BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

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

Datasheet for the decision of 27 January 2011

Case Number: T 0628/08 - 3.3.09

Application Number: 00965982.2

Publication Number: 1220620

IPC: A23L 1/29

Language of the proceedings: EN

Title of invention:
Composition comprising casein protein and whey protein

Patentee:
SOCIETE DES PRODUITS NESTLE S.A.

Opponent:
Friesland Brands B.V.
Numico Research B.V.

Headword:
-

Relevant legal provisions:
RPBA Art. 13(1)
EPC Art. 54, 56, 83, 84, 123(2)

Keyword:
"Late-filed requests (admitted)"
"Disclosure - sufficiency (yes)"
"Novelty (main request, no)"
"Inventive step (Auxiliary Request 1, no)"
"Amendments - added subject-matter (Auxiliary Request 2, yes)"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0628/08 **-** 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 27 January 2011

Appellant: (Patent Proprietor)
SOCIETE DES PRODUITS NESTLE S.A.
Case postale 353
CH-1800 Vevey (CH)

Representative:
Wright, Robert Gordon McRae
Elkington and Fife LLP
Prospect House
8 Pembroke Road
Sevenoaks
Kent TN13 1XR (GB)

Respondent I: (Opponent I)
Friesland Brands B.V.
Blankenstein 142
NL-7943 PE Meppel (NL)

Representative:
Winckels, Johannes Hubertus F.
Vereenigde
Johan de Wittlaan 7
NL-2517 JR Den Haag (NL)

Respondent II: (Opponent II)
Numico Research B.V.
Postbus 7005
NL-6700 CA Wageningen (NL)

Representative:
Meekel, Arthur Augustinus P.
Nederlandsch Octrooibureau
P.O. Box 29720
NL-2502 LS Den Haag (NL)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 23 January 2008 revoking European patent No. 1220620 pursuant to Article 102(1) EPC 1973.**

Composition of the Board:

Chairman: W. Sieber
Members: M. O. Müller
R. Menapace

Summary of Facts and Submissions

I. The present decision is on the appeal by the proprietor of European patent No. 1 220 620 against the decision of the opposition division to revoke the patent.

II. Opponent I (Friesland Brands B.V.) and Opponent II (Numico Research B.V.) had requested revocation of the patent in its entirety on the grounds that the claimed subject-matter was neither novel nor inventive (Article 100(a) EPC, Opponents I and II), that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by the person skilled in the art (Article 100(b) EPC, Opponent II) and that the subject-matter of the patent extended beyond the content of the application as filed (Article 100(c) EPC, Opponent I).

The documents cited during opposition proceedings included:

D1: EP 0 418 593 A2;

D2: US 5,916,621 A;

D10: P. Walstra et al, "Dairy Chemistry and Physics", JOHN WILEY & SONS, New York, Chichester, Brisbane, Toronto, Singapore, 1984, pages 1-11, 402, 403, 416-422, Table A.16;

D11: A. Imbert-Pondaven, "Étude de l'évolution de la composition des lactosérums au cours de leur conservation", LE LAIT 568, 1977, pages 521-546;

D12: C. Alais et al, "Milk Proteins: Biochemical and Biological Aspects", World Review of Nutrition and Dietetics, volume 20, pages 66-167; and

D13: "Food Composition and Nutrition Tables", edited by Deutsche Forschungsanstalt für Lebensmittelchemie, 5th edition, Scientific Publishers Stuttgart and CRC Press Boca Raton, Ann Arbor, London, Tokyo, 1994, pages 41-46.

III. By its decision, which was announced orally on 12 December 2007 and issued in writing on 23 January 2008, the opposition division revoked the patent because none of the requests on file (main request, six auxiliary requests) met the requirements of the EPC.

Claim 1 of the main request read as follows:

"1. A composition for an infant formula which comprises whey protein, wherein the whey protein is acid or sweet whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; and either tryptophan rich milk protein; free tryptophan or a mixture thereof."

Claim 1 of Auxiliary Request 3 contained the additional feature that the composition comprised from about 9.0 to about 10.0 w/w% of protein.

The opposition division's position can be summarised as follows:

The opposed patent disclosed the invention in a manner sufficiently clear and complete for it to be carried

out by the skilled person in the art. The contention of Opponent II that the extent of removal of caseino-glyco-macropeptide (in the following "GMP") was not disclosed in the opposed patent concerned clarity rather than sufficiency of disclosure. Furthermore, no evidence was presented to show that it was not possible to rework embodiments that fell under the scope of the claims.

The subject-matter of the main request lacked novelty in view of Example 1 of D2. This example disclosed a composition which was suitable for an infant formula and comprised casein and sweet whey from which GMP had been removed. Sweet whey inherently comprised free amino acids.

The subject-matter of Auxiliary Request 3 was novel but not inventive in view of D2. In particular, the distinguishing feature was the protein content, no effect was linked to this feature and the choice of a protein concentration which was identical to that of human milk was trivial. Moreover, D1 showed that the claimed protein concentration was known for a composition for infant formulas.

IV. On 25 March 2008, the appellant (proprietor) filed a notice of appeal against the above decision and paid the prescribed fee on the same day. A statement setting out the grounds of appeal was filed on 29 May 2008 together with

D23: M. C. R. Räihä et al, "Protein Nutrition During Infancy: Effects on Growth and Metabolism",

Nutrition and Growth, Nestlé Nutrition Workshop Series, Pediatric Program, volume 47, 2001; and

D24: E. E. Ziegler, "Protein Requirements in Infancy", Nestlé Nutrition Workshop Series, Pediatric Program, volume 47 supplement, 2002,

as well as a main request and Auxiliary Requests 1-4.

The claims of the main request and Auxiliary Request 1 corresponded to those of the main request and Auxiliary Request 3 before the opposition division (see point III above).

V. By letter of 12 December 2008, Respondent I (Opponent I) filed its response to the statement of grounds of appeal together with

D25: C. Agostoni et al, "Free Amino Acid Content in Standard Infant Formulas: Comparison with Human Milk", Journal of the American College of Nutrition, volume 69, no. 4, 2000, pages 434-438;

D26: I. P. Mavropoulou et al, "Composition, Solubility, and Stability of Whey Powders", JOURNAL OF DAIRY SCIENCE, volume 56(9), 1973, pages 1128-1134; and

D27: I. P. Mavropoulou et al, "Free Amino Acids and Soluble Peptides of Whey Powders", JOURNAL OF DAIRY SCIENCE, volume 56(9), 1973, pages 1135-1138.

VI. The response of Respondent II (Opponent II) was filed on 22 December 2008.

VII. By communication of 17 September 2010, the board issued a preliminary opinion. With regard to sufficiency of disclosure, the board drew the party's attention to column 2, lines 4-16 of D2, where partial and complete removal of GMP was addressed. Reference was also made to the question of whether the whey-casein ratio as required in Claim 1 of Auxiliary Request 2 met the requirements of Article 123(2) EPC.

VIII. In response to the summons to oral proceedings, Respondent I filed

D28: B. Lönnerdal et al, "A longitudinal study on protein, nitrogen, and lactose contents of human milk from Swedish well-nourished mothers", The American Journal of Clinical Nutrition, volume 29, 1976, pages 1127-1133; and

D29: R. J. W. Beijers et al, "Composition of premature breast-milk during lactation: constant digestible protein content (as in full term milk)", Early Human Development, volume 29, 1992, pages 351-356.

IX. On 27 January 2011, oral proceedings were held before the board. During the oral proceedings, the appellant withdrew all previous requests and submitted a new main request and new Auxiliary Requests 1-4. In the course of oral proceedings, Auxiliary Requests 3 and 4 were withdrawn. The respondents requested the board not to admit the new main and auxiliary requests into the proceedings.

Claim 1 of the main request reads as follows:

"1. A composition for an infant formula which comprises whey protein wherein the whey protein is sweet whey protein from which caseino-glycomacropeptide has been removed; casein protein; free arginine; free histidine; and either tryptophan rich milk protein, free tryptophan or a mixture thereof."

Claim 1 of Auxiliary Request 1 is identical to Claim 1 of the main request with the additional feature that the composition comprises from about 9.0 to about 10.0w/w% of protein.

Claim 1 of Auxiliary Request 2 is identical to Claim 1 of Auxiliary Request 1 with the additional requirement that the ratio of whey protein to casein protein is about 60% : about 40% to about 70% : about 30%.

X. The appellant's position can be summarised as follows:

The new requests should be admitted into the proceedings. Firstly, in view of the positive decision of the opposition division on Article 123(2) EPC, it had not been necessary to submit the new requests at an earlier stage. Secondly the prior art used by the respondents, in particular D2, referred to the embodiment that was kept in the claims. The amendment thus did not necessitate a fresh look at the prior art.

The extent of GMP removal required by the claims did not concern sufficiency of disclosure but was a matter of clarity. No proof had been provided that the skilled

person was unable to remove GMP from sweet whey. The requirements of Article 83 EPC therefore were met.

The subject-matter of Claim 1 of the main request differed from the composition of Example 1 of D2 by the presence of free arginine and histidine. The respondents' argument that these free amino acids were proven by D11 and D27 to form part of the sweet whey of D2 was not convincing as D11 did not relate to sweet whey but deproteinized sweet whey and as, according to Table 2 of D27, not all sweet wheys contained free arginine and histidine. Furthermore, contrary to D2, the free amino acids referred to in Claim 1 of all requests did not form part of the sweet whey but constituted additional components which had to be added separately to the composition.

The subject-matter of Auxiliary Request 1 differed from that of D2 in terms of the protein content. This distinguishing feature solved the problem of providing a composition for an infant formula that was balanced in terms of protein and amino acid amounts. Moreover, D23 and D24 showed that the reduction of the protein level to that required by Claim 1 had several physiologically beneficial effects for an infant. Finally, the reduction of the protein content overcame the technical prejudice proven by D24 of using high relative protein contents in infant formulas. The claimed subject-matter thus was novel and inventive.

The whey-casein ratio introduced into Claim 1 of Auxiliary Request 2 was based on page 3, lines 27-32 of the application as filed. The ratio disclosed in this passage could be read on its own as it stood.

XI. The respondents' position can be summarised as follows:

The appellant's late-filed requests were inadmissible as a complete case should have been made with the statement setting out the grounds of appeal and as they made a fresh look at the prior art necessary.

The subject-matter as claimed in the main request was insufficiently disclosed as, firstly, the claims left it open whether partial or complete removal of GMP was required and, secondly, the skilled person did not know how to remove GMP completely.

Example 1 of D2 disclosed a composition comprising cream and sweet whey. The cream contained casein. Furthermore, as evidenced by D10-D12 and D27, the sweet whey contained free arginine, free histidine and α-lactalbumine, a tryptophan rich milk protein. All components required by Claim 1 of the main request were thus present in the composition of D2. Consequently, the subject-matter of this claim lacked novelty.

Also the subject-matter of Auxiliary Request 1 lacked novelty in view of D2. More particularly, based on the information present in D13, the composition of Example 1 of D2 could be assumed to have a protein content falling within the range required in Claim 1. Even assuming a difference in protein content, the claimed subject-matter was not inventive. The objective technical problem in view of D2 was the provision of an alternative composition. The solution constituted an arbitrary selection of the protein amount. This was within the routine abilities of the skilled person.

Furthermore, a protein content of 9.3 wt% was known from Example 6 of D1.

As to Auxiliary Request 2, page 3, lines 30-32 of the patent could not form a basis for the introduced whey-casein ratio as it disclosed this ratio only in combination with specific whey and casein amounts.

XII. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or Auxiliary Requests 1 and 2, all filed during the oral proceedings before the board.

XIII. The respondents (Opponents I and II) requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. *Admissibility of the appellant's new requests*

The respondents objected to the admission of the new main request and Auxiliary Requests 1 and 2 filed by the appellant during the oral proceedings before the board.

The claims of the new requests differ from those of the previous requests submitted with the statement setting out the grounds of appeal in that the alternative relating to acid whey has been deleted. This was done

in reaction to an objection under Article 123(2) EPC to the acid whey alternative.

The deletion of the acid whey alternative is a straightforward restriction of the claims that does not introduce any new deficiency or further complexity. Moreover, the sweet whey alternative to which the claims are now restricted was already dealt with by the respondents in their responses to the statement setting out the grounds of appeal, in particular when discussing the relevance of D2. The respondents therefore could be expected to deal with the new requests without adjournment of oral proceedings. No conflict with the need for procedural economy thus arises (Article 13(1) RPBA).

The board therefore exercised its discretion under Article 13(1) RPBA and admitted the new requests into the proceedings.

Main Request

3. *Amendments - Articles 123(2) and 84 EPC*

The respondents did not raise any objections under Article 123(2) EPC and the board is satisfied that the claims of the main request are based on the application as filed and thus that the requirements of Article 123(2) EPC are met. Furthermore, no objections were raised by the respondents under Article 84 EPC. The board is equally satisfied that the amendments do not lead to any lack of clarity and thus that the requirements of Article 84 EPC are met.

4. *Sufficiency of disclosure*

4.1 The respondents argued that no information was available on whether partial or complete removal of caseino-glyco-macropeptide ("GMP") from sweet whey was required by the claims. The board acknowledges that the wording "sweet whey protein from which GMP has been removed" in the claims is indeed ambiguous in this respect. However, Article 84 EPC does not form a ground of opposition and thus cannot be invoked against this ambiguity. Furthermore, no evidence is available to the board that this ambiguity leads to any insufficiency of disclosure. There is in particular no evidence that the invention cannot be carried out or the effects aimed at by the invention cannot be obtained if the GMP is removed from the sweet whey only partially. The respondents' argument is therefore not convincing.

4.2 The respondents further argued that the skilled person did not know how to remove completely the GMP from sweet whey. However, they did not provide any proof to substantiate this allegation. In fact, as evidenced by D2 (column 2, lines 4-16), partial and complete removal was possible before the priority date of the opposed patent by means of ultrafiltration. Hence, this argument of the respondents is not convincing either.

4.3 In the absence of any further argument that could support the respondents' attack on sufficiency of disclosure, the board is satisfied that the main request meets the requirements of Article 83 EPC.

5. *Novelty*

5.1 D2 concerns baby milk food with a reduced threonine level (column 1, lines 52-44). Example 1 of this document discloses a spray dried milk baby food made from inter alia cream and demineralised powder of sweet whey after removal of GMP.

The spray dried milk baby food corresponds to the composition for an infant formula as required by Claim 1.

Cream contains milk protein which, as evidenced by Table 1.1 of D10, in turn includes casein, corresponding to the casein protein required in Claim 1.

The sweet whey after removal of GMP corresponds to the sweet whey protein from which GMP has been removed, as required by Claim 1.

As shown by D12 (page 118, first line under the heading "2. α-Lactalbumin"), sweet whey contains the milk protein α-lactalbumin. As apparent from Table A.6 of D10 and Table X of D12, α-lactalbumin contains tryptophan. Thus, the sweet whey of Example 1 of D2 contains α-lactalbumin and this corresponds to the tryptophane rich milk protein required in Claim 1.

Finally, as evidenced by D11 ("Lactosérum doux", Table 5) and D27 (Table 1), sweet whey contains arginine and histidine as free amino acids. Free arginine and histidine are therefore present in the

sweet whey and thus in the composition of Example 1 of D2.

5.2 The appellant argued that D11 disclosed free arginine and histidine as components of deproteinised sweet whey only, but not of sweet whey as such and that furthermore, according to Table 2 of D27 not all sweet whey types contained free arginine and histidine. These arguments are not convincing for the following reasons:

Contrary to the appellant's allegation, free arginine and histidine are disclosed in D11 as components of sweet whey (heading of Table 5). The deproteinisation is only carried out in D11 to determine the amounts of free arginine and histidine in sweet whey (paragraph under Figure 1 on page 529 of D11). D11 thus proves that free arginine and histidine are present in the sweet whey of Example 1 of D2.

Further, Table 2 of D27 does not prove, as alleged by the appellant, the absence of free arginine and histidine in certain sweet whey types. On the contrary, it only points to the absence thereof in the free and soluble peptide fraction of sweet whey (left hand corner at the top of Table 2). In fact, as follows from Table 1 of D27, all sweet whey types of D27 do contain free arginine and histidine. Hence it can also be deduced from D27 that the sweet whey of Example 1 of D2 contains free arginine and histidine.

5.3 In summary, the composition of Example 1 of D2 comprises all the components required by Claim 1. Therefore, the subject-matter of Claim 1 lacks novelty in view of this document.

It is noted in this respect that the appellant's further argument that Claim 1 requires the amino acids to be present in addition to those inherently present in the sweet whey cannot be followed. In fact, all that Claim 1 requires is that the composition comprises sweet whey and certain free amino acids and this, as has been set out above, is the case for the composition of Example 1 of D2.

Auxiliary Request 1

6. *Amendments - Articles 123(2) and 84 EPC*

Claim 1 of Auxiliary Request 1 is identical to Claim 1 of the main request with the additional requirement stemming from granted Claim 2 that the composition comprises from about 9.0 to about 10.0 w/w% of protein.

No objections were raised by the respondents under Article 123(2) EPC and the board is satisfied that the claims of Auxiliary Request 1 are based on the application as filed and thus that the requirements of Article 123(2) EPC are met. Furthermore, no objection to the amendments in the auxiliary request was raised by the respondents under Article 84 EPC. The board is satisfied that no deficiency under this Article has been introduced by these amendments.

7. *Sufficiency of disclosure*

No new objections in relation to sufficiency of disclosure were raised by the respondents. For the same

reasons as given above with regard to the main request, the requirements of Article 83 EPC are met.

8. *Novelty*

Claim 1 requires that the claimed composition comprises from about 9.0 to about 10.0 w/w% of protein. The amount of protein is not explicitly disclosed in Example 1 of D2. Respondent II argued that the composition of Example 1 of D2 implicitly had a protein content of 9.44%, which fell within the range required by Claim 1 of Auxiliary Request 1. To arrive at this value, the respondent assumed that the relative amount of protein present in the cream of Example 1 of D2 was identical to that of the cream described on page 41 of D13. However, the two creams at least differ in the fat content (10.2% in Example 1 of D2 compared to 10.5% in D13) and thus are not identical. It can therefore not be assumed with certainty that the two creams have the same relative protein content. Consequently, the protein content of the cream and thus of the entire composition of Example 1 of D2 is not derivable from D13. Hence, D2 does not clearly and unambiguously disclose the relative protein content of Claim 1 - either explicitly or implicitly. Novelty of the subject-matter of Claim 1 in view of Example 1 of D2 therefore has to be acknowledged.

9. *Inventive step*

9.1 The opposed patent addresses the problem of providing an infant formula with a protein concentration and amino acid profile equivalent to that of human milk while exhibiting a reduced threonine content

(paragraphs [0003] and [0014]). In the same way, D2 (column 1, lines 28 - 31) aims at adapting infant food as much as possible to the composition of human milk while achieving a reduced threonine content. As acknowledged by all parties, D2 can thus be considered to represent the closest prior art.

9.2 As has been set out above, the claimed subject-matter differs from the disclosure of D2 only in terms of the relative protein content. The opposed patent does not attribute any particular effect to this protein content. It merely states that the protein content as required by Claim 1 has the advantage that it is equivalent to that of human milk and it corresponds to the lower limit tolerated by the codex alimentarius (paragraphs [0006] and [0015] of the opposed patent).

According to the appellant, D23 and D24 showed that a reduction of the protein level to that required by Claim 1 had several physiologically beneficial effects for an infant. However, contrary to Claim 1, D23 and D24 firstly do not relate to infant formulas containing sweet whey and secondly require very specific amino acid amounts (D23, Table 2) and types of carbohydrates and fats (D24, last paragraph on page 101). Therefore, D23 and D24 cannot prove any advantageous physiological effect to be achieved by the subject-matter of Claim 1.

Similarly, the appellant's argument that the claimed subject-matter provides a balanced composition in terms of protein and amino acid amounts is not convincing because Claim 1 is not restricted in terms of the amino acid amounts.

Hence, none of the advantageous effects referred to by the appellant can be taken into account in formulating the objective technical problem. The objective technical problem therefore has to be formulated on the basis of the information given in the opposed patent as the provision of a composition for an infant formula that has a certain relative protein content, which is equivalent to that of human milk and to the lower limit tolerated by the codex alimentarius.

9.3 The skilled person starting from D2 and being confronted with this problem would simply have to add more or less protein to the composition of Example 1 of D2 until the desired protein content of human milk is reached. This is clearly within the routine abilities of the skilled person. Moreover, a protein amount as required by Claim 1 is already known from D1, which discloses in Example 6 (Table at the bottom of page 19) a composition for an infant formula with a relative protein content of 9.3 wt% (9.3g per 100g composition). The selection of a relative protein content as required by Claim 1 for the composition of Example 1 of D2 thus cannot involve any inventive step. Consequently, the subject-matter of Claim 1 of Auxiliary Request 1 is not inventive in view of D2 alone or in combination with D1.

9.4 The appellant further argued that the invention as covered by Claim 1 overcame the technical prejudice of using relatively high protein contents in infant formulas. The existence of this prejudice was proven according to the appellant by the penultimate sentence of the comments of Dr. Haschke on page 108 of D24, where he states: "I think it is high time we be allowed

to reduce the protein content substantially in follow-up formulas".

However, D24 was published roughly three years after the priority date of the opposed patent. Thus, the passage referred to by the appellant cannot prove any prejudice existing at the priority date of the opposed patent. Further, the passage does not refer to infant formulas in general but only to "follow-up formulas", which are administered to older infants (first two sentences of Dr. Haschke's comments). Thus no prejudice against low protein contents in general can be derived from D24. Hence, the attempt to derive inventive step from a technical prejudice that has been overcome by the claimed subject-matter must fail.

Auxiliary Request 2

10. *Amendments - Article 123(2) EPC*

10.1 Claim 1 of Auxiliary Request 2 differs from Claim 1 of Auxiliary Request 1 by the inclusion of the wording "and wherein the ratio of whey protein to casein protein is about 60% : about 40% to about 70% : about 30%".

10.2 This whey-casein ratio is disclosed on page 3, lines 27-32 of the application as filed, where it is stated:

"Preferably an embodiment of the composition comprises about 6% to about 50% by weight of whey protein, more preferably about 20% to 40% whey protein, most preferably 30% whey protein. Preferably it comprises

from about 20% to about 40% casein protein, more preferably about 30%. Most preferably, the ratio of whey protein to casein protein is about 60% : about 40% to about 70% : about 30%."

The term "most preferably" used in the last sentence of this passage in relation to the whey-casein ratio indicates that this ratio is the most preferred embodiment of the composition described in the previous section of this passage, ie a composition comprising about 6-50wt% whey protein and 20-40wt% casein protein. Hence, in the above passage, the whey-casein ratio is only disclosed in combination with these specific whey and casein protein amounts. Contrary thereto, Claim 1 covers this whey-casein ratio for any whey and casein protein amounts. In other words, the whey-casein ratio has been taken out of its originally disclosed context. The above passage of the application as filed therefore cannot serve as a basis for the amendment of Claim 1 of Auxiliary Request 2.

10.3 Since no other disclosure of the whey-casein ratio is present in the application as filed, the whey-casein ratio in Claim 1 of Auxiliary Request 2 contravenes the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

C. Eickhoff W. Sieber