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Datasheet for the decision of 11 October 2021

Case Number: T 1527/16 - 3.3.09

Application Number: 06757833.6

Publication Number: 1898724

IPC: A23L1/29, A23L1/305, A61P3/04

Language of the proceedings: EN

Title of invention:
INFANT NUTRITION WITH HYDROLYSED PROTEINS

Patent Proprietor:
N.V. NUTRICIA

Opponents:
ABBOTT LABORATORIES
Société des Produits Nestlé S.A.

Headword:
Infant nutrition comprising hydrolysed proteins for preventing obesity in children/NUTRICIA

Relevant legal provisions:
EPC Art. 56
RPBA Art. 12(4)

Keyword:
Nutritional composition - claim construction
Main request and auxiliary requests 1 and 3 - Inventive Step (no)
Auxiliary request 2 - Admission (no)

Decisions cited:

Catchword:
Claim not allowing a distinction between the ingredients which prevent obesity and those which do not prevent or can even induce it. Identification of the protein hydrolysate as an active ingredient for preventing obesity not distinguishing the claimed subject-matter from the disclosure of the prior art. See reasons, points 1.4 to 1.8.

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Case Number: T 1527/16 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 11 October 2021

Appellant: (Patent Proprietor)	N.V. NUTRICIA Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Appellant: (Opponent 2)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Rupp, Christian Mitscherlich PartmbB Patent- und Rechtsanwälte Sonnenstraße 33 80331 München (DE)
Party as of right: (Opponent 1)	ABBOTT LABORATORIES 100 Abbott Park Road Abbott Park IL 60064 (US)
Representative:	Boult Wade Tennant LLP Salisbury Square House 8 Salisbury Square London EC4Y 8AP (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 22 April 2016 concerning maintenance of the European Patent No. 1898724 in amended form.**

Composition of the Board:

Chairman	A. Haderlein
Members:	A. Veronese
	F. Blumer

Summary of Facts and Submissions

I. Appeals were filed by opponent 2 and the patent proprietor against the decision of the opposition division finding that European patent No. 1 898 724 B1 as amended according to auxiliary request 5 met the requirements of the EPC. As opponent 2 and the proprietor are both appellants in the appeal proceedings, for the sake of simplicity the board will continue to refer to them as opponent 2 and the proprietor.

II. With their notices of opposition, opponents 1 and 2 had requested revocation of the patent in its entirety, *inter alia* on the grounds of Article 100(a) (lack of inventive step).

III. The documents submitted during the opposition proceedings included:

D1: EP 1 424 074 A1
D9: T. Aoyama et al., Biosci. Biotechnol. Biochem., vol. 64(12), 2000, pp. 2594-2600
D10: P.J. Aggett et al., J. Pediatr. Gastroenterol. Nutr., vol. 36(3), 2003, pp. 329-337
D15: WO 03/005836 A2
D21: Experimental report filed by the proprietor by letter dated 6 January 2012
D22: N.M. Delzenne et al., J. Nutr., vol. 129, 1999, pp.1467S-1470S

IV. In its decision, the opposition division found, *inter alia,* that the invention claimed in auxiliary request 5

involved an inventive step over D15, the closest prior art, in combination with the other cited prior-art documents.

V. Claim 1 of that auxiliary request 5 read:

"*1. Use of fat, digestible carbohydrates and protein, wherein the protein comprises at least 25 wt.% peptides with a chain length of 2 to 30 amino acids based on dry weight of protein, and wherein the composition comprises at least 12 mg non-digestible fermentable carbohydrates per g dry weight of the nutritional composition, for the manufacture of a nutritional composition for use in the prevention of childhood obesity, wherein said nutritional composition is for oral administration to an infant.*"

VI. During the appeal proceedings the proprietor filed:

- a main request and auxiliary request 1 (filed as auxiliary requests 2 and 3 respectively with the statement setting out the grounds of appeal)

- auxiliary request 2 (filed as auxiliary request 4 with the reply to the grounds of appeal of opponent 2)

- auxiliary request 3 (filed as auxiliary request 5 during the first-instance proceedings, and considered allowable by the opposition division).

VII. With the exception of the absence of a comma before "for the manufacture", claim 1 of the main request and of auxiliary requests 1 and 3 is identical to claim 1 of the auxiliary request 5 found allowable by the opposition division and shown above.

VIII. Claim 1 of auxiliary request 2 is limited in that the non-digestible fermentable carbohydrates are galacto-oligosaccharides and in that the composition comprises hydrolysed whey protein and hydrolysed casein protein.

IX. The arguments of the proprietor which are relevant for the present decision were as follows.

- The subject-matter of claim 1 involved an inventive step over D15, the closest prior art, when considered alone or in combination with the other cited documents.

- D15 disclosed a nutritional supplement comprising certain fatty acids and hydrolysed proteins. However, unlike the opposed patent, it did not disclose the "essentiality of the hydrolysed proteins" for preventing childhood obesity. This was a technical feature distinguishing the claimed invention from the prior art. Other distinguishing features were the use of digestible and non-digestible carbohydrates, peptides of a selected length and oral administration.

- The patent and D21 showed that the claimed composition was effective in preventing childhood obesity and that hydrolysed proteins and non-digestible fermentable carbohydrates acted synergistically.

- The underlying problem was to provide an oral infant nutritional composition comprising fat, digestible carbohydrates and protein for preventing childhood obesity. D15 taught not to include digestible carbohydrates in the composition. D9,

D10 and D22 did not hint at the proposed solution either.

X. The arguments of opponent 2 which are relevant for the present decision were as follows.

- The subject-matter of claim 1 did not involve an inventive step over D15 as the closest prior art.

- The only technical feature distinguishing the claimed subject-matter from the teaching of D15 was the presence of non-digestible fermentable carbohydrates.

- No effect was associated with this difference, let alone a synergy between hydrolysed proteins and non-digestible fermentable carbohydrates. Neither the patent nor D21 described tests involving the co-administration of these compounds. Comparative tests vis-à-vis the closest prior art were not provided either.

- The underlying problem was to provide an alternative nutritional composition for preventing childhood obesity.

- D10 and D22 prompted the skilled person to include non-digestible fermentable carbohydrates in the composition. The use of hydrolysed proteins for preventing obesity in children was disclosed in D9.

The requests

XI. The proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of:

- the main request or, alternatively, auxiliary request 1, which had been filed as auxiliary requests 2 and 3 respectively with the statement setting out the grounds of appeal, or, alternatively,

- auxiliary request 2, which had been filed with the reply to opponent 2's appeal as auxiliary request 4, or, alternatively,

- auxiliary request 3, which was the same as the auxiliary request 5 found allowable by the opposition division.

XII. Opponent 2 requested that the impugned decision be set aside and that the patent be revoked in its entirety.

XIII. Opponent 1 did not make any requests, nor did it submit any arguments during the appeal proceedings.

Reasons for the Decision

1. *Inventive step*

1.1 The claimed invention relates to a nutritional composition for oral administration to an infant which can be used to prevent childhood obesity. The composition is meant, in particular, to prevent the obesity associated with the use of infant formulas which differ from human milk. According to the opposed patent, the invention is based on the finding that hydrolysed whey and casein proteins reduce post-prandial levels of insulin and glucose. This effect is

said to be beneficial for preventing childhood obesity. See paragraphs [0011] to [0014] of the patent.

The closest prior art

1.2 The opposition division decided that D15, which addresses, like the opposed patent, the problem of preventing childhood obesity and infant nutrition, is the closest prior art to the subject-matter of claim 1. This choice was not contested by the parties and the board sees no reason to disagree with it either.

1.3 D15 discloses a composition comprising specific types of fatty acids and other ingredients which can be administered to infants to prevent obesity in childhood: see the abstract; page 1, lines 25-29; page 2, lines 15-17; page 6, lines 13-15 and 22-23; page 8, line 14; page 13, lines 13-17; and page 15, line 5. According to a preferred embodiment, the composition is formulated as a dietary supplement comprising the fatty acids ("fats" according to paragraph [0033] of the opposed patent) and a protein source which can be, in particular, a hydrolysed protein from casein, whey or soy: see page 2, lines 23-27; page 11, lines 15-17; page 12, lines 16-23; and claim 8. The supplement can be administered as part of the subject's regular diet and can be added to a dairy product: see page 13, lines 24-27. A milk for human consumption is disclosed on page 2, lines 21-23.

Distinguishing features

1.4 The subject-matter of claim 1 differs from the teaching of D15 in that some of the peptides have a specific chain length and in that digestible carbohydrates and a certain amount of non-digestible fermentable

carbohydrates are combined to form a nutritional composition for oral administration to an infant.

1.5 The proprietor argued that the subject-matter of claim 1 differed from the teaching of D15 also in that D15 did not disclose "the essentiality of hydrolysed protein" in the disclosed compositions; in other words, it did not disclose the hydrolysed protein as an active agent for preventing obesity. D15 taught that the active ingredient preventing obesity was a particular mixture of fats. The protein fraction, and in particular the hydrolysed proteins, were to be considered a "dietary supplement", rather than active agents for preventing obesity. In its opinion, claim 1 was drafted in the "Swiss type" format. Thus, the newly discovered effect of the hydrolysed proteins, and their use as active agents for preventing obesity, was a further technical feature distinguishing the invention from the prior art.

1.6 The board does not agree. Claim 1 relates to a mixture of compounds comprising fats, digestible carbohydrates, non-digestible fermentable carbohydrates and a protein fraction including hydrolysed proteins. This mixture is formulated into a nutritional composition for preventing childhood obesity. The claim does not identify any particular component of the composition as the active agent. Furthermore, the mixture includes hydrolysed proteins, the compounds which according to the description prevent obesity and increased glucose and insulin levels, as well as the compounds, like fats and digestible carbohydrates, which potentially induce them. This means that the wording of claim 1 does not allow a distinction to be drawn between the compounds which prevent obesity and those which do not prevent it or can even induce it. What can be inferred from

claim 1 is merely that the entire composition, as such, induces the purported preventive effect.

1.7 D15 provides an analogous teaching. As already mentioned above, D15 discloses a dietary supplement comprising certain fatty acids and a protein source including hydrolysed proteins, and its administration to infants to prevent obesity in childhood. It is true that, as noted by the proprietor, D15 focuses on the use of a mixture of certain fats and describes tests investigating their metabolic effects. However, according to the preferred embodiment, the fats are to be combined with the protein source to form a dietary supplement, and this supplement is proposed for preventing obesity. There is no indication that the protein source is only included for nutritional purposes. Thus, as in the case of claim 1, what can be inferred from D15 is that the nutritional supplement, which includes the specified fats and the protein source, is to be used to prevent obesity.

1.8 For these reasons, "the essentiality of hydrolysed protein" in the disclosed compositions or, in other words, the identification of the protein hydrolysate as an active ingredient for preventing obesity is not a feature distinguishing the subject-matter of claim 1 from the teaching of D15.

Technical effects

1.9 The tests described in paragraphs [0051] to [0057] of the patent show that, when hydrolysed whey and hydrolysed casein are co-administered with lactose, post-prandial levels of glucose and insulin are comparable to those induced by human milk, and are significantly lower than those observed when lactose is

co-administered with intact proteins: see paragraph [0012], Table 1 and Figures 1 and 2 of the patent. The tests described in the experimental report D21, which was filed during the opposition proceedings, show that galacto-oligosaccharides (which are non-digestible fermentable carbohydrates) decrease insulin secretion when they are co-administered with lactose.

1.10 The patent explains that in infants, in particular in formula-fed infants, increased levels of insulin and glucose are associated with insulin resistance, which contributes to the development of childhood obesity. Before the relevant date it was already known that "flattening" glycemic and insulin post-prandial responses has an anti-lipidemic effect and prevents obesity: see D10, a review paper relating to the diets of infants and children (page 334, left column, second paragraph), D22 (the abstract and Tables 2 and 3) and D1 (paragraph [0039]). This makes it credible that the claimed composition can be used as infant nutrition to prevent obesity in children, but it is insufficient to show that there is an improvement over D15.

1.11 The proprietor argued that the combination of hydrolysed proteins and non-digestible fermentable carbohydrates synergistically prevented childhood obesity. In its opinion, this was shown in the description and in Figures 1 and 2 of the opposed patent and in the experimental report D21. This argument is not persuasive, however. Only hydrolysed proteins were administered to carry out the tests described in the patent and only a galacto-oligosaccharide (a non-digestible fermentable carbohydrate) was administered to carry out the tests described in D21. None of these tests involved administering these compounds in combination. Paragraph

[0037] of the patent states that non-digestible fermentable carbohydrates and hydrolysed proteins are "believed" to synergistically prevent and/or treat childhood obesity. However, there is no evidence supporting this speculative statement.

The underlying technical problem

1.12 As mentioned above, there is no evidence that the combination of the claimed ingredients induces an effect which would go beyond those already obtained in the closest prior art. Comparative tests vis-à-vis the closest prior art D15 were not provided either. Thus, an improvement over D15 has not been shown. For these reasons, the underlying technical problem can only be seen to be the provision of an alternative composition for preventing obesity in children.

Obviousness of the claimed solution

1.13 The question which has to be answered is whether, when starting from D15 and confronted with the underlying technical problem, the skilled person would have considered providing a nutritional composition suitable for oral use in infants which includes protein hydrolysates comprising peptides having the specified length, digestible carbohydrates and non-digestible fermentable carbohydrates in the given amounts.

1.14 The proprietor argued that nothing in D15 hinted at combining the claimed ingredients in a composition to prevent obesity, let alone at including digestible and non-digestible fermentable carbohydrates. D15 even taught away from including digestible carbohydrates in that composition: according to a preferred embodiment

on page 2, lines 25-26, and on page 13, lines 18-20, the supplement did not include carbohydrates.

1.15 These arguments are not convincing. D15 teaches that the supplement can be administered as part of the subject's regular diet and can be added e.g. to a dairy product: see page 13, lines 24-27. A dairy product, such as a milk for human consumption, is mentioned on page 2, lines 20-23. The most obvious way to provide an alternative composition would therefore be to formulate the ingredients of the supplement into a nutritional composition for infants, such as a milk which can be administered orally. Such formulations were part of common general knowledge, as shown by paragraph [0011] of the opposed patent, which describes the background of the invention. It was not disputed that such compositions typically contain a certain amount of digestible carbohydrates as the energy source. Thus, these would have been included in the nutritional composition.

1.16 The skilled person would also have considered including non-digestible fermentable carbohydrates in the composition, because their beneficial effects on obesity were well known before the relevant date. D10, an article reviewing the use of non-digestible carbohydrates in the diets of infants and children, teaches that these compounds "flatten" the post-prandial glycemic response and prevent obesity. Their consumption is perceived as beneficial by health professionals: see the abstract; the introduction; page 334, second paragraph; Figure 1; and the passage bridging pages 330 and 331. This is confirmed by D22, which teaches that a diet containing oligo-fructose decreases post-prandial glucose and insulin levels and

has an anti-lipidemic effect (see the abstract and Tables 2 and 3).

1.17 It is also noted that the diets disclosed in the prior art which comprised hydrolysed proteins or non-digestible fermentable carbohydrates also contained digestible carbohydrates: see D9, Table 1 (starch and sucrose) and D22, Table 1 (starch). The fact that the review article D10 states that non-digestible carbohydrates flatten the post-prandial glycemic response attests to the fact that these compounds were typically administered in combination with digestible carbohydrates, which induce such a response. For these reasons, D15 does not teach the skilled person away from including digestible carbohydrates in the composition.

1.18 No evidence has been provided to show that the selection of hydrolysed proteins comprising peptides of a certain length, or particular amounts of the claimed ingredients, is associated with a particular technical effect. It is noted that the length of the peptides comprised in the protein hydrolysates used for the tests shown in the patent has not even been indicated. A composition according to the invention, comprising all the claimed ingredients, has not been tested either. Thus, these technical features cannot contribute to an inventive step.

1.19 For these reasons, it is concluded that the subject-matter of claim 1 does not involve an inventive step.

Auxiliary requests 1 and 3

2. *Inventive step*

Claim 1 of auxiliary requests 1 and 3 is identical to that of the main request. Therefore, the same conclusions apply.

Auxiliary request 2

3. *Admission*

3.1 Auxiliary request 2 was filed by the proprietor with its reply to opponent 2's appeal. The admissibility of this request was contested by opponent 2. The subject-matter of claim 1 of this request was limited in that the non-digestible fermentable carbohydrates were galacto-oligosaccharides and in that the composition comprised hydrolysed whey protein and hydrolysed casein protein.

3.2 In its reply to opponent 2's appeal, the proprietor stated that the request was filed to "further substantiate that the effect is achieved". However, the proprietor did not explain which objection justified the filing of this new auxiliary request in the appeal proceedings, let alone which objection not already raised during the opposition proceedings.

3.3 The board raised this issue in its communication issued in preparation for the oral proceedings. The proprietor addressed this point neither in its reply to the board's communication in preparation for the oral proceedings nor during the oral proceedings held before the board. Therefore, auxiliary request 2 is not

admitted into the appeal proceedings (Article 12(4) RPBA 2007 and Article 25(2) RPBA 2020).

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:

A. Nielsen-Hannerup A. Haderlein

Decision electronically authenticated