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Datasheet for the decision of 15 November 2024

Case Number: T 0249/22 - 3.3.09

Application Number: 14805253.3

Publication Number: 3073844

IPC: A23L33/17, A23L33/00

Language of the proceedings: EN

Title of invention:
AGE-TAILORED NUTRITIONAL COMPOSITIONS WITH A VARYING PROTEIN CONTENT

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponents:
Reckitt Benckiser Health Limited
N.V. NUTRICIA

Headword:
Age-tailored nutritional composition/NESTLE

Relevant legal provisions:
EPC Art. 83, 111(1)
RPBA 2020 Art. 12(4), 11

Keyword:
Sufficiency of disclosure - (yes)
Remittal - (yes)

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Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 0249/22 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 15 November 2024

Appellant: (Patent Proprietor)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Strych, Sebastian Mitscherlich PartmbB Patent- und Rechtsanwälte Karlstraße 7 80333 München (DE)
Respondent: (Opponent 1)	Reckitt Benckiser Health Limited 103-105 Bath Road Slough Berkshire SL1 3UH (GB)
Representative:	Carlin, Robert George Reckitt Benckiser Corporate Services Limited Legal Department - Patents Group Dansom Lane Hull HU8 7DS (GB)
Respondent: (Opponent 2)	N.V. NUTRICIA Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 2 December 2021 revoking European patent No. 3073844 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chair	A. Veronese
Members:	F. Rinaldi
	N. Obrovski

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the patent proprietor (appellant) against the opposition division's decision to revoke the patent.

II. In the opposition proceedings, opponents 1 and 2 (respondents 1 and 2, in the following also "the respondents") had requested that the patent be revoked under Article 100(b) EPC, among other grounds.

III. With its statement setting out the grounds of appeal, the appellant filed nine auxiliary requests. In addition, it filed the following document:

D18: Declaration of Nicholas P. Hays (6 April 2022)

IV. With its reply to the appellant's statement setting out the grounds of appeal, respondent 1 filed the following document:

D19: V. Grote *et al.*, "Effect of milk protein content in toddler formula on later BMI and obesity risk: protocol of the multicentre randomised controlled Toddler Milk Intervention (ToMI) trial", BMJ Open 2021, 11:e048290, 1-8

V. The board summoned the parties to oral proceedings. In its communication under Article 15(1) RPBA, the board set out its preliminary opinion that documents D18 and D19 were to be admitted and that the invention as claimed was sufficiently disclosed. After receiving the

preliminary opinion, the respondents withdrew their requests for oral proceedings. The board then cancelled the oral proceedings.

VI. Only the main request, which consists of claims 1 to 16 as granted (claim 17 as granted was deleted), is relevant to this decision. Claim 1 reads as follows.

"*Age-tailored nutritional composition system comprising:*

- *at least one nutritional composition A that is administered to an infant from birth and until 3-6 months of life of said infant,*
- *at least one nutritional composition B that is administered to an infant from 3-6 months and until 1 year of life of said infant,*
- *at least one nutritional composition C that is administered after the first year of life of the young child,*

wherein the nutritional compositions A, B and C are sequentially administered to the infant/young child;
wherein said nutritional compositions A and B comprise an amount of protein between 1.5 and 3.0 g/100kcal;
wherein the amount of protein of the nutritional composition(s) B is lower than the amount of protein of the nutritional composition(s) A;
and wherein the amount of protein of the nutritional composition C is at least 1.3 g/100kcal but is lower than the amount of protein of the nutritional compositions A and B,
wherein the amount of protein of the at least one nutritional composition C is comprised between 1.3 and 1.5 g/100kcal,
for use in an infant or young child to reduce the risk of developing obesity later in said infant's or young child's life or to reduce the IGF-1 level."

VII. The appellant argued that the technical concept underlying the invention was credibly supported by examples 5 and 6 of the patent and the common general knowledge. This was confirmed by D18 and D19. The opposition division was wrong in requiring absolute proof of the claimed effects. In doing so, it unlawfully shifted the burden of proof onto the patent proprietor.

VIII. The respondents argued that the invention was insufficiently disclosed. The experiments in the patent were carried out with two compositions, A and B, being administered sequentially during an infant's first year of life. However, none of these experiments involved the administration of a nutritional composition system comprising the third composition, "composition C", identified in claim 1. Thus there was no experimental data demonstrating that the claimed effects were achieved after the first year of the infant's life.

IX. Final requests

The appellant requested that the decision under appeal be set aside and that sufficiency of disclosure be acknowledged for the main request, or alternatively for auxiliary requests 1 to 9, all filed with the statement setting out the grounds of appeal, and that the case be remitted to the opposition division for further prosecution.

The respondents requested that the appeal be dismissed and that, if one of the requests were found to be sufficiently disclosed, the case be remitted to the opposition division for further prosecution.

Reasons for the Decision

1. *Opposed patent*

The opposed patent relates to an age-tailored nutritional composition system for use in infants and young children to reduce the risk of developing obesity later in the infant's or young child's life or to reduce the IGF-1 level. The system comprises three nutritional compositions: two nutritional compositions A and B (e.g. two infant formulas), administered during the first year of an infant's life, and one nutritional composition C (e.g. a growing-up milk), administered after the first year of life. The protein content of these nutritional compositions decreases as the age of the infant/young child increases.

2. *Admittance of D18 and D19*

2.1 The appellant filed declaration D18 with its statement setting out the grounds of appeal and requested that the document be admitted into the proceedings. D18 is drafted by a technical expert who is an employee of the patent proprietor.

2.2 The respondents' view was that D18 should not be admitted: it should have been filed earlier, during the opposition proceedings. Moreover, respondent 1 noted that if D18 were admitted, D19 would have to be admitted too. The appellant itself then requested that D19 be admitted into the proceedings.

2.3 The board considers that, while some sections of D18 arguably could have been filed earlier, the part of D18

that concerns a document seemingly not published before 21 November 2021 (namely D19) could not have been filed before the opposition division took its decision at oral proceedings.

2.4 Considering that D18 and in particular D19 supplement the picture presented during the opposition proceedings on sufficiency of disclosure, and that these documents cause no substantial change in the issues which need to be discussed, the board exercised its discretion to admit these documents into the appeal proceedings (Article 12(4) RPBA).

3. *Main request - sufficiency of disclosure*

3.1 The opposition division concluded that the patent in the form of the main request did not meet the requirement of sufficiency of disclosure of the invention. In its view, none of the patent's examples used a nutritional composition system comprising compositions A, B and C of claim 1. There was no tangible experimental data having probative value that the effects achieved in example 5 during the first year of an infant's life, feeding compositions A and B only, could be extrapolated to a period later in life. In the absence of any relevant experimental data rendering the invention sufficiently plausible, the opponents were not required to provide counter-evidence.

3.2 It is uncontested that claim 1 requires that compositions A, B and C be administered sequentially at the child's age specified in the claim. This is implicitly confirmed by the respondents' line of argument provided on sufficiency of disclosure and the underlying interpretation of claim 1. The board will

examine the case based on this interpretation of the claim.

3.3 Claim 1 relates to two separate technical effects or uses in an infant or young child, namely a reduction in:

(i) the IGF-1 level
(ii) the risk of developing obesity later in the infant's or young child's life

3.4 These effects are dealt with separately in the following.

3.5 Effect (i) - reducing the IGF-1 level

3.5.1 Unlike effect (ii), claim 1 does not require that effect (i) be observed later in life. In other words, effect (i) is achieved during the period in which the infant or child is fed the compositions of claim 1.

3.5.2 The opposition division acknowledged that example 5 demonstrated that "*the use of compositions A and B, with a falling amount of protein over time, results in a reduced weight gain and a reduction of IGF-1 levels during the first year of life, as compared to compositions with a constant, high protein level*" (decision under appeal, page 6), but noted that the example did not disclose the protein level after the first year of life. Therefore example 5 did not correspond to the age-tailored nutritional composition system of claim 1 and was not suitable to demonstrate that the effects mentioned in the claim were achieved.

3.5.3 However, the reduction in the IGF-1 level observed in example 5, when switching from composition A (which

comprises a high amount of protein) to composition B (which comprises a lower amount of protein), supports the concept set out in paragraph [0152] of the patent that a high protein intake promotes the secretion of IGF-1. It also makes it credible that a further decrease in the protein amount, e.g. by using composition C, which has an even lower amount of protein than composition B, will induce a further reduction in the IGF-1 level.

3.5.4 The respondents also provided no explanation as to why the skilled person might expect that the additional administration of composition C would reverse the positive effects induced by the sequential administration of compositions A and B.

3.5.5 Finally, as the appellant correctly argued, no "absolute proof" is required to pass the hurdle set by Article 83 EPC.

3.5.6 On this basis, the invention is considered to be sufficiently disclosed as regards effect (i).

3.6 Effect (ii) - reducing the risk of obesity

3.6.1 As to effect (ii), claim 1 requires reducing the risk of developing obesity later in life. So one question is what has to be done to demonstrate that the effect is achieved later in life.

3.6.2 For the appellant it was "*fully plausible for a skilled person that the effects are still present slightly after 1 year of life, which falls within the scope of 'later in life'*" (letter dated 27 October 2022, page 7).

3.6.3 Indeed, based on the data in example 5, there is no reason to doubt that obesity can be prevented in the period shortly after 12 months of a child's life. Young children fed with nutritional compositions A and B show a lower weight after 12 months compared with children of the control group. Shortly after this period, the young children fed with nutritional compositions A and B are not likely to reach the same weight as the children of the control group (or even an obese status). So it is conclusive that the risk of developing obesity is reduced in the first months after the first year of an infant's life.

3.6.4 Claim 1, however, sets out an open-ended time range. In the light of paragraph [0058] of the patent, "later in life" is intended to encompass an age of 4, 5 or 7 years, or even adulthood. The respondents argued that example 5 (in which only data after the first year of the child's life is monitored) and example 6 (in which the weight gain for the first 24 months of a child's life is monitored) cannot provide evidence that effect (ii) is achieved essentially over the entire scope of the claim. In these two examples, no third composition, composition C, was administered.

3.6.5 When assessing whether effect (ii) can be achieved, the skilled person's common general knowledge at the patent's filing date is to be taken into consideration. The concept (as the appellant calls it) of feeding infants with compositions which are stated to be suitable for reducing the risk of developing obesity later in life was well known before the opposed patent's filing date.

3.6.6 As explained in the board's communication, this is shown for example in D19. This document describes a

study aimed at determining the effect of the milk protein content after the first year on body mass index and obesity later in life. Although D19 was published after the patent's filing date, the premise of the study is based on earlier knowledge which was available well before that date. The premise is that a reduction in the milk protein content in infant formula during the first year of life reduces weight gain and obesity later in life, e.g. at school age. This is found in D19, e.g. in the abstract, the introduction and the references to documents describing earlier studies, in particular references 1, 2 and 5 to 9 on page 8.

3.6.7 Reference 1 in D19 is actually the scientific publication authored by Koletzko *et al.*, cited in paragraph [0013] of the opposed patent. The title of this article is mentioned on the cover page of the patent and reads "Lower protein in infant formula is associated with lower weight up to age 2 y: a randomized clinical trial".

3.6.8 A conspicuous number of patent applications based on the same concept were published before the patent's filing date. Some of these patent applications are referred to as prior art in the patent in suit (e.g. paragraphs [0011] and [0012]) or were cited by the respondents for the discussion on patentability (e.g. reply of respondent 2, pages 8 ff).

3.6.9 The person skilled in infant nutrition would be aware, taking into account the aforementioned common general knowledge, that the risk of developing obesity later in life is decreased if infants are administered a formula with a lower concentration of protein in their first year of life. In this respect, the appellant conclusively argued that claim 1 "*merely requires a*

reduction of the risk of developing obesity later in life, but it is not required in claim 1 that the reduced risk is based on effects that occur after the age of 1 year of life" (letter of 27 October 2022, page 10).

3.6.10 It is true that no composition C was administered in examples 5 and 6. Therefore the effects of a feeding pattern involving the use of composition C were not monitored or verified in the experiments described in the patent. And yet, taking into account the common general knowledge, the results of reduction in weight gain observed administering compositions A and B alone make it credible that infants fed according to the pattern according to claim 1 will have a lower risk of developing obesity later in life. The skilled person would expect that additionally administering composition C would not reverse the positive effects that have already been achieved by sequentially administering compositions A and B in the first year of an infant's life.

3.6.11 Respondent 1 has drawn attention to the statement in D19 that "*[i]t remains unclear which child age period is most sensitive to a modified protein intake, and whether limiting protein intake during the second year of life would also achieve benefits for prevention of excessive weight gain and later obesity*" (emphasis by the board).

3.6.12 However, this statement does not contradict but rather confirms the concept that it is the reduction in the protein intake during the first year that leads to a reduction in the risk of developing obesity later in life.

3.6.13 The respondents objected that the composition of example 6 with the lower amount of protein contained *L. rhamnosum*, while the comparative composition (with the higher amount of protein) did not. However, there is no evidence that *L. rhamnosum* interferes with the effect of the tested composition. Thus the difference identified by the respondents is not expected to have a notable impact on the risk of developing diabetes.

3.7 To conclude, the invention according to claim 1 of the main request complies with the requirement of Article 83 EPC.

4. *Remittal*

4.1 All the parties requested that the case be remitted to the opposition division.

4.2 The opposition division did not discuss novelty and inventive step. Examining these grounds for opposition for the first time on appeal would be at odds with the primary object of the appeal proceedings to review the decision under appeal in a judicial manner (Article 12(2) RPBA). Hence these circumstances constitute special reasons within the meaning of Article 11 RPBA for remitting the case to the opposition division (Article 111(1) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution.

The Registrar: The Chair:

K. Götz-Wein A. Veronese

Decision electronically authenticated