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Datasheet for the decision of 29 September 2022

Case Number: T 0618/19 - 3.3.09

Application Number: 13703889.9

Publication Number: 2802222

IPC: A23L33/00, A23L33/17, A61K31/198, A61K38/05, A61K38/06, A61K31/702

Language of the proceedings: EN

Title of invention:
GLUTAMINE ENRICHED NUTRITIONAL COMPOSITION FOR PRETERM INFANTS

Patent Proprietor:
N.V. Nutricia

Opponent:
Fresenius Kabi Deutschland GmbH

Headword:
Glutamine enriched nutritional composition/NUTRICIA

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0618/19 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 29 September 2022

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)	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg (DE)
Representative:	Fresenius Kabi Deutschland GmbH Patent Department Pharmaceuticals Division Borkenberg 14 61440 Oberursel (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 17 December 2018 concerning maintenance of the European Patent No. 2802222 in amended form.**

Composition of the Board:

Chairman	A. Haderlein
Members:	M. Ansorge
	N. Obrovski

Summary of Facts and Submissions

I. The proprietor and the opponent both lodged an appeal against the opposition division's interlocutory decision holding the then auxiliary request 3 allowable.

II. With its notice of opposition, the opponent had requested that the patent be revoked, *inter alia*, on the ground for opposition under Article 100(a) EPC in conjunction with Article 56 EPC (lack of inventive step).

III. The opposition division decided, *inter alia*, that the claimed subject-matter of the then auxiliary request 3 involved an inventive step in view of D1 as the closest prior art.

IV. The following documents were cited in the proceedings:

D1: Korkmaz et al., "Long-term enteral glutamine supplementation in very low birth weight infants: effects on growth parameters", The Turkish Journal of Pediatrics, 2007, volume 49, pages 37-44

D13: Bethlehem et al., "Brain charts for the human lifespan", 2022, Nature 604, pages 525-533.

V. Independent product claim 6 of the then auxiliary request 3 before the opposition division (which is identical to claim 10 of the main request, claim 4 of auxiliary request 1, claim 6 of auxiliary request 2, claim 4 of auxiliary request 3 and claim 1 of auxiliary request 4 on appeal) reads as follows:

"Glutamine-based supplement in the form of a powder in a unit dose comprising at least 15 wt.% glutamine in the form of free glutamine, glutamine dipeptide and/or glutamine tripeptide on dry weight of the powder and further comprising non-digestible oligosaccharides selected from the group consisting of galacto-oligosaccharides and fructo-oligosaccharides."

VI. The parties' relevant arguments, submitted in writing and during the oral proceedings, are reflected in the reasons for the decision set out below.

VII. Requests

The proprietor requested that the decision be set aside and that the patent be maintained on the basis of the main request, the claims as held allowable by the opposition division or one of auxiliary requests 1 to 4, all filed with the proprietor's letter of 23 June 2022.

The opponent requested that the decision be set aside and that the patent be revoked.

Reasons for the Decision

MAIN REQUEST

1. Claim 10 - inventive step

1.1 There was agreement between the parties that D1 qualified as the closest prior art in the present case.

1.2 D1 relates to a study aimed at determining whether long-term glutamine-supplemented enteral nutrition affects growth parameters in very-low-birth-weight (VLBW) preterm infants. In this study, preterm infants with a birth weight of <1500 g were assigned to receive enteral glutamine supplementation (300 mg/kg/day) or a placebo between 8-120 days of life. At the end of each month, the growth parameters weight, length, head circumference, left upper mid-arm circumference (MAC) and left mid-thigh circumference (MTC) were determined, and the enteral glutamine dose was adjusted according to the current weight. In VLBW infants, the glutamine-supplemented group had significantly higher mean weight, length, head circumference, MAC and MTC than the control group at the end of the fourth month (see the summary of D1).

1.3 There was further agreement between the parties that the glutamine-based supplement of claim 10 of the main request only differed from the glutamine-containing supplement according to D1 in the presence of galacto-oligosaccharides (GOS) and fructo-oligosaccharides (FOS) as non-digestible oligosaccharides. The board agrees with this as well.

1.4 There was disagreement between the parties concerning the effect resulting from this single difference from D1.

1.5 The proprietor argued that the presence of GOS and/or FOS in the claimed glutamine-containing supplement led to an improvement in the effect of glutamine on the structural brain volume or growth in that it aided the uptake of glutamine. In this context, reference was made to paragraph [0025] of the patent.

1.6 The opponent contested the argument that any improvement over D1 was shown and it submitted that no evidence for this alleged effect could be derived from the patent. Moreover, this alleged effect was not credible.

1.7 For the reasons set out below, no improvement over D1 can be acknowledged.

1.7.1 Paragraph [0025] of the patent mentions that non-digestible oligosaccharides advantageously improve the effect of the glutamine present upon structural brain volume or growth and stimulate a healthy gut environment, thereby aiding the uptake of glutamine.

1.7.2 However, no example is provided in the patent and there is no other evidence on file that demonstrates the alleged improvement resulting from the presence of GOS and/or FOS in a glutamine-containing supplement.

In this context, it is noted that the glutamine-containing supplement of example 1 of the patent does not contain GOS and/or FOS. Instead, it merely contains glutamine as the essential component, as does the glutamine supplement of D1. Example 2 of the patent relates to a preterm formula enriched in glutamine which comprises GOS and FOS. However, the preterm formula of example 2 of the patent does not relate to the supplement as such and, more importantly, no tests were carried out with this formula. Example 3 of the patent relates to a nutritional supplement enriched in glutamine, but it does not contain any GOS and/or FOS. Thus, the alleged effect cannot be derived from the examples of the patent.

1.7.3 Bearing in mind that the supplement of D1 also contains a significant content of glutamine, being in line with that of example 1 of the patent, it is not credible that an improvement exists over the supplement disclosed in D1. It is noted that the glutamine supplement according to D1 leads to a significant improvement in numerous growth parameters in very-low-birth-weight infants. Thus, no improvement over D1 can be acknowledged.

1.8 As a consequence, the objective technical problem to be solved is the provision of an alternative glutamine-based supplement.

1.9 With respect to the question of obviousness, it is noted that both parties agreed that the addition of GOS or FOS in infant formulas belongs to the common general knowledge of a skilled person in the present technical field. There was also agreement between the parties that it was known that the addition of GOS or FOS leads to a healthy gut environment. The board does not see any reason to doubt this congruent view of the parties concerning the common general knowledge of a skilled person in the present technical field.

1.10 It is consequently an obvious measure for a skilled person to add GOS and FOS to an infant formula such as the glutamine supplement of D1, since the possibility of adding GOS and FOS belongs to the common general knowledge. According to the patent proprietor, the prior art did not teach the use of GOS and FOS to aid in the uptake of glutamine. However, in the absence of a demonstrated improvement over D1, no particular motivation is necessary for adding GOS and FOS. The claimed glutamine-based supplement is an obvious alternative in view of D1.

Thus, the subject-matter of claim 10 of the main request does not involve an inventive step in view of D1 as the closest prior art in combination with the common general knowledge.

AUXILIARY REQUESTS

2. Since claim 10 of the main request is identical to claim 6 of the set of claims upheld by the opposition division, as well as to claim 4 of auxiliary request 1, claim 6 of auxiliary request 2, claim 4 of auxiliary request 3 and claim 1 of auxiliary request 4, the same conclusion equally applies to all other claim requests on file. Thus, there is no allowable claim request on file.

3. Admittance of document D13

During the oral proceedings before it, the board decided not to admit document D13. This document, however, had only been relied on by the proprietor in relation to a claim other than claim 10 of the main request and the corresponding claims of the other requests. Therefore, its non-admittance is not relevant for the present decision.

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:

M. Schalow A. Haderlein

Decision electronically authenticated