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Datasheet for the decision of 26 May 2023

Case Number: T 1133/21 - 3.3.09

Application Number: 15771909.7

Publication Number: 3197295

IPC: A23L33/00, A23L33/10

Language of the proceedings: EN

Title of invention:
INFANT FORMULA SYSTEM WITH ADAPTIVE LEVELS OF HUMAN MILK OLIGOSACCHARIDES (HMOS)

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponents:
Reckitt Benckiser Health Limited
N.V. Nutricia

Headword:
Adaptative infant formula/NESTLÉ

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
Main request and auxiliary requests 1 to 4: selection from lists of converging alternatives - added matter - (yes)

Decisions cited:
G 0002/10, T 1621/16, T 0350/18

Catchword:
The mere fact that features are described in the application as filed in terms of lists of more or less converging alternatives does not give the proprietor a "carte blanche" for freely combining features selected from a first list with features selected from a second list disclosed in the application as filed. Any such amendment will only be allowable under Article 123(2) EPC if it complies with the "gold standard" defined in decision G 2/10 (reasons 2.15 of the present decision).

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Case Number: T 1133/21 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 26 May 2023

Appellant: (Opponent 2)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Respondent: (Patent Proprietor)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Plougmann Vingtoft a/s Strandvejen 70 2900 Hellerup (DK)
Party as of right: (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)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 10 May 2021 concerning maintenance of the European Patent No. 3197295 in amended form.**

Composition of the Board:

Chair	A. Haderlein
Members:	A. Veronese
	R. Winkelhofer

Summary of Facts and Submissions

I. The appeal was filed by opponent 2 (appellant) against the decision of the opposition division finding that the European patent as amended according to auxiliary request 2 met the requirements of the EPC.

II. With their respective notices of opposition, opponents 1 and 2 had requested revocation of the patent, *inter alia*, on the grounds under Article 100(c) EPC.

III. In its decision, the opposition division found, *inter alia*, that:

- the main request and auxiliary request 1 contravened Article 123(2) EPC but that auxiliary request 2 did not

IV. Claim 1 of auxiliary request 2 found allowable by the opposition division read:

"*1. An age-tailored nutritional composition system comprising:*

- *at least one synthetic nutritional composition A for infants from 0 up to 1 month of age, and*

- *at least one synthetic nutritional composition B for infants above 1 month and up to 2 months of age,*

wherein the nutritional compositions A and B comprise human milk oligosaccharides (HMOs),

wherein said nutritional compositions A and B differ from each other in the amount of HMOs present therein,

wherein the amount of HMOs in the at least one nutritional composition A exceeds the amount of HMOs present in the at least one nutritional composition B, and

wherein 2'Fucosyllactose is present in

- *the at least one nutritional composition A in an amount of from 1000 to 2000 mg/L, and*

- *the at least one nutritional composition B in an amount of from 1000 to 1500 mg/L."*

V. During the appeal proceedings, the respondent (patent proprietor) relied on the aforementioned auxiliary request 2 as the main request. With the reply to the appeal, it filed auxiliary requests 1 to 3.

VI. Claim 1 of auxiliary request 1 read:

"*1. An age-tailored nutritional composition system comprising:*

- *at least one synthetic nutritional composition A for infants 5 from 0 up to 1 month of age, and*

- *at least one synthetic nutritional composition B for infants above 1 month and up to 2 months of age,*

wherein the nutritional compositions A and B comprise human milk oligosaccharides (HMOs),

wherein said nutritional compositions A and B differ from each other in the amount of HMOs present therein,

wherein the amount of HMOs in the at least one nutritional composition A exceeds the amount of HMOs present in the at least one nutritional composition B, and wherein

2'Fucosyllactose is present in

- *the at least one nutritional composition A in an amount of from 1000 to 2000 mg/L, and*
- *the at least one nutritional composition B in an amount of from 1000 to 1500 mg/L; and*

3'Sialyllactose is present in
- *the at least one nutritional composition A in an amount of from 200 to 280 mg/L, and*
- *the at least one nutritional composition B in an amount of from 150 to 250 mg/L; and*

6'Sialyllactose is present in
- *the at least one nutritional composition A in an amount of from 450 to 650 mg/L, and*
- *the at least one nutritional composition B in an amount of from 200 to 350 mg/L; and*

Lacto-N-neotetraose is present in
- *the at least one nutritional composition A in an amount of from 150 to 350 mg/L, and*
- *the at least one nutritional composition B in an amount of from 100 to 200 mg/L; and*

Lacto-N-tetraose is present in
- *the at least one nutritional composition A in an amount of from 800 to 1400 mg/L, and*

- *the at least one nutritional composition B in an amount of from 500 to 1000 mg/L.*"

VII. Claim 1 of auxiliary requests 2 and 3 differs from claim 1 of the main request and auxiliary request 1 in that it is directed to a method for providing nutrition to an infant comprising feeding the infant from 0 to up to 1 month of age with composition A and from 1 up to 2 months with composition B, with compositions A and B defined as in the main request and auxiliary request 1, respectively.

VIII. As far as relevant to the present decision, the **appellant's** arguments may be summarised as follows.

- Claim 1 of the main request contained added subject-matter: multiple selections from lists of alternative embodiments disclosed in the application as filed were required to define the presence of 2'Fucosyllactose (2'-FL) in both compositions A and B and its presence in the specified amounts in these compositions.

- There was no statement in the application as filed, let alone claim 10, requiring A and B to comprise the same human milk oligosaccharides (HMOs). Thus, 2'-FL was not necessarily comprised in both compositions.

- The application as filed did not provide any pointer to the claimed combination of ranges: the amounts of 2'-FL in Figures 1A and 2 fell squarely within all ranges defining compositions A and B on pages 35 and 36 and in claim 13 as filed. No pointer to a combination of ranges encompassing the amounts of 2'-FL of Figures 1A and 2 while

excluding those of Figure 1B could be found either. Thus, the criteria outlined in T 1621/16 for making multiple selections without infringing Article 123(2) EPC were not met. The situation in T 350/18 was different from that of the current case.

- The same reasoning applied to claim 1 of auxiliary request 1. Even more choices had to be made to specify the amounts of each HMO mentioned in this claim. The reasoning also applied to auxiliary requests 2 and 3.

IX. As far as relevant to the decision, the **respondent's** arguments may be summarised as follows.

- Amended claim 1 of the main request was based on claims 1, 10, 13 and 14 and Figures 1A and 2 as filed.

- Once 2'-FL was selected from claim 10, it had to be included in both compositions A and B. The use of different HMOs in these compositions was against the teaching of the application as filed.

- The criteria outlined in T 1621/16 for making multiple selections from lists of converging alternatives without violating Article 123(2) EPC were met because of the following.

- There was a pointer to the claimed combination of features. The application as filed identified the 2'-FL concentrations shown in Figure 1A as preferred. Those of Figure 1B were less preferred. The 2'-FL concentration ranges in claim 1 were purposefully selected, these being the broadest

which included the concentrations of 2'-FL of Figures 1A and 2 but excluded those in Figure 1B.

- Claim 1 of auxiliary request 1 required all recited HMOs to be present, this being a preferred embodiment of the application as filed. The claimed scope was limited without singling out embodiments. The amounts of HMOs in claim 1 were purposefully selected. They were the broadest which included the preferred HMO concentrations in Figures 1A and 2 and excluded the less preferred ones in Figure 1B.

- As in T 350/18, the requirements of Article 123(2) EPC were complied with.

X. Opponent 1 did not present any argument or request during the appeal proceedings.

The requests

XI. The appellant requests that the decision under appeal be set aside and that the patent be revoked.

XII. The respondent requests that the appeal be dismissed (main request) or that the patent be maintained on the basis of one of auxiliary requests 1 to 3 submitted with the reply to the appeal.

Reasons for the Decision

Main request

1. *The opposed patent*

1.1 The opposed patent relates to an age-tailored nutritional system for infants. The system contains two

or more nutritional compositions comprising different amounts of human milk oligosaccharides (HMOs). The idea underlying the invention is to provide the infant with different nutritional compositions which reflect its evolving nutritional needs over time, in particular at different ages (see page 1 "Field of the invention", page 3 "Object of the invention" and claim 1). The patent describes a clinical study showing how the concentration of HMOs in human breast milk varies over time during lactation.

2. *Allowability of the amendments (Article 123(2) EPC)*

2.1 What is under dispute in the current case is the opposition division's finding that claim 1 is based on claims 1, 10 and 13; pages 35 and 36; and the Figures of the application as filed.

2.2 Claim 1 as filed reads:

"*1. An age-tailored nutritional composition system comprising:*
- *at least one nutritional composition A for infants from 0 up to 1 month of age, and*
- *at least one nutritional composition B for infants above 1 month and up to 2 months of age,*

wherein the nutritional compositions A and B comprise human milk oligosaccharides (HMOs), and wherein said nutritional compositions A and B differ from each other in the amount of HMOs present therein."

2.3 Claim 1 of the main request differs from claim 1 as filed in at least that:

- the amount of HMOs in composition A exceeds that in composition B

- 2'-Fucosyllactose (2'-FL) is present in both compositions A and B

  furthermore, in that 2'-FL is present in an amount of:

- 1000 to 2000 mg/L in composition A

- 1000 to 1500 mg/L in composition B

2.4 The respondent submitted that although multiple selections had to be made to arrive at the claimed subject-matter, the teaching of the application as filed taught toward the claimed combination of features. It argued essentially the following.

2.5 First, if 2'-FL was present in composition A, it was necessarily also present in composition B. Only one choice had to be made for 2'-FL to be present in both compositions. This was evident from the wording of claim 10 as filed, which specified that the HMOs of the nutritional system were selected from 2'Fucosyllactose (2'-FL), 3'Sialyllactose, 6'Sialyllactose, Lacto-N-neotetraose and Lacto-N-tetraose.

2.6 Second, the selection of the specified ranges defining the amounts of 2'-FL in compositions A and B of claim 1 was made from lists of converging alternatives disclosed in the application as filed.

2.7 Third, the results of the clinical study described in Figures 1A, 1B and 2 of the application as filed provided a pointer toward the combination of ranges now

claimed. Figures 1A and 2 showed the average concentration of HMOs in a population of mothers including "non-secretor mothers"; Figure 1B did so for a population from which non-secretor mothers were excluded. The concentrations of HMOs in Figure 1B were higher, the non-secretor mothers being excluded. It was readily apparent that the ranges listed on pages 35 and 36 and in claim 13 as filed - which defined the amounts of 2'-FL and the other HMOs in compositions A and B - converged toward the concentrations shown in Figure 1A and 2 (1484 mg/L and 1205 mg/L, after 1 and 2 months, respectively) and not those disclosed in Figure 1B. The concentrations in Figures 1A and 2 were thus clearly preferred. This was a pointer to the system now defined in claim 1.

2.8 Since i) the ranges in amended claim 1 were selected from lists of converging alternatives and ii) there was a pointer to the claimed combination of features, claim 1 met the criteria set out in decision T 1621/16 for the requirements of Article 123(2) EPC to be fulfilled.

2.9 The respondent further submitted that, in accordance with T 1621/16, the selection of a more or less preferred range from a list of converging alternative ranges was to be treated as a mere restriction of an already disclosed range and not an arbitrary selection. For this reason alone, even if it was arrived at by making multiple selections from more or less preferred ranges, claim 1 could not contain added subject-matter.

2.10 The respondent's arguments fail to convince.

2.11 Under Article 123(2) EPC, a European patent application or patent must not be amended in such a way that it

contains subject-matter which extends beyond the content of the application as filed.

2.12 The gold standard for assessing compliance with Article 123(2) EPC is that amendments to the claims, description and drawings of a European patent application or patent can only be made within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of these documents as filed (see G 2/10 Reasons 4.3 and "Case Law of the Boards of Appeal of the EPO", 10th edn., II-E.1.1).

2.13 It is established case law of the boards that the content of an application must not be used as a reservoir from which features pertaining to separate embodiments can be combined to artificially create an embodiment. In the absence of any pointer to the combination, the combined selection of features does not, for the person skilled in the art, emerge clearly and unambiguously from the content of the application as filed (see "Case Law of the Boards of Appeal of the EPO", II-E.1.6.1 and the decisions cited there).

2.14 Decision T 1621/16 does not provide for an exception to this rule. It requires, in fact, that a claim amended on the basis of multiple selections from lists of converging alternatives may only be considered to meet the requirements of Article 123(2) EPC if the application as filed includes a pointer to the combination of features resulting from the multiple selections (see the catchword, point 2).

2.15 This means that the mere fact that features are described in terms of lists of more or less converging

alternatives does not give the proprietor carte blanche to freely combine features selected from a first list with features selected from a second list disclosed in the application as filed. Any such amendment will only be allowable under Article 123(2) EPC if it complies with the gold standard.

2.16 The assessment of whether this standard is complied with is very case specific. It requires taking into account the teaching of the application as filed as a whole, avoiding artificial semantic constructions. Factors which may play a role in the assessment are, *inter-alia*, the number of alternatives disclosed in the application; the length, convergence and any preference in the lists of enumerated features; and the presence of examples pointing to a combination of features. For instance, if the values in a number of examples are clustered within specific ranges, this may provide a pointer to those ranges.

2.17 In the current case, the application for the opposed patent was drafted to provide a large reservoir of options and alternatives to be selected and combined to create a vast number of embodiments.

2.18 The application describes a clinical study monitoring the concentration of HMOs in human milk during lactation. The results show that the concentrations of HMOs decrease over time. However, the application was drafted to go far beyond this finding and to encompass age-tailored nutritional systems which can satisfy any foreseeable evolving nutritional need for HMOs, not only their decrease over time.

2.19 Claim 1 as filed encompasses any system comprising two compositions A and B, where A is for infants of 0 up to

1 month and B is for infants of 1 to 2 months of age and where the two compositions comprise different amounts of HMOs. It does not require composition A to contain an excess of HMOs compared to composition B. It does not require compositions A and B to comprise the same HMO/HMOs either. This very broad definition is confirmed on page 1 "Field of the invention" and page 3 "Object of the invention". It is further corroborated by the "and/or" wording used in the passages on page 35 lines 9 to 22; on page 36, lines 1 to 12 and in claim 13 as filed, which define compositions A and B which can contain different HMOs selected from 2'Fucosyllactose, 3'Sialyllactose, 6'Sialyllactose, Lacto-N-neotetraose and Lacto-N-tetraose.

2.20 The respondent's argument that when 2'-FL is selected from the various HMOs listed in claim 10 as filed, this compound must necessarily be present in both compositions A and B, otherwise the claims would not make technical sense, does not convince. Accordingly, two selections have already to be made for 2'-FL to be present in both compositions A and B.

2.21 Furthermore, the "and/or" structure in the aforementioned passages on pages 35 and 36 and in claim 13 implies that to arrive at the subject-matter of claim 1, the following additional selections have to be made:

- a range of 1000 to 2000 mg/L of 2'-FL must be selected from those proposed for composition A in claim 13 and on page 35 as filed

- a range of 1000 to 1500 mg/L of 2'-FL must be selected from those proposed for composition B in claim 13 and on page 36 as filed

2.22 The first range is the third in the list in claim 13 and on page 35 as filed. The second is the first in the list in claim 13 and on page 36.

2.23 The respondent submitted that these selections did not create new subject-matter because Figures 1A and 2 as filed pointed to the claimed combination of features. The skilled person would have recognised that the claimed combination of ranges was the most preferred of the application because the selected ranges were the broadest which included the preferred 2'-FL concentrations shown in Figures 1A and 2 which also excluded the less preferred concentrations shown in Figure 1B.

2.24 The board does not agree with the respondent.

2.25 First, the concentrations shown in Figures 1A and 2 - 1484 mg/L and 1205 mg/L, after 1 and 2 months, respectively - fall squarely within each range proposed for 2'-FL in compositions A and B in claim 13 and on pages 35 and 36 as filed.

2.26 The respondent's argument that the selected values were selected to exclude the values in Figure 1B, which were obtained from the population of normal secreting mothers, is not convincing either. The application as filed describes two examples of systems including age-tailored sets of nutritional compositions comprising variable levels of HMOs (example 1 on pages 54 to 57 and example 2 on pages 57 to 60). Example 1 uses the HMO values shown in Figures 1A and 2, whereas example 2 uses the HMOs values shown in Figure 1B. Both examples are disclosed as systems according to the invention. Even assuming that the concentrations in Figure 1A

and 2 (used to prepare example 1) represent the more preferred embodiment, there is no teaching in the application to provide a system which encompasses this embodiment but excludes the concentrations in Figure 1B used to prepare example 2. Thus, the application does not contain a pointer to the combination of ranges defining the 2'-FL concentrations in claim 1 of the main request.

2.27 The respondent also argued that the current case was similar to that underlying decision T 350/18. In that decision, the board found that claim 1 was in line with the examples and that, in the absence of a contradiction or specific interrelation of individual features which would require additional adaptation or modification, the claimed combinations of numerical ranges defined by the broadest range which converged down towards the most preferred range met the requirements of Article 123(2) EPC. According to the respondent, this same approach had to be applied to the current case.

2.28 This argument is not persuasive either. As mentioned above, the assessment of whether Article 123(2) EPC is complied with is very case specific. In view of the very broad teaching of the application in the current case as filed and the vast number of alternative options disclosed in the application, the current case cannot be compared to T 350/18.

2.29 For these reasons, it is concluded that claim 1 of the main request contains subject-matter extending beyond the content of the application as filed (Article 123(2) EPC).

Auxiliary request 1

3. *Allowability of the amendments (Article 123(2) EPC)*

3.1 Claim 1 of auxiliary request 1 requires compositions A and B to comprise each of 2'Fucosyllactose, 3'Sialyllactose, 6'Sialyllactose, Lacto-N-neotetraose and Lacto-N-tetraose in specific amounts.

3.2 The respondent submitted that a nutritional system containing all recited HMOs in compositions A and B was preferred according to page 35, lines 24 to 28 and page 36, lines 14 to 18 as filed. Furthermore, the concentrations of all individual HMOs were disclosed in claim 13 and on pages 35 and 36 as filed. A system comprising the selected concentrations was the most preferred embodiment of the application as filed because it encompassed all the preferred concentrations shown in Figures 1A and 2 but not the less preferred ones shown in Figure 1B. In other words, the application as filed contained a pointer to the subject-matter of claim 1 of auxiliary request 1. The requirements set out in T 1621/16 for multiple selections to be made without violating Article 123(2) EPC were thus fulfilled. Furthermore, the structure of claim 1 of auxiliary request 1 was similar to that underlying T 350/18. This was apparent from a drawing presented at the oral proceedings before the board including a plot representing the different alternatives encompassed by the application for the opposed patent as filed and those encompassed by the application underlying case T 350/18. Since the pattern was the same, the outcome of the two cases could not be different.

3.3 These arguments are not persuasive. As submitted by the appellant, even more selections from features disclosed in the application as filed are necessary to arrive at the subject-matter of claim 1 of auxiliary request 1 compared to those necessary to arrive at claim 1 of the main request. Furthermore, as with the main request, the figures of the application do not provide a pointer to the claimed combination of features.

3.4 As explained above (point 2.26), even assuming that the concentrations in Figures 1A and 2 (used to prepare example 1) represent the more preferred embodiment, there is no teaching in the application to provide a system which encompasses this embodiment but excludes the concentrations in Figure 1B used to prepare example 2. As noted by the respondent, the amounts of 3'-Sialyllactose, 6'-Sialyllactose, Lacto-N-neotetraose and Lacto-N-tetraose shown in Figure 1B fall within the claimed ranges. Moreover, there is no pointer in the application for selecting the third of the ranges given for both 2'-FL and for Lacto-N-tetraose in composition A and the first of the ranges for the other HMOs. The claimed ranges also do not fulfil the appellant's assertion that the choices were made purposely to combine the broadest ranges which encompassed the values in Figures 1A and 2 but excluded those in Figure 1B.

3.5 Thus, the application as filed does not contain a pointer to the combination of ranges defined in claim 1 of the main request.

3.6 Finally, as already mentioned above (point 2.27), the comparison with decision T 350/18 is not appropriate, also not in the context with auxiliary request 1. Taking into account the very broad teaching of the

application as filed and the number of alternatives described in the application, the current case cannot be compared to that in T 350/18.

3.7 For these reasons, claim 1 of auxiliary request 1 contains subject-matter extending beyond the content of the application as filed (Article 123(2) EPC).

Auxiliary requests 2 and 3

4. *Allowability of the amendments (Article 123(2) EPC)*

4.1 Claim 1 of auxiliary request 2 includes in the method defined in claim 28 as filed the requirement that 2'-FL is present in both compositions A and B in specific amounts. These requirements are the same which characterise claim 1 of the main request.

4.2 Claim 1 of auxiliary request 3 includes in the method defined claim 28 as filed the requirement that both compositions A and B comprise 2'Fucosyllactose, 3'Sialyllactose, 6'Sialyllactose, Lacto-N-neotetraose and Lacto-N-tetraose in specific amounts. These requirements are the same which characterise claim 1 of auxiliary request 1.

4.3 In practice, claim 1 of auxiliary requests 2 and 3 defines a method involving the use of a composition system as defined in claim 1 of the main request and auxiliary request 1, respectively.

4.4 Accordingly, the reasoning for the main request and auxiliary request 1 applies equally to auxiliary requests 2 and 3.

4.5 It follows that claim 1 of auxiliary requests 2 and 3 also contains subject-matter extending beyond the content of the application as filed (Article 123(2) 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 Chair:

M. Schalow A. Haderlein

Decision electronically authenticated