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Datasheet for the decision of 16 June 2020

Case Number: T 2141/16 - 3.3.09

Application Number: 08716883.7

Publication Number: 2129386

IPC: A23L1/30, A61K35/74, A61P3/04

Language of the proceedings: EN

Title of invention:
PROBIOTICS FOR REDUCTION OF RISK OF OBESITY

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponents:
N.V. Nutricia
Hill's Pet Nutrition, Inc.

Headword:
Reduction of risk of obesity/NESTLE

Relevant legal provisions:
EPC Art. 56, 83
Rule 103(4)(c)

Keyword:
Main request - sufficiency of disclosure (yes)
Main request - inventive step (yes)
Decision in written proceedings after withdrawal of request for oral proceedings by both parties
Reimbursement of appeal fee at 25% (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 2141/16 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 16 June 2020

Appellant: (Opponent 1)	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)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 8 July 2016 rejecting the opposition filed against European patent No. 2129386 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Haderlein
Members:	A. Veronese
	D. Rogers

Summary of Facts and Submissions

I. This decision concerns the appeal filed by opponent 1 (appellant) against the decision of the opposition division rejecting the oppositions filed against European patent No. 2 129 386 B1.

II. With their notices of opposition, the two opponents had requested revocation of the patent in its entirety, in particular on the grounds under Article 100(a) EPC in combination with Article 56 EPC and Article 100(b). Opponent 2 withdrew its opposition during the opposition proceedings. Thus, it is not party to the these appeal proceedings.

III. Granted claim 1 reads:

"1. The use of probiotic bacteria capable of promoting the development of an early bifidogenic intestinal microbiota in the manufacture of a medicament or therapeutic nutritional composition for reducing the risk of development of obesity of an infant later in life, wherein the bacteria are of the strain Lactobacillus rhamnosus ATCC 53103 or Lactobacillus rhamnosus CGMCC 1.3724."

IV. The documents submitted during the opposition proceedings included:

D4: H.Y. Lee et al., Biochim. Biophys. Acta, 2006, vol. 1761, pp. 736-744
D6: WO 2006/091103 A2
D9: WO 01/97822 A1
D10: WO 97/00078 A1

D11: US 2005/0186189 A1
D12: WO 2006/019222 A1

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

- The patent contained sufficient information to carry out the invention; even if the claims did not mention the feature "administered to the infant at least during the first two months of the life of the infant", the purported effects were plausible.

- The claimed subject-matter involved an inventive step over D6, the closest prior art, alone or in combination with the other available documents.

VI. In its statement setting out the grounds of appeal, the appellant requested that the decision be set aside and that the patent be revoked in its entirety. The following documents were filed with this statement:

D21: Valio R&D Katri Hallamaa, 2013, "Scientific references on Lactobacillus rhamnosus GG"
D22: N. Blümer et al., Clin. Exp. Allerg., 2007, Vol. 37, pp. 348-357
D23: WO 2006/113035 A1

VII. In its reply to the statement setting out the grounds of appeal, the patent proprietor (respondent) requested that the appeal be dismissed or, alternatively, that the patent be maintained on the basis of one of auxiliary requests 1 to 7, all filed with the reply. Among others, the following documents were filed:

D25: K. Hefner et al, Behav. Brain. Res., 2007, 176(2), pp 210-2015 (Abstract)

D26: T.D. Brandebourg et al., J. Anim. Sci., 2005, Vol. 83, pp. 2096-2015

D27: Y. Park et al., Lipids, 1999, Vol. 34(3), pp. 235-241 (abstract)

D28: M.W. Pariza et al., Prog. Lipid Res., 2001, Vol. 40(4), pp. 283-298 (abstract)

VIII. The sole independent claim 1 of auxiliary request 6 corresponds to claim 1 as granted in which the expression "*are of the strain*" has been amended to "*are the strain*".

IX. Both parties requested oral proceedings. In a written communication issued in preparation for the oral proceedings dated 24 March 2020, the board expressed the preliminary opinion that the claims of the main request and auxiliary requests 1 to 5 did not meet the requirements of the EPC and that the claims of auxiliary request 6 met those requirements.

X. In its letter dated 28 April 2020, the appellant stated that its request for oral proceedings was withdrawn on the condition that auxiliary request 6, but not any higher-ranking request, be held allowable.

XI. In a reply to the board's communication, the respondent stated that its request for oral proceedings was withdrawn on the condition that auxiliary request 6 be held allowable and that, on this condition, auxiliary request 6 was its main request and the higher-ranking requests were withdrawn.

XII. The oral proceedings were cancelled.

XIII. The arguments of the appellant relevant for the present decision were as follows.

- The probiotic bacteria of claim 1 had to be administered for a minimum amount of time to induce the claimed effect. This was confirmed by paragraph [0021] of the patent in suit. Since claim 1 did not contain any limitation as to the duration of the treatment, it encompassed non-working embodiments. Thus, the invention was insufficiently disclosed.

- D4, D11 or D12, which disclosed the use of bacterial strains different from the claimed ones, for treating obesity, had to be selected as the closest prior art. The problem was the provision of an alternative bacterial strain for preventing obesity. D4 hinted at using one of the claimed strains. Further prompts were found in D9 to D12, D21 and D22. Thus, the claimed solution would have been obvious. The same conclusion could be arrived at by selecting as the closest prior art D9, D10, D22 or D23, which disclosed the use of one of the claimed bacterial strains in infants for treating and preventing atopic diseases later in life.

XIV. The arguments of the patent proprietor relevant for the present decision were as follows.

- The patent contained plenty of information as to the bacteria to be used, dosage regimens, subjects and conditions to be treated. A clinical trial showed that the invention could be carried out. The omission in claim 1 of the wording of paragraph [0021] resulted at most in an issue of lack of clarity. There was no evidence that the invention could not be carried out over the claimed scope.

- D6 was the only document disclosing the use of probiotic bacteria in infants to reduce the risk of

obesity later in life. Thus, it was the only suitable closest prior art. D6 did not mention the claimed bacteria. The problem was the provision of an alternative probiotic treatment for reducing the risk that an infant develops obesity later in life. None of the cited documents suggested using the claimed bacteria. D4, D11 and D12 related to the treatment of obesity, not its prevention. Furthermore, D4 and D26 to D28 taught away from using *Lactobacillus rhamnosus* ATCC 53103. D9, D10, D22 and D23 related to the treatment of unrelated diseases and could not be combined with D6.

The final requests

XV. The appellant requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

XVI. The respondent requested that the patent be maintained on the basis of the main request, corresponding to auxiliary requests 6 enclosed with the reply to the statement setting out the grounds of appeal dated 23 March 2017.

Reasons for the Decision

1. *Sufficiency of disclosure*

1.1 The patent describes the probiotic bacteria used to carry out the invention, suitable dosages and the conditions to be treated: paragraphs [0016] to [0018] and [0021] to [0024]. It also describes a clinical study in which *Lactobacillus rhamnosus* ATCC 53103 was administered to pregnant women 2-4 weeks before

delivery and, after delivery, to breast feeding mothers or directly to infants, for 6 months (example 2). As shown in tables 1 and 2, at an age of 4 years, the BMI of the subjects who had been exposed to the *Lactobacillus* was significantly lower than that of a placebo group. This makes it credible that the effect indicated in claim 1 can be achieved carrying out the claimed invention. As correctly pointed out by the respondent, there is no evidence showing that the invention cannot be carried out.

1.2 The timing and duration of the treatment are not indicated in claim 1. Nevertheless, relying on the information in the patent and common general knowledge, the skilled person would have been able to determine dosage regimens suitable to carry out the invention. That skilled person would also have avoided regimens outside the scope of practical application.

1.3 Claim 1, unlike paragraph [0021] of the description, does not indicate that the bacteria are administered for at least two weeks before and after delivery. However, this is at most an issue of lack of clarity resulting from an inconsistency between the claims and the description rather than one of lack of sufficiency. This inconsistency was already present in the granted patent. Thus, it is not open to objection.

1.4 Accordingly, the claimed invention is sufficiently disclosed (Article 83 EPC).

2. *Inventive step*

2.1 Among the other prior art documents cited during the proceedings, D6 is the only one which discloses a treatment aimed at, like the claimed treatment,

promoting the formation of a bifidogenic microbiota early in an infant's life to reduce the risk of obesity later in life. D6 explains that the occurrence of certain afflictions is a consequence of the type of feeding experienced during the earliest stages of life (page 1, lines 13-15). It further discloses the administration of *Bifidobacterium breve*, alone or in combination with *Lactobacillus paracasei*, to an infant to prevent different diseases, including childhood obesity (claims 1, 5, 13 and 16).
Thus, D6 is considered the closest prior art.

2.2 The appellant suggested that one of D4, D9 to D12, D22 or D23 should be selected as the closest prior art.
The board does not agree. D4, D11 and D12 disclose the use of probiotic bacteria to treat obesity but not the principle underlying the claimed invention: to modify the microbiota of an infant to reduce the risk of obesity later in life. D9, D10, D22 and D23 relate to the treatment and prevention of conditions, such as allergies and atopic diseases, differing substantially from obesity in terms of the aetiology and pathological picture. Thus, none of these documents qualifies better than D6 as the closest prior art.

2.3 The subject-matter of claim 1 differs from the closest prior art D6 in that different bacteria are used: *Lactobacillus rhamnosus* ATCC 53103 or *Lactobacillus rhamnosus* CGMCC 1.3724 instead of *Bifidobacterium breve* and *Lactobacillus paracasei*.

2.4 As already mentioned above (points 1.1 to 1.3), the results shown in the patent make it credible that the claimed *Lactobacillus rhamnosus* strains promote the development of an early bifidogenic microbiota in an

infant and reduce the risk of obesity later in life. This was not disputed by the parties.

2.5 The underlying technical problem can thus be formulated as the provision of an alternative probiotic treatment for reducing the risk that an infant develops obesity later in life.

2.6 The question is whether the skilled person confronted with this problem would have considered replacing the bacteria used in D6 with one specified in claim 1.

2.7 The board shares the respondent's view that D6 does not suggest the use of the claimed bacteria because it only mentions bacteria belonging to a different genus or species. It also agrees that none of the other cited prior art documents suggests the claimed solution.

2.8 According to the appellant, D4 provided the strongest suggestion to use the relevant bacterial strains in a method according to claim 1. However, D4 does not mention infants, let alone the prevention of obesity later in life. The rats used to carry out the tests described in D4 cannot be considered models for "infants" either: at most for "peri-adolescent" subjects (see D25). Furthermore, *Lactobacillus rhamnosus* PL60, and not one of the claimed bacteria, was used in the tests. The appellant argued that although only *Lactobacillus rhamnosus* PL60 was tested, D4 suggested that *Lactobacillus rhamnosus* ATCC 53103 was equally effective and possibly even less toxic than *Lactobacillus rhamnosus* PL60. This could be expected comparing the effects of the two bacteria on the metabolism of the different isomers of conjugated linoleic acid (CLA), shown in table 4.

This argument is not persuasive. Table 4 shows that *Lactobacillus rhamnosus* ATCC 53103 (referred to as "GG") does not stimulate the production of t10,c12-CLA. It is the CLA isomer which, according to D4, D12 and D26 to D28, is responsible for inducing body changes, including the reduction of body fat, observed in animals treated with *Lactobacillus rhamnosus* PL60. Thus, table 4 does not provide any obvious suggestion in the direction of the claimed solution.

2.9 D11 and D12 disclose the use of certain *Lactobacillus rhamnosus* types, different from the claimed ones, for treating obesity. However, their teaching, as well as that of D21, does not go beyond that of D4. D9, D10, D22 and D23 relate to the use of the claimed *Lactobacillus rhamnosus* ATCC 53103 for treating and preventing conditions, such as allergic diseases, not related to obesity. Thus, their teaching is even remoter from the claimed subject-matter than D4 and cannot be combined with that of D6.

2.10 For these reasons, none of the cited prior art documents suggests the solution proposed in the patent in suit. Even assuming that the skilled person would have considered testing the claimed bacteria, in the board's judgement, they would not have conducted the tests with a reasonable expectation of achieving the relevant technical effect.

2.11 Accordingly, the board concludes that the claimed subject-matter involves an inventive step (Article 56 EPC).

3. *Reimbursement of the appeal fee*

The appellant withdrew its request for oral proceedings

within the time limit set under Rule 103(4)(c) EPC, and no oral proceedings took place. Thus, the appeal fee is to be reimbursed at 25%.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent with the following claims and a description to be adapted where necessary:

   Claims 1 to 7 of the main request, filed as auxiliary request 6 under cover of the respondent's reply to the grounds of appeal dated 23 March 2017.

3. The appeal fee is reimbursed at 25%.

The Registrar: The Chairman:

A. Nielsen-Hannerup A. Haderlein

Decision electronically authenticated