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**Datasheet for the decision  
of 16 March 2022**

**Case Number:** T 0014/19 - 3.3.09

**Application Number:** 08869051.6

**Publication Number:** 2242382

**IPC:** A23L33/00, A23C21/06

**Language of the proceedings:** EN

**Title of invention:**  
STABLE NUTRITIONAL POWDER

**Patent Proprietor:**  
ABBOTT LABORATORIES

**Opponent:**  
Société des Produits Nestlé S.A.

**Headword:**  
Stable nutritional powder/ABBOTT

**Relevant legal provisions:**  
EPC Art. 123(2)

**Keyword:**  
Amendments - extension beyond the content of the application  
as filed (yes)

**Decisions cited:**

T 0612/09, T 0002/81

**Catchword:**



**Beschwerdekammern**

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**Chambres de recours**

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Case Number: T 0014/19 - 3.3.09

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.09**  
**of 16 March 2022**

**Appellant:** Société des Produits Nestlé S.A.  
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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
29 November 2018 concerning maintenance of the  
European Patent No. 2242382 in amended form.**

**Composition of the Board:**

**Chairman** A. Veronese  
**Members:** M. Ansorge  
F. Blumer

## Summary of Facts and Submissions

- I. The opponent (appellant) lodged an appeal against the opposition division's interlocutory decision holding the main request allowable.
- II. With its notice of opposition, the opponent had requested that the patent be revoked *inter alia* on the ground for opposition under Article 100(c) EPC.
- III. The opposition division decided that the main request was allowable, in particular that claim 1 complied with the requirements of Article 123(2) EPC.
- IV. Claim 1 of the main request reads as follows:  
  
"A composition comprising  
(a) carbohydrate;  
(b) lipid, comprising from 0.25% to 2.5% lecithin by weight of total lipid;  
(c) from 90% to 97% of intact protein by weight of total protein; and  
(d) from 3% to 10% of hydrolyzed whey protein by weight of total protein;  
wherein the hydrolyzed whey protein has a degree of hydrolysis of between 23% and 90%, and wherein the composition is a nutritional powder."
- V. In its statement setting out the grounds of appeal the appellant contested *inter alia* the opposition division's finding that claim 1 complies with the requirements of Article 123(2) EPC.
- VI. With its reply to the statement setting out the grounds of appeal the proprietor (respondent) filed a main

request and auxiliary requests 1 to 3. The main request corresponds to the main request considered allowable by the opposition division.

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the term "nutritional powder" is changed to "infant formula nutritional powder" and in that the feature "and wherein the composition comprises per 100 kcal from 3 to 8 grams of the lipid, from 1 to 6 grams of the protein, and from 8 to 16 grams of the carbohydrate" is added at the end of the claim.

Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the term "nutritional powder" is changed to "infant formula nutritional powder" and in that the feature "and wherein the composition comprises per 100 kcal from 4 to 6.6 grams of the lipid, from 1.5 to 3.4 grams of the protein, and from 9 to 13 grams of the carbohydrate" is added at the end of the claim.

Claim 1 of auxiliary request 3 differs from claim 1 of the main request in that the term "nutritional powder" is changed to "infant formula nutritional powder" and in that the range "90% to 97%" is amended to "95% to 97%" and the range "3% to 10%" is amended to "3% to 5%".

- VII. The board summoned the parties to oral proceedings and issued a communication pursuant to Article 15(1) RPBA.
- VIII. Oral proceedings took place before the board. A decision was announced at the end of the oral proceedings.

IX. The parties' relevant arguments, submitted in writing and during the oral proceedings, are reflected in the reasons for the decision below.

X. Requests

The appellant requested that the decision be set aside and that the patent be revoked.

The respondent requested that the appeal be dismissed (main request), or alternatively that the patent be maintained on the basis of one of auxiliary requests 1 to 3, all filed with the reply to the statement of grounds of appeal.

## Reasons for the Decision

### MAIN REQUEST

1. Article 123(2) EPC

1.1 Claim 1 of the main request differs from claim 1 of the application as filed as follows (deletions are indicated by striking-through and additions are indicated in bold):

"A composition comprising

(a) carbohydrate;

(b) lipid, comprising from ~~about~~ 0.25% to ~~about~~ 2.5% lecithin by weight of total lipid;

(c) from ~~about~~ 90% to ~~about~~ 99.5% **97%** of intact protein by weight of total protein; and

(d) from ~~about~~ 0.5% **3%** to ~~about~~ 10% of ~~at least one hydrolyzed protein selected from the group consisting~~

~~of hydrolyzed casein protein and hydrolyzed whey protein,~~ by weight of total protein;  
wherein the hydrolyzed **whey** protein has a degree of hydrolysis of between ~~about~~ 23% and ~~about~~ 90%, and wherein the composition is a nutritional powder."

1.2 The appellant argued that the combination of the newly-created sub-ranges in features (c) and (d) with the selection of hydrolyzed whey protein was not directly and unambiguously disclosed in the application as filed. The ranges in features (c) and (d) defined a combination of values selected arbitrarily from among a large number of uncorrelated values disclosed in the application as filed. Therefore the subject-matter of claim 1 did not comply with the requirements of Article 123(2) EPC.

1.3 The respondent countered that the requirements of Article 123(2) EPC were met. The two sub-ranges "90% to 97%" and "3% to 10%" defining the intact protein and the hydrolyzed whey protein, respectively, were derived from the application as filed, applying the principles established in T 612/09. Furthermore, it was clear from the third paragraph of page 5 and from the last paragraph of page 7 of the application as filed that the drafter's intention was to create a specific relationship between the relative proportion of "intact protein" and "hydrolyzed whey protein" included in the composition: the amount of intact protein and hydrolyzed whey protein had to add up to 100%. This teaching characterised the application as filed. Claim 1 was drafted in accordance with this teaching, because the numerical ranges in features (c) and (d) matched up with each other and added up to 100%. The skilled person would understand that, if the upper limit of the range in (c) was lowered to 97%, the lower

limit of the range in (d) had to be raised to 3%. It was also clear from claim 1 that intact protein and hydrolyzed whey protein mentioned in (c) and (d) were the only proteinaceous ingredients present in the composition. Thus claim 1 did not contain added subject-matter.

1.4 The board does not agree with the respondent. Claim 1 of the main request contains the following three relevant amendments:

- the limitation of the range "90% to 99.5%" to the sub-range "90% to 97%" in feature (c) (first amendment);
- the limitation of the range "0.5% to 10%" to the sub-range "3% to 10%" in feature (d) (second amendment); and
- the selection of hydrolyzed whey protein in feature (d): put differently, the deletion of "at least one hydrolyzed protein selected from the group consisting of hydrolyzed casein protein and" in claim 1 of the application as filed (third amendment).

1.5 First amendment

Page 7, lines 1 to 3 from the bottom of the application as filed discloses a first, broadest, range "90% to 99.5%" (corresponding to feature (c) of claim 1 of the application as filed), a second range "95% to 99.5%" lying within the first range and a third range "97% to 99.2%" lying within the second range. The new sub-range "90% to 97%" of claim 1 of the main request was created by combining the lower limit "90%"



of the first range "**90%** to 99.5%" with the lower limit "97%" of the third range "**97%** to 99.2%".

For the following reasons, this amendment, in isolation, is not objectionable, because it is in line with the findings of earlier case law in which newly-created sub-ranges were created in an analogous manner, see e.g. T 612/09, point 13 of the reasons.

In case T 612/09, point 13 of the reasons, the deciding board ruled as follows (emphasis added):

*"However, the board agrees with the appellant that only the first step of the analysis carried out in decision T 2/81, supra, (see point 11 above) is necessary to arrive directly and unambiguously at the range of **3 to 10** mg/kg of daptomycin. In the present case, claim 49 as filed discloses the use of daptomycin for the manufacture of a medicament for treating a bacterial infection in a patient in need thereof, wherein a dose for such use is **3 to 75** mg/kg of daptomycin at a dosage interval of once every 24 hours. According to dependent claim 52 as filed the dose is **10 to 25** mg/kg. Applying the principles of decision T 2/81, supra, to the present case, the two part-ranges lying within the overall range on either side of the narrower range and hence also directly and unambiguously disclosed to the person skilled in the art are i) a dose of **3 to 10** mg/kg of daptomycin and ii) a dose of 25 to 75 mg/kg of daptomycin. Claim 49 in combination with claim 52 as filed thus disclose the following four ranges of daptomycin doses - 3 to 75 mg/kg, 10 to 25 mg/kg, **3 to 10** mg/kg and 25 to 75 mg/kg - at a dosage interval of once every 24 hours for treating a bacterial infection in a patient in need thereof."*

When transferring this latter ruling in T 612/09 to the present case, there is direct and unambiguous disclosure in the application as filed for the new sub-range "90% to 97%" of claim 1, which is created by combining the lower limit "90%" of the first, broad, range "**90%** to 99.5%" with the lower limit "97%" of the third, narrower, range "**97%** to 99.2%" (in analogy to the broad range "**3** to 75 mg/kg" and the narrower range "**10** to 25 mg/kg" in T 612/09, which *inter alia* disclosed the sub-range "3 to 10 mg/kg").

The crucial question is whether the application as filed directly and unambiguously discloses the combination of this first amendment with the aforementioned second and third amendments, and whether there is a pointer towards this combination.

#### 1.6 Second and third amendments

1.6.1 The range "0.5% to 10%" in feature (d) of claim 1 as filed, which defines the amount of hydrolyzed protein, was amended to "3% to 10%". Furthermore, the definition of the hydrolyzed protein, originally selected from the group consisting of hydrolyzed casein protein and hydrolyzed whey protein, was limited to hydrolyzed whey protein.

1.6.2 In the respondent's view, page 5, lines 13 to 17 of the application as filed provided a basis for the sub-range "3% to 10%". This sub-range resulted from a combination of an upper limit of a specifically-disclosed narrower range with an upper limit of a broader range, the narrower range lying completely within the broader range, which is to be considered as

being disclosed in the application as filed, as in T 612/09.

- 1.6.3 Furthermore, the sub-range "3% to 10%" matched up with the sub-range "90% to 97%" to add up to 100%. This was in line with the teaching of the application as filed. No new subject-matter was created by combining these ranges because, once the first sub-range was selected, the second one was automatically determined so that their values added up to 100%.
- 1.6.4 The respondent argued that according to the application as filed this principle also applied when selecting hydrolyzed whey protein. Although claim 1 had an open language (comprising), the intact protein and hydrolyzed whey protein mentioned in (c) and (d) were the only proteinaceous ingredients present in the composition. The presence of hydrolyzed casein protein, possible according to claim 1 of the application as filed, was excluded by claim 1 of the main request. This claim having been drafted to comply with the aforementioned principle, it did not contain added subject-matter.
- 1.7 For the following reasons, the board does not agree with the respondent:
  - 1.7.1 Page 5, lines 13 to 17 of the application as filed discloses that the composition may comprise from 0.5% to 10% of at least one hydrolyzed protein selected from the group consisting of hydrolyzed casein protein and hydrolyzed whey protein, by weight of total protein, including from 0.5% to 5% and also from 0.8% to 3% by weight of total protein.

- 1.7.2 However, this passage on page 5, alone or combined with that on page 7, does not directly and unambiguously teach that the ranges defining the amount of intact protein of feature (c) and of hydrolyzed whey protein of feature (d) must match up to give 100% of the total protein.
- 1.7.3 Furthermore, for the respondent's line of argumentation directed to the matching-up of the newly created sub-ranges in features (c) and (d) of claim 1 to be convincing, it would be necessary for claim 1 of the main request to exclude any proteinaceous ingredients other than intact protein and hydrolyzed whey protein. This is not the case. The composition of claim 1 of the main request is defined in an open manner, as comprising *inter alia* intact protein and a specific hydrolyzed protein, namely hydrolyzed whey protein. Hydrolyzed proteins other than hydrolyzed whey protein are not excluded by this claim and may also be present. Thus the sum of intact protein and hydrolyzed whey protein does not necessarily add up to 100%. Claim 1 of the main request merely requires intact protein and hydrolyzed whey protein to be present in the given ranges, but does not require both ingredients to add up to 100%.
- 1.7.4 In a similar manner, in claim 1 of the application as filed the sum of intact protein and hydrolyzed whey protein does not necessarily add up to 100%, since hydrolyzed casein protein may also be present. It is noted that Example 4 of the application as filed shows a composition in which hydrolyzed casein protein is present in addition to hydrolyzed whey protein.
- 1.7.5 In addition, the intact protein may be soy-based, milk-based, casein protein, whey protein, rice protein, beef

collagen, pea protein, potato protein (see page 8, lines 10 to 13, of the application as filed) and may contain some hydrolyzed protein, but less than 1.0% by weight (see page 8, lines 6 to 9 of the application as filed). While it is true that this information concerning the intact protein applies equally to claim 1 of the application as filed and to claim 1 of the main request, it underlines that hydrolyzed proteins other than hydrolyzed whey protein may be present in the claimed composition.

- 1.7.6 The respondent also referred to the following text passages on page 9, lines 3 to 5 from the bottom, and page 10, paragraph directly below the table, of the application as filed:

"These powder formulas comprise protein, carbohydrate, and a lipid, as described herein. The formulas may further comprise vitamins, minerals, or other ingredients suitable for use in powder nutritional formulas." (emphasis added)

"Different sources and types of carbohydrates, lipids, proteins (described hereinbefore), minerals, and vitamins are known and may be used in the embodiments herein, provided that such nutrients are compatible with the added ingredients in the selected formula, are safe for their intended use, and do not otherwise unduly impair product performance." (emphasis added)

In its view, the terms "as described herein" and "described hereinbefore" (see underlined terms) in these latter passages of the application as filed support only the proteins explicitly mentioned in the claims and in the description being allowed as the proteinaceous ingredients in the claimed composition.

The board does not agree, since example 4 of the application as filed as well as claim 1 of the application as filed clearly allow that, for instance, hydrolyzed casein protein may be present as a proteinaceous ingredient of the claimed composition.

- 1.7.7 Nor does the board find in the application as filed any pointer to the specific combination of the two newly-created sub-ranges characterising features (c) and (d) wherein hydrolyzed whey protein has also been selected, either. Thus it is concluded that the subject-matter of claim 1 of the main request is not directly and unambiguously disclosed in the application as filed.

Accordingly, the subject-matter of claim 1 of the main request does not meet the requirements of Article 123(2) EPC.

#### AUXILIARY REQUESTS

2. Claim 1 of auxiliary requests 1 and 2 contains the same sub-ranges "90% to 97%" and "3% to 10%" as well as the selection of hydrolyzed whey protein as claim 1 of the main request. Thus the conclusion reached for claim 1 of the main request applies equally to claim 1 of auxiliary requests 1 and 2.

Claim 1 of auxiliary request 3 identifies two more-narrowly defined sub-ranges, "95% to 97%" and "3% to 5%", in combination with the selection of hydrolyzed whey protein. These more-narrowly defined ranges were, however, constructed in the same manner as those characterising the main request.

As recognised by both parties, the same conclusions as for claim 1 of the main request apply analogously to claim 1 of each of auxiliary requests 1 to 3.

Thus the subject-matter of claim 1 of auxiliary requests 1 to 3 does not meet the requirements of Article 123(2) EPC either.

3. In view of the above, there is no allowable request on file.

**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:



A. Nielsen-Hannerup

A. Veronese

Decision electronically authenticated