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Datasheet for the decision of 9 March 2021

Case Number: T 1431/17 - 3.3.09

Application Number: 09015087.1

Publication Number: 2332428

IPC: A23L1/305, A61K38/01

Language of the proceedings: EN

Title of invention:
Nutritional Formulation comprising a cow's milk peptide-containing hydrolysate and/or peptides derived thereof for tolerance induction

Patent Proprietor:
MJN U.S. Holdings LLC

Opponent:
N.V. Nutricia

Headword:
Cow's milk peptide-containing hydrolysate/MJN HOLDING

Relevant legal provisions:
EPC Art. 54, 100(a)
RPBA 2020 Art. 13(2)

Keyword:
Novelty - main request (no)
Amendment to appeal case - taken into account (no)

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Case Number: T 1431/17 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 9 March 2021

Appellant: (Opponent)	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)	MJN U.S. Holdings LLC 225 North Canal Street 25th Floor Chicago, Illinois 60606 (US)
Representative:	Cawdell, Karen Teresa Reckitt Benckiser Corporate Services Limited Legal Department - Patents Group Dansom Lane Hull HU8 7DS (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 25 April 2017 rejecting the opposition filed against European patent No. 2332428 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Haderlein
Members:	F. Rinaldi
	E. Kossonakou

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the opponent (appellant) against the decision of the opposition division to reject the opposition against European patent No. 2332428.

II. In the notice of opposition, the opponent had requested revocation of the patent based on, *inter alia*, Article 100(a) EPC for lack of novelty.

III. The documents relevant for this decision are:

D9: G. Oldaeus et al., "Extensively and partially hydrolysed infant formulas for allergy prophylaxis", Archives of Disease in Childhood 77, 1997, 4-10

D24: L. Carroccio et al., "Intolerance to hydrolysed cow's milk proteins in infants: clinical characteristics and dietary treatment", Clinical and Experimental Allergy 30, 2000, 1597-1603

D24 was filed with the statement setting out the grounds of appeal.

IV. In the reply to the statement setting out the grounds of appeal, the patent proprietor (respondent) made no substantive submissions and requested that the appeal be dismissed and oral proceedings otherwise.

V. The board summoned the parties to oral proceedings (summons dated 17 June 2020) and issued a communication

under Article 15(1) RPBA 2020 dated 20 August 2020 in which it set out its preliminary opinion.

VI. By letter dated 25 January 2021, the respondent made substantive submissions on the case and filed, *inter alia*, six auxiliary requests.

VII. Oral proceedings before the board were held on 9 March 2021. At the oral proceedings, the respondent withdrew auxiliary requests 1, 3 and 5.

VIII. Final requests

The appellant requested that the decision under appeal be set aside and that European patent No. 2332428 be revoked.

The respondent requested that the appeal be dismissed (main request), alternatively, that the patent be maintained on the basis of one of auxiliary requests 2, 4 or 6 filed with its submission of 25 January 2021.

Reasons for the Decision

1. *The patent*

1.1 The patent relates to induction of tolerance to cow's milk using specific cow's milk peptides.

1.2 Claim 1 of the patent as granted (main request) reads:

"A nutritional formulation or supplement comprising an extensively hydrolyzed cow's milk peptide-containing hydrolysate and/or a peptide-containing fraction of the

extensively hydrolyzed cow's milk peptide-containing hydrolysate and/or one or more T cell epitope-containing peptides isolated from the extensively hydrolyzed cow's milk peptide-containing hydrolysate for use in the induction of tolerance to cow's milk, a protein contained in cow's milk or an allergen contained in cow's milk in a human subject, wherein said peptides contained in the hydrolysate or fraction of hydrolysate comprise T cell epitope-containing peptides or wherein said one or more peptides are T cell epitope-containing peptides, wherein said T cell epitope-containing peptides are capable of driving the immune reaction upon intake of the nutritional formulation towards tolerance and wherein the extensively hydrolyzed cow's milk peptide-containing hydrolysate comprises less than 1% of peptides having a size of greater than 1.5kD."

2. *Novelty (main request)*

2.1 In the decision under appeal (point 12.2.2), the opposition division decided that the prior art, in particular D9, was not novelty-destroying. It explained that the extensively hydrolysed cow's milk peptide-containing hydrolysate Nutramigen used in the prior art (and in the patent in suit) implicitly disclosed the T cell epitope-containing peptides and the cow's milk hydrolysate. The subject-matter of claim 1 did not differ from D9 in this respect. However, D9 disclosed an allergy preventive effect and not the induction of tolerance to cow's milk. In view of this difference, the opposition division acknowledged novelty over D9.

2.2 In its statement setting out the grounds of appeal, the appellant referred to the opposition division's conclusions on Nutramigen in the context of D9, with

which it agreed. It further argued that based on these findings, D24 anticipated the subject-matter of claim 1.

2.3 In the reply to the statement setting out the grounds of appeal, the respondent did not make any substantive comment.

2.4 In its preliminary opinion, the board agreed with the appellant that D24 was novelty-destroying. The board has no reason to reconsider this assessment. The reasons are as follows.

2.4.1 In the study described in D24 (summary), cow’s milk intolerant infants were treated with a casein hydrolysate formula. This treatment was compared with a treatment which involved the use of ass milk. The patients were followed up for a median period of four years and challenged every year with cow's milk to check for tolerance. As described on page 1598, left column, the formula used in the treatment was Nutramigen (Mead Johnson, Nijmegen, The Netherlands). Table 1 shows that 55 out of 70 cow’s milk intolerant infants treated with Nutramigen became cow's milk tolerant. This is confirmed in the section "Discussion" on page 1602. Therefore, D24 discloses that Nutramigen induces tolerance to cow's milk.

2.4.2 The opposition division correctly acknowledged that Nutramigen discloses the features of claim 1 with regard to the extensively hydrolyzed cow's milk peptide-containing hydrolysate and that the peptides in it comprise the T cell epitopes in question.

2.4.3 Paragraph [0033] of the patent in suit discloses that extensively hydrolyzed cow's milk peptide-containing

hydrolysate is able to suppress the proliferation of T cells when these are re-stimulated with cow's milk protein and that tolerance to cow's milk protein is induced by it. Nutramigen (sample VTP 3 in the patent) is described as most potent to induce tolerance and as a preferred example of a nutritional formulation comprising an extensively hydrolyzed cow's milk peptide-containing hydrolysate in accordance with the invention.

2.4.4 Therefore, D24 discloses the induction of tolerance to cow's milk in a human subject. With Nutramigen, D24 implicitly discloses a nutritional formulation comprising extensively hydrolyzed cow's milk peptide-containing hydrolysate which comprises less than 1% of peptides having a size of greater than 1.5kD. It is also part of the implicit disclosure in D24 that the peptides contained in the hydrolysate comprise T cell epitope-containing peptides capable of driving the immune reaction upon intake of the nutritional formulation towards tolerance.

2.5 By letter dated 25 January 2021, i.e. about six weeks before the oral proceedings, the respondent provided the following brief submission on the matter: "D24 does not explicitly disclose that the peptides of the nutritional formulation comprise T cell epitope-containing peptides. Claim 1 of the Main Request can therefore be considered novel over D24."

2.6 At the oral proceedings, the respondent did not maintain this. Instead, and for the first time in the entire proceedings, the respondent made the allegation that Nutramigen did not comprise less than 1% of peptides having a size of greater than 1.5kD. It acknowledged that Nutramigen was a known product but

submitted that a process involving for instance membrane filtration had to be carried out to obtain the extensively hydrolyzed cow's milk peptide-containing hydrolysate comprising the peptides having the required size.

2.7 These submissions constitute an amendment (both factual and argumentative) to the respondent's appeal case at the oral proceedings before the board, i.e. at the latest possible point in time. The appellant contested their admission into the proceedings.

For assessing whether the submissions can be admitted, Article 13(2) RPBA 2020 applies. It sets out that an amendment must not be taken into account unless there are exceptional circumstances which have been justified with cogent reasons by the party concerned.

2.8 The respondent did not argue that any such circumstances had occurred, nor can any be acknowledged when considering the facts and evidence on file. Thus, the respondent's submissions cannot be taken into account (Article 13(2) RPBA 2020).

2.9 For the sake of completeness, the following is observed on the substance of the objection. The submissions are at variance with the statement in the patent that Nutramigen is an extensively hydrolyzed cow's milk peptide-containing hydrolysate in accordance with the invention (paragraph [0033]). Moreover, the patent discloses membrane filtration but only in the context of isolating individual peptides (paragraph [0029]). Contrary to the respondent's allegation, there is no disclosure in the patent that the extensively hydrolyzed cow's milk peptide-containing hydrolysate which comprises less than 1% of peptides having a size

of greater than 1.5kD is prepared by membrane filtration of Nutramigen.

2.10 Accordingly, the subject-matter of claim 1 lacks novelty over D24 (Articles 100(a) and 54 EPC).

3. *Admission of auxiliary requests*

3.1 The respondent requested that auxiliary requests 2, 4 and 6 be admitted into the proceedings. In its view, they did not raise new issues, nor did they involve new matter because they resulted from the deletion of alternatives covered by the claims as granted. The appellant contested their admission into the proceedings.

3.2 These aspects may be considered when the board exercises its discretion in allowing the respondent to amend its case under Article 13(1) RPBA 2020. The applicable law for deciding on admission of the auxiliary requests is Article 13(2) RPBA 2020 (see also point 2.7 above).

3.3 To support the late filing of the auxiliary requests, the respondent argued that the patent attorney in charge at the time of filing the reply was no longer at the company. It was therefore not possible to find out why the case had been dealt with the way it had been. In addition, the respondent stated that it never had the intention to abandon this case.

3.4 However, a change of representative is not a valid ground justifying the late filing of requests (Case Law of the Boards of Appeal of the EPO, 9th edition, 2019, Chapter V.A.4.8.2, first paragraph). Furthermore, it is manifest from the respondent's letter dated

18 December 2018 that (i) the representative who filed the reply had left the company at or before that time and (ii) a new representative had assumed responsibility for the case. While it may be inferred from this letter that the respondent had no intention to abandon the case, it is evident that no submission was made even after the new representative had assumed the responsibility.

3.5 In summary, the board fails to identify exceptional circumstances justified with cogent reasons for filing the auxiliary requests so late in the proceedings. Therefore, the auxiliary requests are not admitted in the proceedings (Article 13(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