1599/09, the board considered enteral feeding (i.e. tube feeding) to be therapeutic. This is apparent from the passage bridging pages 10 and 11 of the decision, where the board stated:

"Enteral feeding is used to provide nutrition to patients who cannot obtain nutrition by mouth or are unable to swallow safely. Such patients are suffering from an incapacity or disease. Even though enteral feeding does not cure the underlying cause, it clearly alleviates and lessens the symptoms thereof".

And then concluded that:

"Accordingly, enteral feeding is considered to fall under the meaning of the term 'therapy'."

Whether or not the enteral feeding according to T 1599/09 also includes administration of a therapeutically active agent, as pointed out by the appellant (see point VIII above), is irrelevant in the light of this finding.

The appellant also argued that decision T 1599/09 does not entirely follow G 1/07. This argument is not convincing because G 1/07 is concerned with the exclusion of methods of treatment not by therapy but by surgery. Any possible discrepancy between T 1599/09 and G 1/07 on aspects related to the exclusion of methods of treatment by surgery has no bearing on the reasons of the present decision and does not need to be clarified in the present proceedings.

The appellant has not cited any decision in which providing nutrition artificially to a patient who cannot receive nutrition by a normal diet would be considered as not being therapeutic.

Hence, the conditions required by Article 112(1)(a) EPC for referring questions to the Enlarged Board of Appeal, namely that a decision is needed to ensure

uniform application of the law, or a point of law of fundamental importance arises, are not fulfilled, and consequently the appellant's request is rejected.

4. Admission of auxiliary request 8 - Article 13(1) RPBA

The appellant filed auxiliary request 8 more than one year after the statement of grounds of appeal. The admission of the request into the appeal proceedings is hence at the board's discretion, taking into account, *inter alia*, the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy (Article 13(1) RPBA).

The filing of auxiliary request 8 was an attempt by the appellant to overcome the objection that the method of claim 1 of the previous requests was considered to be therapeutic. This objection had been raised in the notice of opposition (point 5.1), and had been accepted by the opposition division in the appealed decision (point 21). Thus, auxiliary request 8 could and should have been filed earlier. Moreover, claim 1 of auxiliary request 8 introduces a change of category with respect to all previous requests on file, from a method claim to a purpose-related product claim. This change of category represents an amendment of the appellant's case at a late stage in the proceedings and *prima facie* extends the protection conferred by the patent, contrary to Article 123(3) EPC. Taking these facts into consideration, the board decided not to admit auxiliary request 8 into the appeal proceedings.

Regarding the appellant's argument, that the reformulation of claim 1 does not contravene Article 123(3) EPC because claim 1 as granted encompassed the nutrition product by virtue of

Article 64(2) EPC, the board notes that the method defined in claim 1 as granted is not a method of preparation of the nutrition product, so Article 64(2) EPC does not apply. Hence, contrary to claim 1 of auxiliary request 8, claim 1 as granted did not provide any protection for the nutrition product.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated