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**Datasheet for the decision
of 11 October 2011**

Case Number: T 0633/09 - 3.3.09
Application Number: 98912118.1
Publication Number: 975235
IPC: A23L 1/09, A23L 1/304,
A23L 1/302, A23C 9/20
Language of the proceedings: EN

Title of invention:
Nutritional formulations containing oligosaccharides

Patentee:
ABBOTT LABORATORIES

Opponents:
Friesland Brands B.V.
N.V. Nutricia

Headword:
-

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

Relevant legal provisions (EPC 1973):
-

Keyword:
"Compliance with Articles 84, 123(2) after amendments -
Remittal"

Decisions cited:
T 0381/02

Catchword:
-



Case Number: T 0633/09 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 11 October 2011

Appellant:
(Patent Proprietor) ABBOTT LABORATORIES
CHAD 0377/AP6D-2
100 Abbott Park Road
Abbott Park IL 60064-3500 (US)

Representative:
Hayes, Adrian Chetwynd
Boulton Wade Tennant
Verulam Gardens
70 Gray's Inn Road
London WC1X 8BT (GB)

Respondent I:
(Opponent 1) Friesland Brands B.V.
Blankenstein 142
NL-7943 PE Meppel (NL)

Representative:
van Loon, C.J.J.
Vereenigde
Johan de Wittlaan 7
NL-2517 JR Den Haag (NL)

Respondent II:
(Opponent 2) N.V. Nutricia
Eerste Stationsstraat 186
NL-2712 HM Zoetermeer (NL)

Representative:
Meekel, Arthur Augustinus P.
Nederlandsch Octrooibureau
P.O. Box 29720
NL-2502 LS Den Haag (NL)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted 13 February 2009
revoking European patent No. 975235 pursuant to
Article 101(3)(b) EPC.**

Composition of the Board:

Chairman: W. Sieber
Members: W. Ehrenreich
 R. Menapace

Summary of Facts and Submissions

- I. Mention of the grant of European patent No. 0 975 235 in respect of European application No. 98 912 118.1, filed as International application No. PCT/US98/06216 in the name of Abbott Laboratories on 30 March 1998, was announced on 24 May 2006 in Bulletin 2006/21.

The patent was granted with 12 claims, independent claims 1 and 7 reading as follows:

"1. A synthetic nutritional composition comprising one or more human milk oligosaccharides, wherein the human milk oligosaccharides in the composition are selected from the group consisting of:

from 1456 to 1750 mg/liter of 3-fucosyllactose;
from 507 to 1100 mg/liter of lacto-N-fucopentaose III;
from 361 to 750 mg/liter of lacto-N-fucopentaose II;
from 393 to 1450 mg/liter of difucosyllactose;
from 2240 to 2400 mg/liter of 2'-fucosyllactose;
from 845 to 1650 mg/liter of lacto-N-fucopentaose I;
from 258 to 450 mg/liter of lacto-N-neotetraose; or
from 120 to 1600 mg/liter of lacto-N-fucopentaose V;
and said composition further comprises edible macronutrients,

wherein said composition is intended for use with normal, healthy infants, children, adults or subject having specialized needs such as those that accompany certain pathological conditions."

"7. A process for manufacturing a synthetic nutritional composition comprising one or more human milk

oligosaccharides, wherein the human milk oligosaccharides in the composition are selected from the group consisting of:

from 1456 to 1750 mg/liter of 3-fucosyllactose;
from 507 to 1100 mg/liter of lacto-N-fucopentaose III;
from 361 to 750 mg/liter of lacto-N-fucopentaose II;
from 393 to 1450 mg/liter of difucosyllactose;
from 2240 to 2400 mg/liter of 2'-fucosyllactose;
from 845 to 1650 mg/liter of lacto-N-fucopentaose I;
from 258 to 450 mg/liter of lacto-N-neotetraose; or
from 120 to 1600 mg/liter of lacto-N-fucopentaose V;
and said composition further comprises edible macronutrients,

wherein said composition is intended for use with normal, healthy infants, children, adults or subject having specialized needs such as those that accompany certain pathological conditions, said process comprising the step of preparing said oligosaccharides by chemical synthesis."

Claims 2 to 6 and 8 to 11 were dependent claims.

II. On 23 February 2009 oppositions against the patent were filed by

Friesland Brands B.V. (opponent I) and

N.V. Nutricia (opponent II).

The opponents requested revocation of the patent in its entirety on the grounds according to Article 100(a) EPC

(lack of novelty and lack of inventive step), 100(b) and 100(c) EPC.

- III. With its decision announced orally on 15 January 2009 and issued in writing on 13 February 2009 the opposition division revoked the patent. The only reason for revocation was that the subject-matter of the independent claims 1 and 7 as granted did not comply with the requirements of Article 123(2) EPC.

The opposition division argued in particular that, owing to the wording "selected from the group consisting of" the oligosaccharides in the composition of claims 1 and 7 as granted were now strictly limited to the presence of at least one of eight specified oligosaccharides, while excluding the oligosaccharide lacto-N-tetraose (LNT) and any other (non-specified) oligosaccharides. In contrast, claim 1 as originally filed required the presence of at least one of nine oligosaccharides including LNT, and left room for further non-specified oligosaccharides. In addition, the amounts of the respective oligosaccharides were restricted by combining the lower levels of original claim 17 with the upper levels of original claim 16. The omission of LNT, the restriction of the amounts of the other specified oligosaccharides in accordance with original claims 16 and 17 and the exclusion of other non-specified oligosaccharides was a multiple selection of features which did not comply with Article 123(2) EPC.

- IV. Notice of appeal was filed by the patent proprietor (hereinafter: appellant) on 18 March 2009. The

prescribed fee was paid on the same day. The grounds of appeal were received on 19 June 2009.

The appellant contradicted the arguments of the opposition division concerning non-compliance with Article 123(2) EPC and filed three sets of claims as a basis for a main request and first and second auxiliary requests. The claims of the main request were identical with the granted claims.

- V. Opponents I and II (hereinafter respondents I and II) responded to the grounds of appeal with their letters dated 6 November 2009 (respondent I) and 18 January 2010 (respondent II) and maintained their objections under Article 123(2) EPC.
- VI. With the letter dated 14 July 2011 the appellant filed a further set of claims as basis of a third auxiliary request.
- VII. In a communication sent per fax on 9 September 2011 the board noted that the only reason for revocation of the patent was added subject-matter (Article 123(2) EPC). This issue would be dealt with in the oral proceedings scheduled for 11 October 2011. In respect of this issue, the board gave its preliminary view on the interpretation of claims 15 to 20 as originally filed and on the amendment of the wording "comprising" in the original claims to "consisting of" in the claims of all current requests.
- VIII. In their letters dated 9 September 2011 and 6 October 2011 the respondents provided further arguments as to non-compliance with Article 123(2) EPC and raised

objections under Article 84 and 123(3) EPC against various requests of the appellant. In addition, respondent II pointed out that the description of the opposed patent, in particular the text relating to the single illustrative example, also contravened Article 123(2) EPC.

IX. On 11 October 2011 oral proceedings were held before the board. At the beginning, the appellant re-ordered its requests. The third auxiliary request became the main request and the claims as granted (old main request) and the first and second auxiliary requests became the first to third auxiliary requests. After the discussion of the main request, which was admitted into the proceedings, with regard to Article 123(2) and 84 EPC, the appellant filed a set of claims 1 to 4 as the basis for a new main request replacing the former (re-ordered) main request. Independent claims 1 and 3 of this request read as follows:

"1. A synthetic nutritional composition comprising one or more human milk oligosaccharides, wherein the human milk oligosaccharides in the composition are selected from the group consisting of:

from 1456 to 1750 mg/liter of 3-fucosyllactose;
from 507 to 1100 mg/liter of lacto-N-fucopentaose III;
from 361 to 750 mg/liter of lacto-N-fucopentaose II;
from 393 to 1450 mg/liter of difucosyllactose;
from 2240 to 2400 mg/liter of 2'-fucosyllactose;
from 845 to 1650 mg/liter of lacto-N-fucopentaose I;
from 258 to 450 mg/liter of lacto-N-neotetraose; or
from 120 to 1600 mg/liter of lacto-N-fucopentaose V;

and said composition further comprises edible macronutrients, formulated for feeding to an infant selected from one or more of coconut oil, soy oil, mono- and diglycerides, glucose, food grade lactose, electro dialysed whey, electro dialysed skim milk and milk whey, one or more of vitamins A, C, D, E, and B complex; and one or more of minerals, calcium, magnesium, manganese, sodium, potassium phosphorus, copper, zinc chloride, iodine, selenium and iron,

wherein said composition is intended for use with normal, healthy infants, children, adults or subject having specialized needs such as those that accompany certain pathological conditions."

"3. A process for manufacturing a synthetic nutritional composition comprising one or more human milk oligosaccharides, wherein the human milk oligosaccharides in the composition are selected from the group consisting of:

from 1456 to 1750 mg/liter of 3-fucosyllactose;
from 507 to 1100 mg/liter of lacto-N-fucopentaose III;
from 361 to 750 mg/liter of lacto-N-fucopentaose II;
from 393 to 1450 mg/liter of difucosyllactose;
from 2240 to 2400 mg/liter of 2'-fucosyllactose;
from 845 to 1650 mg/liter of lacto-N-fucopentaose I;
from 258 to 450 mg/liter of lacto-N-neotetraose; or
from 120 to 1600 mg/liter of lacto-N-fucopentaose V;
and said composition further comprises edible macronutrients, formulated for feeding to an infant selected from one or more of coconut oil, soy oil, mono- and diglycerides, glucose, food grade lactose, electro dialysed whey, electro dialysed skim milk and

milk whey, one or more of vitamins A, C, D, E, and B complex; and one or more of minerals, calcium, magnesium, manganese, sodium, potassium phosphorus, copper, zinc chloride, iodine, selenium and iron,

wherein said composition is intended for use with normal, healthy infants, children, adults or subject having specialized needs such as those that accompany certain pathological conditions, said process comprising the step of preparing said oligosaccharides by chemical synthesis."

The respondents requested that the new main request be not admitted into the proceedings.

X. The arguments of the respondents, as far as they are related to the subject-matter of the new main request may be summarized as follows:

(a) Article 123(2) EPC

(i) Main request submitted during the oral proceedings

The open wording "comprising" relating to the presence of at least one of nine specified human milk oligosaccharides in the composition claimed in claim 1 as originally filed not only embraced the nine oligosaccharides but also left room for the presence of other non-specified oligosaccharides.

Replacement of the wording "comprising" by "consisting of" and the similar deletion of the ninth oligosaccharide lacto-N-tetraose (LNT) in

claim 1 of the main request, with the consequence that no other oligosaccharide, except for the specified eight remaining ones, could be present in the claimed composition did not comply with Article 123(2) EPC.

It emerged in particular from the first paragraph on page 2 of the application as filed, that the deleted oligosaccharide LNT was a biologically beneficial human milk oligosaccharide. This was confirmed by the chromatogram depicted in figure 1 showing that LNT was a major fraction in human milk. There was thus a pointer in the application as filed that LNT was an essential ingredient of the claimed nutritional composition which was formulated for feeding infants in order to replace human milk. Deletion of this essential LNT was therefore a shift of the invention for which no basis existed in the application as filed.

Furthermore, the additional exclusion of the presence of other non-specified oligosaccharides, together with the deletion of LNT, had to be considered a combination of two distinct measures which was not allowable under Article 123(2) EPC.

Furthermore, claim 1 could also not be derived from a combination of the features of independent claim 18 and dependent claims 19 and 20 as originally filed because the composition according to claim 18 neither had to be synthetic nor did it specify the intended use, as required by claim 1.

(ii) Example in the patent specification

The single example in the patent specification mentioned, in the introductory section, a list of only 5 of the nine originally disclosed oligosaccharides. This did not correspond to original example 4 from which this example was derived and which indicated a complete list of all nine oligosaccharides. The amendment in the example of the patent specification was therefore objectionable under Article 123(2) EPC.

(b) Article 84 EPC

The composition of claim 1 included, in addition to the specified oligosaccharides, edible macronutrients which are "*formulated for feeding to an infant*". This limited property is in contradiction to the extended use of the composition which, according to the last phrase in the claim "*is intended for use with normal, healthy infants, children, adults or subject having specialized needs...*".

The scope of claim 1 was therefore unclear, contrary to Article 84 EPC.

XI. The appellant's counterarguments were as follows:

(a) Article 123(2) EPC

(i) Reformulation of claim 1 into a closed language in respect of the oligosaccharides excluded the presence of further oligosaccharides which were hypothetical and nowhere disclosed in the

application as filed. Furthermore, deletion of the optional oligosaccharide LNT from the list was simply a restriction of the list from nine to eight possible oligosaccharides.

In this context it had to be noted that, contrary to the respondents' view, there was no pointer in the application as filed that LNT was an essential component which was indispensable for the claimed composition. Paragraph 2 at page 1 of the description listed LNT as only one of nine possible oligosaccharides which could be present in the synthetic nutritional composition. Moreover, the passage on page 11 of the description explaining the chromatograms depicted in the figures of the application related to human milk and not to the synthetic composition of the present invention.

As to the respondents' objection that claim 1 was not derivable from a combination of claims 18 to 20 as originally filed because the claims were not directed to a synthetic composition it should be noted that the invention as a whole pertained to a synthetic nutritional composition. This became evident from the paragraph relating to the "Technical Field of the Invention" on page 1 of the application as filed, which indicated that *"The present invention relates generally to the composition of synthetic nutritional products containing oligosaccharides from human milk"*.

- (ii) Original example 4 from which the single example of the patent was derived, unambiguously disclosed a ready-to-feed infant formulation including only

five of the nine possible oligosaccharides listed in the recipe on page 16 under the heading "Nutrients:". Deletion of the oligosaccharides in the introductory section of the example, which were not intended to be used in the recipe was therefore just a harmonisation of both parts of the example.

(b) Article 84 EPC

The inconsistency in claim 1 between the formulation of the edible macronutrients comprised in the claimed nutritional composition and the intended use of the composition was not objectionable under Article 84 because these features resulted from a combination of claims 1 and 2 as granted.

XII. The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution on the basis of claims 1-4, filed as main request during the oral proceedings, alternatively, on the basis of the claims as granted (1st auxiliary request) or on the basis of the sets of claims filed with the letter dated 19 June 2009 as "First" and "Second" auxiliary requests.

XIII. The respondents requested that the appeal be dismissed, alternatively, in the event of the decision being set aside, that the case be remitted to the opposition division for further prosecution.

Reasons for the Decision

1. The appeals are admissible.

2. Admission of the new main request into the proceedings

Independent claims 1 and 3 of the new main request are based on claims 1, 2 and 7 as granted with the amendment that the claims now clearly indicate that the macronutrients formulated for feeding to an infant, as well as the vitamins and minerals are those defined in claim 18 as originally filed. This amendment was a reaction to the respondents' objections under Article 84 submitted in writing at short notice (9 September 2011 and 6 October 2011, respectively) and reiterated in the oral proceedings, that definition of the macronutrients in claim 1 of the former third auxiliary request was not clear.

Since the amendment is nothing but a further clarification of the wording already proposed in the former third auxiliary request and introduces nothing which would have shifted the claimed subject-matter in a surprising manner, the board exercised its discretion according to Article 13(1) of the Rules of Procedure of the Boards of Appeal and admitted the new main request into the proceedings.

3. Article 123(2) EPC - main request
 - 3.1 Claim 1 is directed to a nutritional composition comprising one or more human milk oligosaccharides.

The composition is characterised by the following elements

- (i) the composition is synthetic;
- (ii) the oligosaccharides are selected from eight out of nine originally specified oligosaccharides in specific restricted amounts;
- (iii) the composition further comprises edible macronutrients formulated for feeding to an infant;
- (iv) the macronutrients under (iii) are selected from specified components;
- (v) the composition comprises one or more of specified vitamins and minerals;
- (vi) the composition is intended for a specific use.

Basis for this claim is found in claims 1 to 3 as filed (features (i), (iii)), claims 18 to 20 as filed (features (ii), (iv), (v)) and the paragraph bridging pages 4 and 5 of the application as filed (feature vi)).

- 3.2 As to feature (i) the respondents objected that claims 18 to 20 as filed could not be combined with claim 1 as filed because independent claim 18 was not directed to a synthetic composition. This argument is, however, not convincing, as it is apparent from the application as a whole, and in particular from the second paragraph at page 1 of the application as filed, that the invention in general is directed to a composition of synthetic nutritional products (emphases by the board).

3.3 As regards feature (ii) all parties agreed that independent claim 1 is formulated in a "closed" language. It allows solely the presence of one or more of eight recited human milk oligosaccharides within the claimed concentration ranges.

3.3.1 The specified concentration ranges for the eight oligosaccharides can be derived from a combination of the upper limits according to claim 19 as filed and the lower limits according to claim 20 as filed. This was not contested by the respondents.

3.3.2 The respondents, however, contested that it did not comply with Article 123(2) EPC to delete one (ie LNT) of the nine originally specified oligosaccharides and to exclude additionally any other oligosaccharide by replacing the open definition in claim 1 as filed ("A synthetic nutritional composition comprising at least one of the following oligosaccharides") with the closed definition of claim 1 as granted and claim 1 of the main request, respectively ("A synthetic nutritional composition comprising one or more human milk oligosaccharides, wherein the human milk oligosaccharides in the composition are selected from the group consisting of").

3.3.3 The board does not share the respondents' view for the following reasons:

- (a) The wording of original claims 1 and 18 "*at least one of...*" clearly allows the presence of only one of the nine specified oligosaccharides. This unambiguously implies that one oligosaccharide must be present and the other eight can or cannot

be an ingredient in the claimed composition. In other words, each of the nine oligosaccharides - including LNT - is an optional composition as long as one of the nine is present. In this context the deletion of the optional LNT merely means that the list of nine potentially optional oligosaccharides has been reduced to a list of eight. This deletion does not introduce an individualisation or specific non-disclosed combination of the remaining eight oligosaccharides. In fact, the deletion of one member of the list does not change the level of generality as regards the information concerning the oligosaccharides.

Furthermore, no disclosure is found in the application as filed which would give clear advice to a skilled person that LNT is particularly preferred over the other eight oligosaccharides or is indispensable for the claimed composition. Therefore, contrary to the respondents' view, the deletion of LNT does not shift the claimed subject-matter to a different invention.

- (b) The exclusion of the optional presence of any other human milk oligosaccharides is the consequence of the introduction of the "closed" definition for the oligosaccharides. The board accepts that there is no explicit disclosure in the application as filed for the exclusion of other oligosaccharides. However, when it comes to human milk oligosaccharides, the application as filed refers only to the originally listed nine oligosaccharides; no reference can be found to any other oligosaccharide. Also all the original

examples relating to synthetic nutritional formulations, ie examples 3 to 8, use only oligosaccharides listed in original claim 1. Thus, the skilled reader would at least implicitly learn from the application as filed that the invention concerns only the oligosaccharides listed in the claims.

(c) In summary, the deletion of LNT and the closed definition in claim 1 comply with Article 123(2) EPC.

3.4 The basis for features (iii) to (vi) in the application as filed, namely claims 3 and 18 as filed and the paragraph bridging pages 4 and 5 of the application as filed was not contested. The board is satisfied that these features also comply with Article 123(2) EPC.

3.5 The above considerations also apply to claim 3 of the main request.

4. Article 123(2) - description

4.1 In the patent specification only one example is left, which is an "Illustrative example of a Ready-to-Feed Infant Formulation Containing Oligosaccharides being not part of the invention" (page 8, lines 24-25).

Paragraph [0040] describes the formulation as follows:

"A ready-to-feed infant formulation containing the oligosaccharides 3-fucosyllactose, lacto-N-fucopentaose III, lacto-N-fucopentaose II,

difucosyllactose, 2'-fucosyllactose, has the following composition (147.9 ml (5 fluid ounces) = 100 Cal):

<u>Nutrients:</u>	<u>Per 100 Cal:</u>
Protein	2.14 g
Fat	5.40 g
Carbohydrates	10.7 g
3-Fucosyllactose	206.6 mg
Lacto-N-Fucopentaose III	72.0 mg
Lacto-N-Fucopentaose II	51.3 mg
Difucosyllactose	55.8 mg
2'-Fucosyllactose	318.1 mg
Water	133 g
Linolic Acid	1300.0 mg

... "

Respondent II argued that the first sentence of paragraph [0040] in the patent specification violated Article 123(2) EPC, since the corresponding passage in the application as filed (example 4, page 15 last paragraph) listed nine oligosaccharides. In the illustrative example of the patent specification lacto-N-fucopentaose I, lacto-N-neo-tetraose, lacto-N-fucopentaose V and lacto-N-tetraose had been deleted from the introductory sentence.

- 4.2 Examples 3 to 8 of the application as filed all begin with the phrase "*A ready-to-feed infant formulation containing the oligosaccharides...*", followed by a literal enumeration of all nine oligosaccharides. This paragraph ends with the phrase that the formulation "... *has the following composition ...*". The respective composition is then presented by a "recipe-type" list

indicating protein, fat, oligosaccharides, vitamins and minerals as outlined above. Although the same introductory text module has been used for examples 3 to 8, the board notes that the actual "recipe-type" list of only example 3 contains all 9 oligosaccharides. The "recipe" of examples 4 to 8 contain less than 9 oligosaccharides (example 4 (5), (example 5 (4), (example 6 (5), (example 7 (3), (example 8 (7)). It is therefore immediately evident to a skilled person that, irrespective of the introductory section of each example, it is the "recipe" that characterises each exemplified infant formulation. Therefore, the enumeration of only those oligosaccharides in the introductory part of each example which are indeed mentioned in the subsequent recipe does not violate Article 123(2) EPC.

This also applies to the single illustrative example in the patent specification which is based on example 4 as filed describing a nutritional formulation containing no LNT. Reduction of the oligosaccharides mentioned in the introductory phrase to those five mentioned in the "recipe" of the composition of example 4 simply removes an inconsistency and is certainly not objectionable under Article 123(2) EPC.

5. Article 84 EPC

5.1 It is established case law that amendments to the claims which originate from the claims as granted are not objectionable under Article 84 EPC (eg T 381/02, point 2 of the reasons).

The wording in claim 1 of the main request "... and said composition further comprises edible macronutrients formulated for feeding to an infant ..." followed by the wording "wherein said composition is intended for use with normal, healthy infants, children, adults or subject having specialized needs ..." stems from a combination of claims 1 and 2 as granted, the latter referring back to claim 1. Although a certain inconsistency may arise between the purpose of the macronutrients ("formulated for feeding to an infant") and the extended use of the claimed composition ("children, adults ..."), this inconsistency cannot be attacked under Article 84 EPC.

5.2 The change of the definition of the macronutrients formulated for feeding to an infant by the wording "selected from ...", ie in the sense that they are now exactly those literally indicated in the claim does not introduce any inconsistency into the claim which is objectionable under Article 84 EPC. On the contrary, it removes an inconsistency which arose from the former main request (ie the old third auxiliary request filed with the letter dated 14 July 2011) by the separation of the wording "macronutrients formulated for feeding to an infant" and the subsequent literal enumeration of macronutrients via a semicolon ("macronutrients formulated for feeding to an infant; one or more of coconut oil, soy oil, ...").

5.3 The same considerations also apply to claim 3.

6. For the above reasons, the amendments to the claims according to the main request and the example of the patent specification comply with Article 123(2) EPC.

Furthermore, the claims are not objectionable under Article 84 EPC. It is therefore not necessary to deal with the other requests.

7. Remittal

Since the decision under appeal has dealt only with the issue of added subject-matter, the board decided to remit the case to the opposition division for further prosecution, this all the more as it was requested by all parties.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition for further prosecution on the basis of claims 1-4, filed as main request during the oral proceedings before the board.

The Registrar

The Chairman

A. Counillon

W. Sieber