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Datasheet for the decision of 6 July 2018

Case Number: T 1038/16 - 3.3.09

Application Number: 09736944.1

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Title of invention:
NUTRITIONAL COMPOSITION WITH ANTI-REGURGITATION PROPERTIES

Applicant:
Nestec S.A.

Headword:

Relevant legal provisions:
EPC Art. 84

Keyword:
Claims - unclear characterization by parameters

Decisions cited:
T 0908/04

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Case Number: T 1038/16 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 6 July 2018

Appellant: (Applicant)	Nestec S.A. Avenue Nestlé 55 1800 Vevey (CH)
Representative:	Plougmann Vingtoft a/s Rued Langgaards Vej 8 2300 Copenhagen S (DK)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 23 October 2015 refusing European patent application No. 09736944.1 pursuant to Article 97(2) EPC**

Composition of the Board:

Chairman	W. Sieber
Members:	F. Rinaldi
	P. Guntz

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the applicant against the decision of the examining division to refuse European patent application No. 09 736 944.1.

II. In the appealed decision the examining division had decided that the present application failed to provide any guidance concerning the method for determining the degree of hydrolysis (**DH**), let alone any measurement conditions (point 1.2 of the reasons). It concluded that "[i]n the absence of any indication of the methodology and the appropriate measurement conditions, the skilled person is not able to establish the exact meaning of the degree of hydrolysis, whereby a meaningful comparison with the prior art is clearly impossible". Therefore, the claims of the main request (filed by letter of 21 May 2014) and of auxiliary requests 1 to 3 (filed by letter of 24 August 2015) lacked clarity (Article 84 EPC).

III. Claim 1 of the main request read as follows:

> "*1. A nutritional composition for the management of regurgitation in infants which composition includes a protein source consisting of partially hydrolysed proteins having a degree of hydrolysis between 15 and 25%, a lipid source and a carbohydrate source comprising a starch selected from cereal starch or potato starch wherein the starch amounts to between 18 to 25% of the nutritional composition on a dry weight basis.*"

Claim 1 of auxiliary request 1 differed from claim 1 of the main request in that the partially hydrolysed proteins were defined as partially hydrolysed whey proteins and in that they were present at a certain concentration.

Claim 1 of auxiliary request 2 differed from claim 1 of the main request in that the partially hydrolysed proteins were partially hydrolysed sweet whey proteins from which the caseino-glycomacropeptide had been removed.

Claim 1 of auxiliary request 3 differed from claim 1 of the main request in that the partially hydrolysed proteins were partially hydrolysed sweet whey proteins from which the caseino-glycomacropeptide had been removed and in that they were present at a certain concentration.

IV. The documents cited in the appealed decision included:

D7: "Whey Protein Products", Davisco Foods International Inc., 2007;
D10: S.M. Rutherfurd, Journal of AOAC International, 93(5), 2010, 1515-1522.

V. In the statement setting out the grounds of appeal, the applicant (in the following: the appellant) requested that the appealed decision be set aside and that the case be remitted to the examining division for further prosecution. Further, documents D14 and D15 were filed:

D14: "Food chemistry", 4th ed., Boca Raton, CRC Press, 2007, 293-294;
D15: "Protein-based surfactants", New York Marcel Dekker. Inc., 2001, 32-34.

VI. The board summoned the appellant to oral proceedings and in its communication dated 30 April 2018 expressed its preliminary opinion.

VII. Oral proceedings were held on 6 July 2018.

VIII. The relevant arguments of the appellant with respect to clarity for all requests may be summarised as follows:

At the oral proceedings, the appellant stated that it no longer pursued one of the arguments presented in the statement setting out its grounds of appeal, namely that the skilled person would know that they had to employ the pH-stat method to establish the DH and that it was therefore unnecessary to indicate the measuring method in the claim or the application. Instead, the appellant focused on the argument that all prior-art methods which the skilled person would consider for establishing the DH yielded the same results. In this context, the appellant relied on D10, in which various methods for establishing the DH were discussed. It further pointed out that the examining division had not correctly interpreted the disclosure of D7. The DH was generally defined as the proportion of the number of peptide bonds that were cleaved during hydrolysis.

IX. The appellant's final request was that the decision be set aside and that the case be remitted to the examining division for further prosecution on the basis of the requests underlying the impugned decision (main request and auxiliary requests 1 to 3).

Reasons for the Decision

1. The subject-matter of the present application

Claim 1 of the main request relates to a composition that prevents regurgitation in infants. The composition includes a protein source, a lipid source and cereal or potato starch in an amount of 18 to 25% of the nutritional composition, based on dry weight, whereby the protein source consists of partially hydrolysed proteins having a degree of hydrolysis (DH) between 15 and 25% (for the exact wording of the claim see point III above).

In claim 1 of the auxiliary requests, the partially hydrolysed proteins are further characterised, among other things, as being partially hydrolysed whey proteins (auxiliary request 1) or specific partially hydrolysed sweet whey proteins (auxiliary requests 2 and 3). The further more specifically characterised partially hydrolysed whey proteins still have to have a DH between 15 and 25%.

2. The sole issue in the present appeal is whether the absence of any indication of the method for determining the DH in the claims leads to a lack of clarity of the scope of the claims (Article 84 EPC).

2.1 The board agrees with the appellant that the DH is generally defined as the proportion of the number of peptide bonds that are cleaved during hydrolysis and is often expressed as a percentage (D10, page 1515, right-hand column; D14, page 294):

$$\%DH = n / n_{tot} \times 100$$

where n is the number of hydrolysed bonds and n_{tot} is the total number of peptide bonds present.

2.2 Although there are various methods for estimating the total number of peptide bonds (D10, page 1516, right column, first full paragraph), this was not an issue either in the opposition division's decision or in appeal. Thus, the appeal deals only with the question of whether a lack of clarity is associated with the method(s) of determining the number of hydrolysed bonds.

2.3 It is generally known that there are several methods for determining the number of hydrolysed peptide bonds. These methods do not determine the number of hydrolysed peptide bonds directly. Instead, they make use of the fact that when a peptide bond is cleaved by hydrolytic reaction, both a free α-amino group and a carboxylic group are liberated. By measuring a change in the pH value within the reaction mixture, or by reacting the liberated free α-amino group with a marker substance, it is possible to indirectly determine how many peptide bonds have been hydrolysed. The marker substance may for instance be OPA (o-phthaldialdehyde) or TBNS (trinitrobenzenesulfonic acid). These substances react with the free α-amino group, thereby rendering it spectrophotometrically detectable.

2.4 The scope of the claims is defined *inter alia* by the DH of the partially hydrolysed proteins, which has to be between 15 and 25%. However, neither claim 1 (or any other claim) nor the description of the present application defines the method and the condition used for establishing this parameter. As set out in decision T 908/04 (Reasons 3.8), there are circumstances where

an indication of the measuring method and conditions is not required:

"[T]he *method of determination and the conditions of measurement [...] should be indicated in the claims, either expressly or, if appropriate, by way of reference to the description according to Rule 29(6) EPC [1973]. Such indication would only become superfluous, provided it could be shown*

- *that the skilled person would know from the outset which method and conditions to employ because, for instance, this methodology was the methodology commonly used in the technical field, or*

- *that all the methodologies known in the relevant technical field for determining this parameter would yield the same result within the appropriate limit of measurement accuracy*" (formatting modified by the board).

2.5 Ultimately the appellant argued that the second possibility referred to in T 908/04 was applicable in the present case, namely that no indication of the measuring method for the DH was necessary, because the various methods the skilled person would use yielded the same result within experimental error.

3. Thus, the decisive issue is whether the board is satisfied that those methods yield the same result.

3.1 As stated in T 908/04, the definition of the method for determining a parameter (in the claims or in the description) is superfluous with regard to Article 84 EPC, "provided it could be shown" that all methodologies lead to the same result. Hence, in the

present case, it is incumbent upon the appellant to demonstrate that all methodologies yield the same result within the limit of measurement accuracy and that, as a consequence, the appellant would be entitled to omit the method of measurement for the DH in the claim.

3.2 The appellant has not provided any experimental evidence demonstrating that the known methods in fact yield the same result. Instead, it relied on D10 to demonstrate that all methods which the skilled person would take into consideration for establishing the DH yielded the same result.

3.2.1 D10 was published about two years after the priority date of the present application. However, it is a review article which summarises facts which were certainly known, at least to a large extent, well before both the publication date of D10 and the priority date of the present application. Therefore, in the board's view, the document can be relied upon as evidence in this context.

3.2.2 According to D10 (e.g. abstract), there are several methods for determining the DH. The most commonly used (for determining the number of hydrolysed peptide bonds) include the pH-stat, trinitrobenzenesulfonic acid (TNBS), o-phthaldialdehyde (OPA), trichloroacetic acid soluble nitrogen (SN-TCA) and formol titration methods. The passage bridging pages 1518 and 1519 also refers to other methods, *inter alia* the reaction between ninhydrin and amino groups to determine DH and the α-amino N content of the hydrolysates, although it is acknowledged that this method is not commonly used. D10 discusses the various methods and draws some

comparison between them in view of the need for standardisation of DH methodologies.

4. In its analysis of D10, the appellant argued that the skilled person would rule out most of the methods cited therein for determining the DH in the present application. They would not use the SN-TCA method (even D10 itself describes this method as misleading; page 1521, left-hand column), the pH-stat method (not suitable for all proteins) or the ninhydrin method (old method, not commonly used). Instead, they would rely on the OPA and TNBS methods. The fact that one study quoted in D10 (Spellman et al., page 1519) showed a difference of 13% for the TNBS and the OPA methods was apparently insignificant to the author of D10, because it is stated in the abstract of D10 that these two methods generally compare well. A similar statement can be found on page 1521, left-hand column ("Generally, the TNBS and OPA methods compared well across most studies."). Thus, following the teaching of D10 the skilled person would use the OPA or TNBS method for determining the DH in the present application, which yielded the same result within the appropriate limit of measurement accuracy.

5. The board is not convinced by the appellant's arguments for the following reasons:

5.1 First of all, the board notes that there is apparently no such thing as **the** methodology commonly used in the technical field to determine the DH. Thus, there is no valid reason to rule out, for example, the ninhydrin method, just because it was allegedly an old method or not commonly used. There is simply nothing in the application as filed to indicate the method on which the applicant relied at the filing date. As to the

ninhydrin method, it is explicitly stated in D10 (page 1519, right-hand column) that this method yielded much lower values compared to the TNBS and OPA methods.

5.2 But even if it were to be accepted, in the appellant's favour, that the skilled person would choose only the OPA and TNBS methods, D10 itself shows that the two methods do not yield the same result.

5.2.1 As is apparent from the discussion of the publication of Spellman et al. in D10, the OPA method underestimated the DH by 13% as compared to the TNBS method. This difference considerably blurs the scope of claim 1 with regard to the DH, which has to be between 15 and 25%. Depending on the measuring method effectively used, this range is shifted to a lower limit of about 13% or to a higher limit of about 28%. Thus, different results are obtained, which may or may not fall within the scope of claim 1, depending on the measuring method used.

5.2.2 The appellant has also been unable to convince the board that the variations obtained for the DH are within "the appropriate limit of measurement accuracy". In this context, the appellant referred to some passages in D10 which reported a good correlation between the OPA and TBNS methods (discussion of Panasiuk et al. and Nielsen et al.) or that the methods compared well (abstract). However, a good correlation does not mean that the same results are obtained within measurement accuracy. Furthermore, the skilled person would not understand the statement in D10 that "the OPA underestimated the DH by 13%" as an indication of a measuring (in)accuracy. Rather, it would rely on the normal meaning of the word "underestimate", namely estimating something smaller or lower than it really

is. The difference is significant and potentially allows for an extension of the claimed range from 10% (15 to 25%) to 15% (13 to 28%).

5.2.3 In summary, the appellant has failed to convince the board that the two methods which the skilled person would allegedly use to determine the DH (OPA and TNBS) yield the same result *within the appropriate limit of measurement accuracy*.

6. In view of these considerations, the board concludes that the absence of any indication of the measuring method for the DH required in claim 1 of the main request leads to a lack of clarity with regard to the required DH between 15 and 25% (Article 84 EPC). Therefore, the main request is not allowable.

7. Since claim 1 of all auxiliary requests still requires a DH between 15 and 25% for the more specifically defined partially hydrolysed proteins, and as the clarity issue described above regarding the measuring method for the DH arises independently of the choice of hydrolysed proteins, none of the auxiliary requests complies with the requirements of Article 84 EPC either.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Cañueto Carbajo W. Sieber

Decision electronically authenticated