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Datasheet for the decision of 7 November 2014

Case Number: T 0641/13 - 3.3.09

Application Number: 06826479.5

Publication Number: 1945045

IPC: A23L1/29

Language of the proceedings: EN

Title of invention:
INFANT FORMULAS CONTAINING DOCOSAHEXAENOIC ACID AND LUTEIN

Applicant:
ABBOTT LABORATORIES

Headword:

Relevant legal provisions:
EPC Art. 84, 123(2), 54(2), 56

Keyword:
Claims - clarity (yes)
Amendments - allowable (yes)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:

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Case Number: T 0641/13 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 7 November 2014

Appellant: (Applicant)	ABBOTT LABORATORIES 100 Abbott Park Road Abbott Park, IL 60064-3500 (US)
Representative:	Boult Wade Tennant Verulam Gardens 70 Gray's Inn Road London WC1X 8BT (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 26 October 2012 refusing European patent application No. 06826479.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	W. Sieber
Members:	M. O. Müller
	K. Garnett

Summary of Facts and Submissions

I. European patent application No. 06 826 479.5, filed on 23 October 2006 as international application PCT/US2006/041303 in the name of Abbott Laboratories was refused by the decision of the examining division announced orally on 24 July 2012 and issued in writing on 26 October 2012.

II. In the examining division's communications and the decision the following documents were cited:

D1: US 2005/0208179 A1;

D2: US 2003/0228392 A1;

D3: S. E. Carlson et al, "Visual-acuity development in healthy preterm infants: effect of marine-oil supplementation", Am J Clin Nutr, 58, 1993, pages 35 to 42;

D4: H.-H. Koh et al, "Plasma and macular responses to lutein supplement in subjects with and without age-related maculopathy: a pilot study, Experimental Eye Research, 79, 2004, pages 21 to 27;

D5: V. C. Jewell et al, "Nutritional factors and visual function in premature infants", Proceedings of the Nutrition Society, 60, 2001, pages 171 to 178;

D6: Pediatric Nutrition Guide 2011, Abbott, 5 pages; and

D7: J. Bettler et al, "Serum lutein concentrations in healthy term infants fed human milk or infant formula with lutein", Eur J Nutr, 49, 2010, pages 45 to 51.

III. The decision of the examining division was based on a main request and auxiliary request 1. Claim 1 of the main request read as follows:

"1. An infant formula comprising fat, protein, carbohydrate, vitamins, and minerals, including docosahexaenoic acid and, on a ready-to-feed basis, at least 75 µg/liter of lutein, wherein the weight ratio of lutein (µg) to docosahexaenoic acid (mg) is from about 1:2 to about 10:1 and the formula is free of egg phospholipids."

Claim 1 of auxiliary request 1 differed from claim 1 of the main request in that the infant formula was defined as a liquid infant formula.

IV. In its decision, the examining division essentially reasoned as follows:

The requirements of Articles 123(2), 84 and 54 EPC were met for the main request and auxiliary request 1. The two requests were however not inventive.

D1 was the closest prior art, from which the claimed subject-matter essentially differed in that, on a ready-to-feed basis, the infant formula contained a minimum lutein content of about 75 µg/l. The problem to be solved was the provision of an alternative infant formula with high lutein content. The application as filed demonstrated a reduced bioavailability of lutein in infant formulae as compared to breast milk and a

positive correlation between lutein intake and plasma lutein concentration. Thus, the applicant had discovered a problem, i.e. the reduced bioavailability of lutein in infant formulae compared to that of breast-milk. However once the problem was known, increasing the content of lutein in the infant formula was a straightforward extrapolation not requiring any inventive skill. In order to achieve similar plasma lutein values as found in breast fed infants, the infant formula had to be formulated with higher levels of lutein, which levels could be determined by trial and error. In fact, the applicant had not solved the problem of poor bioavailability but circumvented the problem by merely adding more lutein to compensate for its low bioavailability. As the difference with D1 was related to an obvious technical effect, i.e. an increase in the lutein intake increased the concentration of lutein in the plasma, the claimed subject-matter did not involve an inventive step over D1, optionally in combination with D2 or D3, which taught the supplementation of DHA in infant formulae.

V. On 13 December 2012, the applicant (hereinafter: "the appellant") 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 26 February 2013 together with a first auxiliary request and a copy of decision T 2/83.

VI. Following the board's first communication, the appellant filed, with letter of 7 July 2014, new amended main, first and second auxiliary requests as well as

D8: Appendix 1: Calculations on caloric density; and

D9: Commission Directive of 14 May 1991 on infant formulae and follow-on formulae.

VII. On 23 July 2014, the board issued a second communication. In its communications, the board raised several objections under Articles 84 and 123(2) EPC (for details see points 2 and 3 below). In view of the unclear definition of the amount of lutein in claim 1, the board considered the subject-matter of claim 1 to lack novelty over examples 1 and 3 of D1. The board also observed that an inventive step might be acknowledged over D1 as the closest prior art if the appellant were able to restrict claim 1 such that the amount of lutein as claimed was higher than that in D1.

VIII. By letter of 9 September 2014, the appellant filed a replacement main request and replacement first and second auxiliary requests.

IX. On 7 November 2014, oral proceedings were held before the board. In view of the board's objections under Article 84 EPC, the appellant filed a new replacement main request and amended description pages 1 to 28. All previous requests were withdrawn.

Claim 1 of the replacement main request reads as follows:

"1. A ready-to-feed liquid infant formula comprising fat, protein, carbohydrate, vitamins, and minerals, including docosahexaenoic acid and at least 75 µg/liter of lutein, wherein the weight ratio of lutein (µg) to docosahexaenoic acid (mg) is from 1:2 to 10:1 and the formula is free of egg phospholipids."

X. The appellant's position in the written and oral proceedings, in as far as relevant to the present decision, was as follows:

The claimed subject-matter was novel over D1. Example 1 of this document disclosed a liquid infant formula, the lutein amount of which was below the lower limit of claim 1. For examples 2 and 3, it was impossible to determine the total volume of the liquid composition that was subjected to spray drying since it contained an unknown amount of water. Therefore, the amount of lutein per litre of this composition could not be calculated. After spray drying, the composition was in a powder form, unlike the claimed infant formula, which was a ready-to-feed liquid.

The claimed subject-matter was furthermore inventive. It differed from the closest prior art document D1 in terms of a higher lutein amount. According to the present application, it had been surprisingly found that, in order to obtain with infant formulae the same plasma lutein concentration as found in human milk, the lutein amount in the infant formulae had to be much higher than that in human milk. In D1, the lutein was not added to provide bioavailable lutein in the plasma but rather was added to reduce or eliminate the red-orange hue of beta-carotene when it was used as an antioxidant in a powder nutritional formulation. Therefore, the plasma lutein levels obtained after feeding the infant formula of D1 were not relevant to the underlying disclosure of this document since the lutein only needed to be part of an antioxidant system up until the formulation was consumed. The skilled person reading D1 would thus have had no reason to increase the amount of lutein in the infant formula disclosed in this document.

As regard's the appellant's clarity arguments, reference is made to point 2 below.

XI. The appellant requested that the decision under appeal be set aside and the case be remitted to the examining division with an order to grant a patent based on the claims of the replacement main request, filed during the oral proceedings of 7 November 2014.

Reasons for the Decision

1. The appeal is admissible.

2. Article 84 EPC

2.1 Claim 1 of the requests previously on file covered an infant formula in powder form. In its communications, the board had considered the lutein amount in claim 1 to be unclear for this type of infant formula. For this embodiment, the amount of lutein could only be determined after an event in the future had taken place, namely after the infant formula in powder form had been reconstituted into one that was ready to be fed to an infant, an event which was not defined in claim 1.

The infant formula has now been restricted to a ready-to-feed liquid infant formula such that this clarity objection no longer applies.

2.2 In the board's first communication, the wording "or related structures as described or otherwise suggested herein" used for the definition of lutein in paragraph [0026] was considered to be unclear. This wording has now been deleted.

2.3 In the board's first communication, the board had raised the objection that it was not clear whether the amount of lutein in claim 1 had to be calculated on the basis of the amount of free lutein if the lutein was present as an ester or salt.

However, since claim 1 refers to the amount of "lutein" rather than any lutein salt or ester, the board accepts the appellant's argument that the skilled person reading claim 1 would know that this amount has to be calculated on the basis of the amount of free lutein rather than that of lutein ester or salt. This is supported by paragraph [0024] of the application as filed, where it is stated that "All lutein concentrations and ratios referenced herein are calculated on a free lutein basis, unless otherwise specified".

2.4 The same objection was made in the board's first communication with regard to the amount of docosahexaenoic acid (expressed in claim 1 as the weight ratio of lutein to docosahexaenoic acid). In the same way as for the lutein, the skilled person reading claim 1 would understand that this amount refers to the free docosahexaenoic acid, since claim 1 refers to the acid and not any derivative thereof.

2.5 In the board's first communication, the board observed that it was not clear how the amount of lutein per litre formula in examples 1.1 and 2.1 (lower part of the tables on pages 15 and 17) could be identical while the amount of lutein per kilogram formula in these two examples (upper part of the tables) was different.

As explained by the appellant, the amount of lutein per litre formula refers to the formula in the ready-to-feed liquid form (first line of paragraph [0072] for example 1.1 and the entry "mcg/liter as fed" in the lower part of the table on page 17 for example 2.1). The amount of lutein per kilogram formula in example 1.1 is equally based on the amount of the ready-to-feed liquid formula while that in example 2.1 refers to the powdered infant formula before being reconstituted to the ready-to-feed liquid (first line of paragraph [0080]). This is why the amount of lutein per kilogram of formula in examples 1.1 and 2.1 differs.

The same applies to examples 1.2 and 2.2 and 1.3 and 2.3, respectively.

2.6 The replacement main request including the amended description-pages thus meets the requirements of Article 84 EPC.

3. Article 123(2) EPC

3.1 Claim 1 differs from claim 1 as filed in that (i) the lower limit of the amount of lutein has been increased to 75 µg, (ii) the infant formula has been defined to be a ready-to-feed liquid infant formula, (iii) "mcg" has been replaced by "µg" and (iv) "about" has been deleted.

The lutein amount (amendment (i)) is based on paragraph [0024] of the application as filed. The feature of a ready to feed liquid infant formula (amendment (ii)) is based on paragraph [0049] of the application as filed. Both the lutein amount and the type of formula are disclosed in the two passages in

very general terms. The skilled person thus would consider the two features to apply to all embodiments described in the application as filed. The combination of the two features (amendments (i) and (ii)) in claim 1 therefore does not extend the claimed subject matter over the content of the application as filed.

The replacement of "mcg" by "µg" does not add anything to the claims since "mcg" is commonly used as an abbreviation of microgram (µg). Finally, the deletion of the term "about" in claim 1 is not objectionable under Article 123(2) EPC.

3.2 Claim 2 corresponds to claim 2 as filed except that (i) the term "wherein the composition" has been replaced by "wherein the formula", (ii) the amount of lutein has been defined to be 75 to 230 µg/l, (iii) "mcg" has been replaced by "µg" and (iv) "about" has been deleted.

Amendment (i) is allowable under Article 123(2) EPC since this claim 2 refers to "The infant formula of Claim 1" such that it is clear that "wherein the composition" in claim 2 actually refers to an infant formula. Amendment (ii) is based on paragraph [0024] of the application as filed. Finally, for the same reasons as given with regard to claim 1, amendments (iii) and (iv) do not lead to any objections under Article 123(2) EPC.

The objection raised in the board's first communication under Article 123(2) EPC with regard to the wording "added lutein" in claim 2 of the previous main request has been met by the deletion of the term "added".

3.3 Claim 3 is based on paragraph [0024] and claim 3 of the application as filed.

3.4 Claims 4 and 5 are based on claims 5 and 6 as filed.

3.5 Claim 6 corresponds to claim 7 as filed except that the unit kcal/fluid ounce has been converted to kcal/litre.

3.6 Claim 7 is based on claim 12 as filed.

3.7 Claims 8 to 10 are based on claims 14 to 16 as filed with the claim category having been changed from a therapeutic method to a product claim.

3.8 The board does not see any reason to object to the amended description pages under Article 123(2) EPC.

3.9 The replacement main request thus meets the requirement of Article 123(2) EPC.

4. Novelty

4.1 The only documents that might be considered to be of relevance as regards novelty are D1 and D2.

4.2 Example 1 of D1 discloses a liquid infant formula being free of egg phospholipids and containing fat (various oils), protein (whey protein), carbohydrate (lactose), vitamins (water soluble vitamin premix and Vitamin ADEK premix), minerals (calcium carbonate, magnesium chloride, potassium chloride, ferrous sulphate and potassium hydroxide), lutein ("Lutein solution (5.0% active)") and docosahexaenoic acid ("DHA-containing oil (40% DHA)").

The lutein is present in the form of 0.388g of a 5% solution in 454 kg of the liquid composition. The lutein concentration thus is 43 µg/kg liquid

composition. Assuming in the appellant's favour a density of this liquid composition as low as 1 kg/litre, this corresponds to a lutein amount of 43 µg/litre liquid composition, which is below the lower limit of claim 1. For higher densities, the lutein amount in µg/litre would even be lower and thus still farther away from the claimed lower limit.

4.3 Examples 2 and 3 of D1 refer to powdered formulae contrary to the formula of claim 1, which is a ready-to-feed liquid.

The powdered formulae of examples 2 and 3 are prepared by spray drying previously liquid compositions. The ingredients used to prepare these liquid compositions are disclosed in the tables on pages 8 and 9 of D1. One of these ingredients is 0.003 kg of a 5% lutein solution (example 2) and 0.000939 kg of a 20% lutein solution (example 3), respectively. In addition to the ingredients listed in the two tables, water is added (Example 2: third line of paragraph [0082], second line of paragraph [0083], and first two lines of paragraph [0086]; Example 3: fifth line of paragraph [0090], second and third line of paragraph [0092], second and third line of paragraph [0094] and and first to second line of paragraph [0095]). The amount of added water is not specified in the two examples, which means that the total amount of liquid composition present before spray drying is unknown. Therefore, it is not possible to calculate the amount of lutein per litre of this liquid composition. Hence, the liquid compositions of examples 2 and 3 prior to spray drying cannot anticipate the subject-matter of claim 1.

The composition of the only remaining example 4 of D1 differs from the claimed subject-matter in that no docosahexaenoic acid is present.

The subject-matter of claim 1, and by the same token of all remaining claims 2 to 10, is thus novel over D1.

4.4 D2 discloses infant formulae containing lutein and zeaxanthin ([0001]) and reports positive effects on the human retina and visual acuity ([0003]). The combined amount of lutein and zeaxanthin is preferably 15 to 44 µg ([0015]). The composition of the only example (example 1) contains 25 µg of a combination of lutein and zeaxanthin in one litre reconstituted composition. The lutein amount must thus be below the claimed lower limit.

Consequently, the subject-matter of claim 1 and by the same token of all remaining claims 2 to 10 differs from the disclosure of D2 at least in terms of the lutein amount per litre of liquid (reconstituted) formula.

4.5 The subject-matter of the replacement main request thus is novel.

5. Inventive step

5.1 The present application concerns infant formulae containing a select combination of docosahexaenoic acid and lutein for promoting retinal health and vision development in infants (paragraph [0001]).

5.2 In the same way as the present application, D1 deals among others with the problem of vision development in infants (paragraphs [0005] and [0006]) and discloses compositions comprising both lutein and docosahexaenoic

acid (examples). In line with the examining division's decision, D1 can therefore be considered to represent the closest prior art.

As set out above, in the only formula exemplified in D1 for which the amount of lutein per litre of ready-to-feed liquid formula is known (example 1), this amount is below the lower limit of the claimed range.

5.3 The problem underlying the present application in the light of D1 is the provision of an infant formula that leads to the same plasma lutein concentration as found in infants fed with human milk (paragraph [0007]), which is generally considered to be the "gold standard".

5.4 As a solution to this problem, the present application proposes the ready-to-feed liquid formula according to claim 1 which contains lutein and docosahexaenoic acid and which is characterised by having a lutein amount of at least 75 µg/litre.

5.5 It has been found in the present application that having an identical lutein content in an infant formula and human milk leads to considerably different plasma lutein concentrations. It would normally be expected that if the lutein content was the same in both compositions, identical plasma concentrations would result. However this has been found in the present application not to be the case (paragraph [0007]). This is demonstrated by figure 1 of the present application which is a graph of lutein intake and corresponding plasma lutein concentrations. The formulation L1 contains the same amount of lutein as human milk HM (see the bars in the figure indicating a lutein intake of slightly more than 30 µg/l for both the formula L1

and human milk HM). However, the plasma lutein level is significantly lower when infants are fed with the formula L1 rather than human milk. More specifically, the formula L1 leads to a plasma lutein concentration of 2.21 µg/dl while a plasma lutein concentration as high as 5.88 µg/dl is achieved with human milk (table on page 27 and figure 1).

It has furthermore been found, as shown for composition L2 in figure 1, that increasing the lutein content in the infant formula results in increased plasma lutein levels. More specifically, by increasing the lutein amount from 32.6 µg/l (formula L1) to 52.6 µg/l (formula L2), the plasma lutein concentration increased from 2.21 µg/dl to 3.25 µg/dl (table on page 27 and figure 1). It is thus credible that by even further increasing the lutein concentration in the infant formula to a level of at least 75 µg/l (the lower limit of claim 1), the plasma lutein concentration can be increased to a level similar to that found in human breast milk. The problem of providing an infant formula that leads to the same plasma lutein concentration as found in breast fed infants has thus been solved. Consequently, this problem constitutes the objective technical problem. It is noted in this respect, that the problem formulated by the examining division, namely the provision of an alternative infant formula with high lutein content, already contains part of the claimed solution, namely the use of a high amount of lutein. This is not permissible when formulating the objective technical problem.

5.6 In D1, the lutein is not added to provide bioavailable lutein in the plasma but is rather added to reduce or eliminate the red-orange hue of beta-carotene when it is used as an antioxidant in a powder nutritional

formulation (paragraphs [0015] and [0016] of D1). Therefore, the plasma lutein levels obtained after feeding the infant formula of D1 are not relevant to the underlying disclosure of this document since the lutein only needs to be part of an antioxidant system up until the formulation is consumed. The skilled person reading D1 and trying to obtain plasma lutein concentrations similar to those in breast fed infants would thus have had no reason to increase the amount of lutein in the infant formula of D1.

Furthermore, D2 teaches away from the claimed high lutein amount since it teaches a lutein amount equal to that present in human breast milk (first sentence of paragraph [0016] of D2) with the most preferred amount being about 25 µg/l (paragraph 0015]). The skilled person would thus not have chosen the claimed high lutein amounts in the infant formula of D1 when having read D2.

D3 is not relevant since this document does not deal with lutein. The same is true for D4 since this document deals with adult subjects. Finally, D5 is of no relevance since it cannot be concluded from this document that lutein amounts higher than those present in human breast milk need to be administered.

5.7 The subject-matter of claim 1, and by the same token of all remaining claims 2 to 10, is therefore inventive.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division with the order to grant a patent on the basis of:

   (a) claims 1 to 10 according to the replacement main request,

   (b) the amended description pages 1 to 28,

   both as filed during the oral proceedings of 7 November 2014, and

   (c) the figures, sheets 1/1 and 2/2, as originally filed.

The Registrar: The Chairman:

M. Cañueto Carbajo W. Sieber

Decision electronically authenticated