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Datasheet for the decision of 27 May 2025

Case Number: T 0961/23 - 3.3.09

Application Number: 16757260.1

Publication Number: 3340810

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Language of the proceedings: EN

Title of invention:
SYNTHETIC NUTRITIONAL COMPOSITIONS TAILORED FOR INFANTS OF SPECIFIC AGES, AND NUTRITIONAL SYSTEMS COMPRISING THEM

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponents:
MJN U.S. Holdings LLC
N.V. NUTRICIA

Headword:
Synthetic nutritional compositions/NESTLÉ

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

Keyword:
Inventive step
Amendments

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Boards of Appeal

Chambres de recours

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Case Number: T 0961/23 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 27 May 2025

Appellant: (Opponent 2)	N.V. NUTRICIA Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
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Representative:	Bovill, Sally Marina Reckitt Benckiser Corporate Services Limited Legal Department - Patents Group Dansom Lane Hull HU8 7DS (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on**

8 May 2023 concerning maintenance of the European Patent No. 3340810 in amended form.

Composition of the Board:

Chairman	A. Haderlein
Members:	F. Rinaldi
	N. Obrovski

Summary of Facts and Submissions

I. This decision concerns the appeal filed by opponent 2 (appellant) against the opposition division's interlocutory decision.

II. With the notice of opposition, the opponent had requested that the patent be revoked for lack of inventive step, Article 100(a) EPC, among other grounds for opposition.

III. The documents submitted during the opposition proceedings included:

D1: E. R. Boersma *et al.*, "Vitamin E, lipid fractions, and fatty acid composition of colostrum, transitional milk, and mature milk: an international comparative", The American Journal of Clinical Nutrition 53, 1991, 1197-204

D2: Y. Katoku *et al.*, "Effect of the cholesterol content of a formula on the lipid compositions of plasma lipoproteins and red blood cell membranes in early infancy", The American Journal of Clinical Nutrition 64, 1996, 871-7

D7: J. Bitman *et al.*, "Comparison of the lipid composition of breast milk from mothers of term and preterm infants", The American Journal of Clinical Nutrition 38, August 1983, 300-12

D8: G. Harzer *et al.*, "Changing patterns of human milk lipids in the course of the lactation and during the day", The American Journal of Clinical Nutrition 37, April 1983, 612-21

D9: H. M. M. Ramalho *et al.*, "Total Cholesterol and Desmosterol Contents in Raw, UHT, Infant Formula Powder and Human Milks Determined by a New Fast Micro-HPLC Method", Food Analytical Methods 4, 2011, 424-30

D10: US 2012/135103 Al

D11: EU regulation 2016/127

D14: C. Barbas *et al.*, "Lipid composition and vitamin E content in human colostrum and mature milk", Journal of Physiology and Biochemistry 54(3), 1998, 167-74

D15: G. Harzer *et al.*, "Biochemistry of human milk in early lactation", Zeitschrift für Ernährungswissenschaft 25, 1986, 77-90

IV. In the decision under appeal, new auxiliary request 3 was found to be allowable. This request is the main request that underlies this decision.

V. On appeal, the patent proprietor (respondent) maintained a total of 11 auxiliary requests, all filed by letter dated 17 March 2025.

VI. The following claims are relevant for this decision.

Claim 1 of the main request reads:

"*Use of a nutritional system comprising a synthetic nutritional composition tailored for an infant of up to 2 months of age wherein the cholesterol concentration is 30.34 to 100.19 µg/ml, and a synthetic nutritional composition tailored for an infant from 2 months of age wherein the cholesterol concentration is 14 to 114.26 µg/ml, wherein, the cholesterol concentration in said synthetic nutritional composition tailored for an infant of up to*

2 months of age is higher than that of said synthetic nutritional composition tailored for an infant from 2 months of age,
and wherein
wherein [sic] the synthetic nutritional compositions tailored for an infant of up to 2 months of age comprises 13 to 47 µg/ml more cholesterol than the synthetic nutritional compositions tailored for an infant from 2 months of age,
and wherein
a nutritional system is a collection of more than one synthetic nutritional composition
and wherein
the synthetic nutritional composition tailored for an infant of a specific age is [sic] infant formula to feed an infant, wherein the synthetic nutritional composition tailored for an infant of up to 2 months of age is only fed to the infant up to 2 months of age and the synthetic nutritional composition tailored for an infant from 2 months of age is only fed to the infant from 2 months of age."

Claim 1 of auxiliary request 1 is based on claim 1 of the main request, with the feature that the nutritional system is a collection of more than one synthetic nutritional composition being deleted.

Claim 1 of auxiliary request 2 is based on claim 1 of the main request, with the feature regarding the collection being further characterised.

Claim 1 of auxiliary request 3 is based on claim 1 of the main request, with the composition tailored for an infant of up to 2 months of age, the cholesterol concentration being restricted to the range of 43 to 78 µg/ml, and the composition tailored for an infant

from 2 months of age, the cholesterol concentration being restricted to the range of 26 to 69 µg/ml.

Claim 1 of auxiliary requests 4 and 5 include the modified ranges of claim 1 of auxiliary request 3.

Claim 1 of auxiliary requests 6 to 11 is based on claim 1 of the main request and auxiliary requests 1 to 5, respectively, with the further modification that the claims are directed to a specified medical use.

VII. The appellant's arguments are summarised as follows.

- Claim 1 of the main request lacked inventive step. Starting from D10 as the closest prior art, there were only two distinguishing features, namely:
  - the cholesterol concentration of the composition for an infant of up to 2 months of age
  - switching the administration of the compositions at the age of 2 months

  In light of the scientific publications D1, D7 to D9, D14 and D15, no effect was demonstrated. The problem was to provide an alternative feeding regime for infants. The claimed solution would have been obvious to the skilled person.
- The amendment in claim 1 of auxiliary request 3 was not allowable in view of the combination of ranges, among other things.

VIII. The respondent's arguments are summarised as follows.

- Claim 1 of the main request involved an inventive step. Its subject-matter differed over D10 in:
  - the cholesterol concentration of the composition for an infant of up to 2 months of age

- the difference in cholesterol concentrations between the first and second compositions
- the feature that the compositions for an infant of up to 2 months of age is only fed to infants of up to 2 months of age and the composition for an infant from 2 months of age is only fed to the infant from 2 months of age

In view of the results of the clinical study in the patent (example 1), it was possible to provide nutritional compositions that accurately reflected the cholesterol concentrations found in human milk produced for infants at the corresponding stage of lactation. The problem was to provide an improved nutritional system for infants, and it was solved in a non-obvious way.

- The amendment in claim 1 of auxiliary request 3 was allowable. There were pointers to the combination of features included in the claim.

IX. Final requests

The appellant requested that the decision under appeal 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 11, filed by letter dated 17 March 2025.

Reasons for the Decision

1. *Patent in suit and main request*

1.1 The patent concerns a nutritional system comprising synthetic nutritional compositions tailored for infants of specific ages and their use to provide an optimised amount of cholesterol and health benefits to an infant (paragraph [0001]).

1.2 The sole claim of the main request, as amended during the opposition proceedings, is restricted to the use of the compositions of the nutritional system for feeding an infant. The restriction involves, among other things, that the synthetic nutritional composition tailored for an infant of up to 2 months of age is only fed to the infant up to 2 months of age and that the synthetic nutritional composition tailored for an infant from 2 months of age is only fed to the infant from 2 months of age.

1.3 The board's view is that the term "tailored for" does not imply any restriction other than that the composition has to be suitable for being fed to the infant.

2. *Main request - inventive step*

2.1 The opposition division arrived at the conclusion that starting from D10 as the closest prior art, the subject-matter claimed of the current main request involved an inventive step. Its reasoning was as follows.

- D10 included a teaching to provide a first composition having a higher cholesterol concentration than the second composition, namely:

  - a first nutritional composition for feeding a newborn infant (from birth through 4 months of age) that comprised at least about 3.95 mg/100 kcal of cholesterol, more preferably, from about 4.00 to about 4.90 mg/100 kcal of cholesterol
  - a second nutritional composition for feeding a later stage infant (from 4 months of age through 1 year) that comprised no more than about 3.90 mg/100 kcal of cholesterol, more preferably, from about 2.60 to about 3.85 mg/100 kcal of cholesterol

- Thus, D10 did not disclose the combination of the following features of claim 1:

  - the cholesterol concentration for the composition for an infant of up to 2 months of age
  - the difference in cholesterol concentration between the two compositions
  - the feature that the compositions for an infant of up to 2 months of age is only fed to infants of up to 2 months of age and the composition for an infant from 2 months of age is only fed to the infant from 2 months of age

- In view of the data in the patent, a method of feeding an infant using a nutritional system containing two nutritional compositions was provided that more accurately reflected the cholesterol concentrations found in human milk

produced for infants at the corresponding stage of lactation.

- The problem to be solved was to provide an improved process for feeding an infant.
- The solution would not have been obvious to the skilled person in view of the cited prior art.

2.2 The parties agree that D10 is the closest prior art. The board concurs.

2.3 The distinguishing features of claim 1 were in dispute.

2.3.1 D10 concerns a staged nutritional feeding regime for infants which involves a first composition having a higher cholesterol concentration than the second composition. As correctly set out in the decision under appeal (see point 2.1 above), in the first composition, the preferred cholesterol concentration is 4.00 to 4.90 mg/100 kcal; in the second, it is 2.60 to 3.85 mg/100 kcal.

2.3.2 The appellant argued that the difference in cholesterol concentration between the two compositions was not a distinguishing feature. Considering both the ranges for the preferred cholesterol concentrations disclosed in D10 and the fact that infant milk formula typically comprised 60 to 70 kcal per 100 ml (as set out in EU Regulation 2016/127, D11, Annex 1), a value within the range of claim 1 was disclosed.

2.3.3 Still according to the appellant's calculations, if the nutritional composition were to comprise 60 kcal per 100 ml, the difference between the first and the second composition was between about 1 to 14 µg/ml. If the nutritional composition comprised 70 kcal per 100 ml,

the difference was slightly higher, namely, up to about 16 µg/ml.

2.3.4 The appellant's calculations are made on the reasonable assumption that nutritional compositions correspond to normative requirements, such as those set out in D11. The respondent did not propose an alternative approach for converting the units used in D10 (mg/100 kcal) into those applied in the patent in suit (µg/ml).

2.3.5 Nevertheless, taking the appellant's calculations at face value, they illustrate that there is only a partial overlap between the value ranges calculated from D10 and those in claim 1.

2.3.6 In the case in hand, it is not required to conclude whether in view of the partial overlap a distinguishing feature is to be acknowledged.

2.3.7 In view of the negative conclusion on inventive step arrived at below, the question as to whether the difference in cholesterol concentration between the two compositions constitutes a distinguishing feature can remain open. The board proceeds assuming that the difference between the first and the second composition is a distinguishing feature, in line with the view of both the opposition division and the respondent.

2.3.8 In sum, the following features are regarded as being distinguishing features of claim 1 over D10.

- The cholesterol concentration of the composition suitable for an infant of up to 2 months of age is 30.34 to 100.19 µg/ml.

- The difference in cholesterol concentration between the two compositions is 13 to 47 µg/ml.

- The feature that the compositions for an infant of up to 2 months of age is only fed to the infant of up to 2 months of age and the composition for an infant from 2 months of age is only fed to the infant from 2 months of age.

2.4 Technical effect and problem

2.4.1 As regards the effect of the distinguishing features, the respondent argued that the inventors had designed a nutritional system containing the synthetic nutritional compositions for infants of specific ages. The nutritional system was based on a representative study, shown in example 1 of the patent, and its statistically significant results obtained from analysing human milk. The system of claim 1 comprised cholesterol in a concentration that more accurately reflected the cholesterol concentrations found in human milk produced for infants at the corresponding stage of lactation. In view of this, the problem had be formulated as the provision of an improved process for feeding an infant.

2.4.2 The board observes first that to acknowledge an effect to be retained for formulating the problem to be solved, this effect must be credible in view of D10, the closest prior art. In D10, switching from the first infant formula to the second is carried out at 4 months (see paragraphs [0001] and [0056]).

2.4.3 Example 1 of the patent discloses data collected from a clinical trial with 50 lactating mothers. Milk was sampled at 30, 60 and 120 days after birth and quantitatively analysed for cholesterol. The mean

cholesterol concentrations at 30, 60 and 120 days are 60.48, 47.16 and 47.62 µg/100 ml, respectively. The minimum and maximum values measured are also disclosed in example 1. The study's conclusion is that there is a statistically significant difference in the cholesterol content of human milk produced at 0 up to 2 months after birth and from 2 months after birth.

2.4.4 The administration pattern of claim 1 is modelled upon the results shown in the study of example 1. It can be accepted that emulating human milk, the gold standard in human infant nutrition, is generally considered desirable. However, the question is whether in the case in hand implementing the results of the study provides an improvement that can be reflected in the formulation of the problem to be solved. The question is whether the claimed subject-matter results in a better emulation of human milk over the closest prior art D10 or, put differently, whether by applying the claimed uses, the profile of the administered cholesterol comes closer to the one of human milk when compared to the one administered in D10.

2.4.5 The respondent argued that by switching from the first composition to the second composition at 4 months, as done in D10, the infant would be receiving too much cholesterol during the period of 2 to 4 months. Put differently, according to the respondent, the claimed use results in a cholesterol level in the period of 2 to 4 months which is closer to the one of human milk.

2.4.6 This is not persuasive. As can be seen from the calculations of the appellant, in D10 the cholesterol concentrations administered to an infant in the first four months are at the lower end of those envisaged by the (wide) ranges disclosed in claim 1 (both for the

first and the second compositions). In other words, according to claim 1, much higher cholesterol concentrations can be administered to an infant from 2 months of age than those disclosed in D10 during the period of 2 to 4 months. This means that it cannot be concluded that the cholesterol profile according to the claimed use comes closer to the one according to D10.

2.4.7 Moreover, there is no evidence that the distinguishing features provide any difference in effect over the system disclosed in D10. The patent presents no comparison between switching cholesterol intake at 2 months after birth rather than at 4 months. There is also no data demonstrating that maintaining the levels of cholesterol in the period of 2 to 4 months after birth at the levels shown in D10 results in a less optimal outcome for the infant.

2.4.8 In the absence of comparative data, lowering the cholesterol levels in the nutritional system at 2 months of age rather than at 4 months can only be seen to be arbitrary, in particular given the scope of the claim. Similarly, there is no evidence that the changes in concentrations provide a technical effect going beyond that of D10.

2.4.9 For completeness, even if it were acknowledged that there was some kind of improvement for an infant when the amount of cholesterol is reduced after 2 months from birth, any such improvement could only be accepted if it were the same infant who receives the first composition up to 2 months of age and then, from 2 months of age, the second composition, as would be the case with an infant obtaining milk from its mother. Claim 1, however, does not provide for this requirement. The same infant receiving the first

composition up to 2 months of age and then, from 2 months of age, the second composition is not required by claim 1, as even the respondent acknowledged.

2.4.10 The appellant also argued that the studies in D1, D7 to D9, D14 and D15 showed that the subject-matter of claim 1 did not provide an improvement that can be retained in the formulation of the problem to be solved. The respondent argued that the credibility of these publications was somewhat lower than of the study of example 1 of the patent due to the large number of participants and the statistical significance of the data in the latter.

2.4.11 On this matter, the following observations are made.

- Each of the publications D1, D7 to D9, D14 and D15 discloses a study on the composition of human milk, including its cholesterol concentration. Taken together, these studies - carried out independently in various regions of the world - show that the cholesterol concentration in human milk is highest in the first 2 weeks after birth and then gradually drops over the period monitored in the study (e.g. days 40, 60 and 120 after birth in D9).

- The studies in D1, D7 to D9, D14 and D15 were published in journals in the field of nutrition and analytics. It has to be assumed that the content of the studies was peer reviewed prior to publication. The data in the publications are presented together with the deviations measured. In some cases, the statistical significance of the data is explicitly mentioned. Thus, no reason can be seen for not taking the disclosure and the results of these publications at face value.

- Nevertheless, in view of the conclusions arrived at above, documents D1, D7 to D9, D14 and D15 do not need to be discussed for the effects achieved by the subject-matter of claim 1.

2.4.12 To conclude, the problem to be solved is to provide an alternative nutritional system.

2.5 Obviousness

2.5.1 Considering the general, comprehensive teaching in the prior art on the concentration of cholesterol in human milk over the first months of lactation, it cannot be concluded that the claimed solution would have been non-obvious to the skilled person.

2.5.2 In view of the disclosure in the scientific publications D1, D7 to D9, D14 and D15, the skilled person would have modified the feeding regime of D10 by starting the administration of the second formula at a time earlier than 4 months after birth, for example, at 2 months after birth. They would have been motivated to increase the amount of cholesterol in the composition administered in the first period after birth. It stands to reason that any mean value between what the prior art discloses and the low concentration disclosed in D10 would be acceptable. Increasing the amount of cholesterol in the composition administered in the first period after birth would also have increased the difference in cholesterol concentration between the first and the second compositions.

2.5.3 For completeness, the adjustments provided, namely the amount of the cholesterol concentration for the first composition (30.34 to 100.19 µg/ml) and the difference

in cholesterol concentrations between the first and second compositions (13 to 47 µg/ml), also involve obvious features.

2.5.4 Moreover, the difference in cholesterol concentrations between the first and second compositions of claim 1 overlaps with the range that D10 suggests. Furthermore, D2 shows that wide ranges of cholesterol concentrations (42 and 84 µg/ml) are generally suitable for feeding infants.

2.6 Therefore, the subject-matter of claim 1 of the main request does not comply with the requirement of Article 56 EPC.

3. *Auxiliary requests 1 and 2*

3.1 As can be seen from point VI. above, the modifications in claim 1 of auxiliary requests 1 and 2 concern the term "collection" in claim 1. These requests were filed to address objections raised by the appellant under grounds for opposition other than Article 56 EPC.

3.2 It was not argued that these requests were suitable to resolve any of the issues of lack of inventive step identified above for the main request. The board cannot discern that these requests would lead to a different assessment of inventive step compared to the main request, either.

3.3 Therefore, claim 1 of auxiliary requests 1 and 2 does not involve an inventive step (Article 56 EPC).

4. *Auxiliary requests 3 to 5*

4.1 The appellant argued that claim 1 of auxiliary request 3 did not comply with the requirement of Article 123(2) EPC.

4.2 Claim 1 of auxiliary request 3 (see the wording in point VI. above) is characterised, among other things, by the following features.

- The category of the claim was changed from a product claim to a use claim, and the suitability of the compositions was specified to be a step of the use.

- The cholesterol concentration in the first composition is restricted to 43 to 78 µg/ml.

- The cholesterol concentration in the second composition is restricted to 26 to 69 µg/ml.

- The first composition comprises 13 to 47 µg/ml more cholesterol than the second composition, i.e. the difference in cholesterol concentration between the two compositions is 13 to 47 µg/ml.

4.3 To assess whether claim 1 of auxiliary request 3 complies with the requirement of Article 123(2) EPC, claim 7 of the application as filed has to be considered. The respondent referred to claim 7 as being the basis for the amendments.

4.4 Claim 7 of the application as filed is directed to a nutritional system, not a use with specified use steps. By back reference to claim 3 of the application as

filed, the system comprises a composition for an infant of up to 2 months of age (i.e. the first composition) with a cholesterol concentration of 30.34 to 100.19 µg/ml and a composition for an infant from 2 months of age (the second composition) with a cholesterol concentration of 14 to 114.26 µg/ml. Claim 7 also requires that the cholesterol concentration of the first composition is higher than in the second composition (although the range for the second composition discloses the highest value, namely 114.26 µg/ml).

4.5 The amendment regarding the cholesterol concentration in the first composition is taken from a passage on page 4, lines 16 to 18 of the application as filed that discloses four possible ranges for this composition. Similarly, the cholesterol concentration in the second composition is taken from a passage on page 4, lines 19 to 21 of the application as filed that also discloses four possible ranges for this composition.

4.6 There is no disclosure in the application as filed that, if in the first composition the cholesterol concentration is 43 to 78 µg/ml, the cholesterol concentration in the second composition has to be 26 to 69 µg/ml. In other words, there is no reason for combining these two ranges.

4.7 The respondent argued that the two ranges added to claim 1 were mentioned in the same position within the list of possible ranges disclosed in lines 16 to 18 and in lines 19 to 21. This constituted a pointer towards combining the two ranges added to claim 1.

4.8 Even if this argument were accepted, there is no direct and unambiguous disclosure for combining these two

ranges with the range for the difference in cholesterol concentration between the first composition and the second composition.

4.9 Claim 7 of the application as filed only requires that the cholesterol concentration of the first composition is higher than in the second composition. Examples 2 and 3 of the application as filed disclose that the difference between the cholesterol concentration of the first composition is 10 µg/ml higher than for the second composition. The study in example 1 apparently suggests a difference of 13 µg/ml. In addition, ranges for the difference between the two compositions are disclosed on page 10, lines 20 to 22. But there is no disclosure that would have led the skilled person, directly and unambiguously, to combine the range of the difference in cholesterol concentration between the two compositions of 13 to 47 µg/ml with the other two ranges (43 to 78 µg/ml and 26 to 69 µg/ml) required by claim 1.

4.10 To conclude, claim 1 of auxiliary request 3 does not comply with the requirement of Article 123(2) EPC.

4.11 Claim 1 of auxiliary requests 4 and 5 include the same amendments as auxiliary request 3. Thus, these requests do not fulfil the requirement of Article 123(2) EPC either.

5. *Auxiliary requests 6 to 11*

5.1 Claim 1 of auxiliary requests 6 to 11 includes the further modification that the claims are directed to a specified medical use. The amendments to these requests were made to address an objection under

Article 53(c) EPC raised by the appellant in its statement of grounds of appeal.

5.2 The respondent did not argue that this request was suitable for resolving any of the issues of lack of inventive step identified above for the main request. The board cannot discern that these requests would lead to a different assessment of inventive step compared to main request, either.

5.3 It follows from this that these requests do not comply with the requirement of Article 56 EPC.

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:

K. Götz-Wein A. Haderlein

Decision electronically authenticated