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Title of invention:
Nutritional composition comprising indigestible oligosaccharides

Applicant:
N.V. Nutricia

Headword:
Nutritional composition comprising indigestible oligosaccharides/NUTRICIA

Relevant legal provisions:
EPC Art. 83, 111(1)
RPBA Art. 11, 12(2)

Keyword:
Sufficiency of disclosure
Appeal decision - remittal to the department of first instance (yes)

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Case Number: T 1963/18 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 12 November 2020

Appellant: (Applicant)	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 Examining Division of the European Patent Office posted on 8 March 2018 refusing European patent application No. 10 180 272.6 pursuant to Article 97(2) EPC**

Composition of the Board:

Chairman	B. Claes
Members:	A. Schmitt
	M. Blasi

Summary of Facts and Submissions

I. The appeal of the applicant (hereinafter "appellant") lies from the decision of the examining division refusing European patent application No. 10 180 272.6 entitled "*Nutritional composition comprising indigestible oligosaccharides*" (hereinafter "the application"). The application is a divisional application of European patent application No. 05 775 158.8, which had been filed as an international application published as WO 2005/022542.

II. The examining division held that the application did not disclose the invention defined in claims 1 and 15 of the main request and an auxiliary request in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Claims 1 and 15 of the main request read as follows:

"1. A composition for use in the treatment and/or prevention of respiratory tract infection and/or respiratory tract infection disease, comprising orally administering said composition to a mammal, said mammal being an infant with the age between 0 and 4 years, said composition comprising
a) a galactose containing indigestible oligosaccharide containing at least two terminal saccharide units, wherein said galactose containing indigestible oligosaccharide is selected from the group consisting of transgalactooligosaccharides, galactooligosaccharides, lacto-N-tetraose (LNT), lacto-N-neotetraose (neo-LNT), fucosyl-lactose, fucosylated LNT and fucosylated neo-LNT; and

b) at least 5 wt.% digestible galactose saccharide based on total dry weight of the composition, said saccharide being selected from the group consisting of galactose and digestible galactose containing saccharide containing at least two terminal saccharide units, wherein at least one terminal saccharide unit is selected from the group consisting of glucose and galactose; and at least one terminal saccharide is selected from the group consisting of galactose and fucose, and wherein said composition administered does not consist of human milk."

"15. Use of a composition in the manufacture of a product for the treatment and/or prevention of respiratory tract infection and/or respiratory tract infection disease, comprising orally administering said composition to a mammal, said mammal being an infant with the age between 0 and 4 years, said composition comprising
a) a galactose containing indigestible oligosaccharide containing at least two terminal saccharide units, wherein said galactose containing indigestible oligosaccharide is selected from the group consisting of transgalactooligosaccharides, galactooligosaccharides, lacto-N-tetraose (LNT), lacto-N-neotetraose (neo-LNT), fucosyl-lactose, fucosylated LNT and fucosylated neo-LNT; and
b) at least 5 wt.% digestible galactose saccharide based on total dry weight of the composition, said saccharide being selected from the group consisting of galactose and digestible galactose containing saccharide containing at least two terminal saccharide units, wherein at least one terminal saccharide unit is selected from the group consisting of glucose and galactose; and at least one terminal saccharide is selected from the group consisting of galactose and

fucose, and wherein said composition administered does not consist of human milk."

III. With the statement of grounds of appeal, the appellant upheld the main request and the auxiliary request on which the decision under appeal was based. The arguments of the appellant with respect to sufficiency of disclosure can be summarised as follows.

The examining division had not provided evidence based on verifiable facts which substantiated that the additional amount of 10% fructooligosaccharides (FOS) present in the composition used in example 6 was instrumental for the effect of the composition or potentiated the effect of the galactooligosaccharides (GOS) in the composition. The examining division's objections were thus based on speculations and unsubstantiated assertions.

The invention was that respiratory tract infections in infants could be prevented or treated with a composition comprising a combination of a galactose containing indigestible oligosaccharide and a relatively high amount of a digestible galactose saccharide (see e.g. paragraph [0011] and example 6 of the application). The non-digestible oligosaccharide fraction of the composition used in example 6 comprised 90% GOS based on the total of non-digestible oligosaccharides. The skilled person would derive from example 6 that intervention with non-digestible oligosaccharides resulted in the reduction of incidences of respiratory tract infection.

Post-published document WO 2012/092154 (paragraph 8) confirmed that a method of administering 3'sialyllactose, 6'-sialyllactose, 2'-fucosyllactose or

lacto-N-neotetraose improved airway respiratory health of an infant.

In view of the available evidence in the application and the post-published confirmation, the burden of proof was on the examining division to substantiate its allegations, which it failed to do. Accordingly, no case of insufficient disclosure has been made, and it had to be concluded that the application sufficiently disclosed the invention of claim 1 of the main request.

IV. The board appointed oral proceedings, in accordance with the appellant's corresponding request. The board subsequently issued a communication pursuant to Article 15(1) RPBA dated 11 August 2020, informing the appellant that the appeal appeared allowable and asking the appellant, within a period of two months, to clarify its procedural requests, in particular concerning a potential remittal to the examining division. Furthermore, the appellant's attention was drawn to the provisions of Rule 103(4)(c) EPC.

V. By letter received on 19 October 2020, the appellant withdrew its request for oral proceedings on the condition that the decision be set aside and that the case be remitted to the examining division for further prosecution.

VI. The board cancelled the oral proceedings and indicated that the proceedings would be continued in writing.

VII. The appellant requested that the decision under appeal be set aside and the case be remitted to the examining division for further prosecution on the basis of the claims of the main request.

Reasons for the Decision

1. The appeal is admissible.

Sufficiency of disclosure (Article 83 EPC)

2. Claims 1 and 15 of the main request (see section II) relate to the treatment or prevention of respiratory tract infections in an infant aged between 0 and 4 years with a composition comprising a galactose containing indigestible oligosaccharide and at least 5 wt% digestible galactose saccharide based on total dry weight of the composition, wherein the composition does not consist of human milk. The galactose containing *indigestible* oligosaccharide is selected from the group consisting of transgalactooligosaccharides (TOS), GOS, lacto-N-tetraose (LNT), lacto-N-neotetraose (neo-LNT), fucosyl-lactose, fucosylated LNT and fucosylated neo-LNT (see part a) of the claim). The *digestible* galactose saccharide is also further defined in the claims (see part b) of the claim).

3. The examining division held that the data shown in example 6 did not disclose to the skilled person that treatment or prevention of respiratory tract infection could be achieved in the absence of a second indigestible oligosaccharide selected from FOS, hydrolysed inulin or inulin. Hence, a new multicentre trial "*without a reasonable expectation of success*" was required to elucidate the effect of such a composition. This represented an "*undue burden*" on the skilled person (see decision under appeal, point 12.1 of the Reasons, last paragraph).

4. The board agrees that the composition used in the clinical trial disclosed in example 6 of the application does not exactly correspond to the claimed composition. However, Article 83 EPC does not require a claimed invention to have actually been carried out by the applicant. Consequently, the fact that the application does not explicitly disclose experiments demonstrating the claimed therapeutic effect for the claimed composition is not, as such, a sufficient reason to cast doubts on the occurrence of this effect.

5. The examining division further held that since the preventive or therapeutic effect of a given compound was "*not always dose-dependent*" and "[i]*t may well be the case that the presence of FOS potentiates the effect of GOS (TOS) or that it is responsible to a large extent for the observed preventive response*", the skilled person had serious doubts that the therapeutic effect defined in claims 1 and 15 could be achieved with a composition that comprised GOS (TOS) but not FOS (or (hydrolysed) inulin; see decision under appeal, point 12.2 of the Reasons, second paragraph). Furthermore, since "*plausibility is not established in the application*", the post-published disclosure (WO 2012/092154) could not be used to establish sufficiency of disclosure (*ibid.*, fourth paragraph).

6. The board notes that it is established jurisprudence of the boards of appeal that a successful objection of lack of sufficiency of disclosure presupposes that alleged serious doubts are substantiated by verifiable facts (see also Case Law of the Boards of Appeal of the European Patent Office, 9th edition 2019, II.C.5.3., II.C.7.1.4 and II.C.9.).

7. It goes without saying that the skilled person is aware that other events as well could explain the therapeutic effect of the composition shown in example 6 rather than straightforwardly attributing it to the major component of the indigestible oligosaccharides of the composition (GOS (TOS)) alone. The board notes, however, that in the absence of particular evidence that the minor component FOS plays a decisive role for the occurrence of the therapeutic effect, any alleged "serious doubts" remain unsubstantiated and fail to go beyond speculation.

8. Considering the evidence before it, the board hence finds the reasoning of the examining division as to why the claimed invention is not sufficiently disclosed in the application not convincing. The examining division has thus not made a case that the skilled person would not deem the application sufficient to demonstrate that the claimed compound provides the required technical effect. The post-published evidence, therefore, is not of decisive value in the present case.

9. Thus, in view of the above considerations, the board is of the opinion that the arguments and evidence brought forward by the examining division are not sufficient to arrive at the conclusion that the application does not sufficiently disclose the invention defined in the claims of the main request. Accordingly, the appeal is allowable.

Remittal (Article 111(1) EPC)

10. Pursuant to Article 111(1), second sentence, EPC, the board may either exercise any power within the competence of the department which was responsible for

the decision appealed or remit the case to that department for further prosecution.

11. Pursuant to Article 11 RPBA 2020, the board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so.

12. In the present case, the board considers that special reasons present themselves for remitting the case to the examining division. The sole reason for refusing the application was that it did not meet the requirements of Article 83 EPC, and the board has reviewed this decision (see points 3 to 9 above). The examining division has not assessed, in the appealable decision, any further requirements of the EPC, including the requirements for patentability with respect to the claims of the main request. Thus, in the appeal proceedings, the board would have to deal with a number of fresh aspects unrelated to the issues addressed in the decision under appeal. As confirmed by Article 12(2) RPBA 2020, it is the primary object of the appeal proceedings to review the decision under appeal in a judicial manner (see also Case Law of the Boards of Appeal, 9th edition 2019, section V.A.1.1, second paragraph and decisions referred to there). Furthermore, the appellant requested remittal of the case to the examining division for further prosecution as its main procedural request.

13. Accordingly, exercising its discretion under Article 111(1), second sentence, EPC, the board decides to remit the case to the examining division for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division for further prosecution on the basis of claims 1 to 15 of the main request filed by letter dated 12 October 2017.

The Registrar: The Chairman:

I. Aperribay B. Claes

Decision electronically authenticated