Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 24 March 2020

Case Number: T 0811/17 - 3.3.01

Application Number: 10751504.1

Publication Number: 2405918

IPC: A61K31/702, A61P1/06, A61P1/14

Language of the proceedings: EN

Title of invention:
PREBIOTIC OLIGOSACCHARIDES

Patent Proprietor:
The Regents of the University of California
DSM Food Specialties USA Inc.

Opponent:
N.V. Nutricia

Relevant legal provisions:
EPC Art. 53(c)

Keyword:
Exceptions to patentability - (yes)

Decisions cited:
G 0009/92

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0811/17 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 24 March 2020

Appellant: (Patent Proprietor 1)	The Regents of the University of California 1111 Franklin Street, 12th Floor Oakland, CA 94607 (US)
Appellant: (Patent Proprietor 2)	DSM Food Specialties USA Inc. 45 Waterview Boulevard Parsippany, New Jersey 07054 (US)
Representative:	J A Kemp LLP 14 South Square Gray's Inn London WC1R 5JJ (GB)
Appellant: (Opponent)	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:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 30 January 2017 concerning the maintenance of European Patent No. 2405918 in amended form.**

Composition of the Board:

Chairman	A. Lindner
Members:	R. Hauss
	P. de Heij

Summary of Facts and Submissions

I. European patent No. 2 405 918 (the patent in suit) was granted with a set of fourteen claims.

II. A notice of opposition was filed, requesting the revocation of the patent under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step, related to a method which was not patentable pursuant to Article 53(c) EPC, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and extended beyond the content of the application as filed.

III. The decision under appeal is based on an amended main request and six auxiliary requests presented by the patent proprietors in the course of the opposition proceedings.

The independent claims of the main request read as follows:

> "1. A composition comprising galacto-oligosaccharides for use in a therapeutic or prophylactic method for stimulating colonization of a beneficial *Bifidobacterium* strain in the gut of an animal,
>
> (i) wherein at least 50% of the galacto-oligosaccharides by weight are tetra or penta galacto-oligosaccharides or wherein at least 30% of the galacto-oligosaccharides by weight are tetra galacto-oligosaccharides; and
>
> (ii) wherein less than 10% of the galacto-oligosaccharides by weight are trimeric galacto-oligosaccharides; and

wherein the strain is a strain of *Bifidobacterium breve* or *Bifidobacterium longum* bv. *infantis*."

"11. Use of a composition comprising galacto-oligo-saccharides for stimulating beneficial *Bifidobacterium* microflora in an animal administered in an amount sufficient to stimulate colonization of the gut of the animal by at least one beneficial *Bifidobacterium* strain,

(i) wherein the strain is a strain of *Bifidobacterium breve* or *Bifidobacterium longum* bv. *Infantis;* and

(ii) wherein at least 50% of the galacto-oligo-saccharides by weight are tetra or penta galacto-oligosaccharides or wherein at least 30% of the galacto-oligosaccharides by weight are tetra galacto-oligosaccharides; and

(iii) wherein less than 10% of the galacto-oligosaccharides by weight are trimeric galacto-oligosaccharides; and

wherein methods for treatment of the animal body by surgery and therapy as well as diagnostic methods practiced on the animal body are disclaimed."

IV. The decision under appeal is the interlocutory decision of the opposition division, announced on 2 December 2016 and posted on 30 January 2017, rejecting the patent proprietors' amended main request and auxiliary requests 1 to 5 and finding that the patent as amended in the form of auxiliary request 6 met the requirements of the EPC.

V. According to the decision under appeal,

(a) claim 7 of the main request contained added subject-matter (Article 123(2) EPC); the same

objection applied to the corresponding claims in auxiliary requests 1 to 5;

(b) claim 11 of the main request related to a therapeutic use excepted from patentability (Article 53(c) EPC), since the stimulation of the colonisation of the gut with the *Bifidobacterium* strains as specified in that claim was inextricably associated with prophylactic or therapeutic effects; the same objection applied to the corresponding claims in auxiliary requests 1 to 5;

(c) auxiliary request 6 corresponded to the main request, except that claims 7 and 11 had been deleted;

(d) the amendments carried out in auxiliary request 6 did not introduce added subject-matter relative to the application as filed (Article 123(2) EPC);

(e) the claimed subject-matter met the requirement of sufficiency of disclosure (Article 83 EPC);

(f) the subject-matter of auxiliary request 6 involved an inventive step having regard to the state of the art (Articles 52(1) and 56 EPC).

VI. Both the opponent and the patent proprietors filed an appeal against that decision.

VII. In its notice of appeal, the opponent requested the revocation of the patent in suit.

VIII. The opponent subsequently withdrew its appeal, stating that it wished to participate in the proceedings as respondent (opponent's letter dated 9 June 2017).

IX. The opponent did not present any substantive submission in the course of the appeal proceedings, nor did it present any request in its role as respondent.

X. With their statement setting out the grounds of appeal, the appellants (patent proprietors) submitted seven sets of claims entitled main request A and auxiliary request 1A, 2A, 3A, 4A, 5A and 6A.

XI. The claims of ***auxiliary request 6A*** are identical to those of former auxiliary request 6 deemed allowable by the opposition division (see point V(c) above).

The ***main request A*** and ***auxiliary requests 1A to 5A*** correspond to the former main request and auxiliary requests 1 to 5 pending before the opposition division, except that, in each of the new requests, dependent claim 7 was deleted and the subsequent claims adapted with regard to claim numbering and claim dependencies.

- Thus, independent claims 1 and 10 of **main request A** are identical to claims 1 and 11 of the former main request considered in the decision under appeal (see point III above).

- Independent claim 10 of **auxiliary request 1A** is identical to claim 10 of main request A.

- Independent claim 10 of **auxiliary request 2A** is identical to claim 10 of main request A, except that in point (ii), the alternative

"or wherein at least 30% of the galacto-oligosaccharides by weight are tetra galacto-oligosaccharides"

was replaced by

"or wherein at least 40% of the galacto-oligosaccharides by weight are tetra galacto-oligosaccharides".

- Independent claim 10 of **auxiliary request 3A** is identical to claim 10 of auxiliary request 2A, except that point (iii) was deleted.

- Independent claim 10 of **auxiliary request 4A** is identical to claim 10 of main request A, except for the added requirement

"and wherein the composition is a food product or dietary supplement product".

- Independent claim 10 of **auxiliary request 5A** is identical to claim 10 of main request A, except for the added requirement

"and wherein the composition is a food product which is selected from the group consisting of an infant formula, a follow-on formula and a toddler beverage."

XII. The appellants requested that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims of the main request A, enclosed with the statement setting out the grounds of appeal, or in the alternative, the claims of one of auxiliary requests 1A to 6A, all enclosed with the statement setting out the grounds of appeal.

XIII. The appellants' arguments may be summarised as follows:

Added subject-matter (Article 123(2) EPC)

Due to the deletion of former claim 7 in all current requests, the objection concerning added subject-matter (see point V(a) above) was moot.

Exception to patentability (Article 53(c) EPC)

Claim 10 of main request A and auxiliary requests 1A to 5A expressly disclaimed the use of the composition in a method according to Article 53(c) EPC.

The therapeutic use (addressed in independent claim 1 drafted in the format according to Article 54(5) EPC) and the non-therapeutic use (addressed in claim 10) of the compositions were two aspects of the invention which were completely separable. In the therapeutic embodiment, the compositions were to be administered to patients having a disease condition, as set out in paragraph [0066] of the patent in suit. In contrast, in other embodiments the compositions were used non-therapeutically, e.g. in a food product or dietary supplement for healthy subjects (see paragraphs [0013] and [0014] of the patent in suit). According to established case law, feeding a subject, e.g. an animal or an infant, was not considered a therapeutic activity.

It was perfectly possible to stimulate beneficial *Bifidobacteria* in a non-therapeutic context; for instance, the use of the compositions of the invention in infant formula merely mimicked the effect of breastfeeding babies, which was a nutritional rather than a therapeutic activity.

Decision T 385/09 supported the conclusion that feeding was not generally considered to be therapeutic. The present case was similar to that of decision T 469/94 in that the composition of the invention could be used for either a therapeutic or a non-therapeutic purpose.

XIV. In response to a summons to oral proceedings pursuant to Rule 115(1) EPC issued by the board, the appellants withdrew their request for oral proceedings, stated

that they would not attend the oral proceedings and requested a decision according to the state of the file (appellants' letter dated 10 February 2020). The withdrawal was conditional on the board deciding that the patent could be maintained on the basis of auxiliary request 6A or a higher-ranking request.

Reasons for the Decision

1. Admissibility of the appeal

The appeal complies with Articles 106 to 108 EPC and Rule 99 EPC and is therefore admissible.

2. Scope of the appeal

2.1 If the patent proprietor is the sole appellant against an interlocutory decision maintaining a patent in amended form, neither the Board of Appeal nor the non-appealing opponent may challenge the maintenance of the patent as amended in accordance with the interlocutory decision (see Enlarged Board Decision G9/92, OJ EPO 12/1994, 875).

2.2 The opponent's initial request that the patent be revoked, as presented in the notice of appeal (see point VII above), is withdrawn in result of the withdrawal of the opponent's appeal. Such a request would in any case go against the principle of prohibition of *reformatio in peius* (see point 2.1 above), in a situation in which the patent proprietors are the sole appellants.

2.3 Furthermore, since the claims of auxiliary request 6A are identical to those of former auxiliary request 6 considered allowable by the opposition division, this request cannot result in a decision more favourable to the appellants than the dismissal of the appeal. Hence, the examination of auxiliary request 6A is not within the scope of the present appeal.

3. Claim 10 - patentability (Article 53(c) EPC)

3.1 According to Article 53(c) EPC, European patents shall not be granted in respect of, *inter alia*, methods for treatment of the human or animal body by therapy.

3.2 It is established case law that both prophylactic and curative measures are covered by the word therapy.

3.3 If a method of treatment or corresponding use may have both therapeutic and non-therapeutic aspects, it has to be established whether the non-therapeutic use can be distinguished and separated from the therapeutic use (see the decisions cited in Case Law of the Boards of Appeal of the European Patent Office, ninth edition 2019, I.B.4.4.2). If that is not the case, a claim directed to such a use is not patentable pursuant to Article 53(c) EPC, since the therapeutic aspect of the use cannot effectively be disclaimed.

3.4 Different from the present case, in decision T 385/09 cited by the appellants the separability of therapeutic and non-therapeutic use was not an issue that needed to be considered, whereas in decision T 469/94 this was considered (reasons 4.4) but both uses were not considered to be inextricably linked. These decisions do not provide much guidance for the present case.

3.5 According to the patent in suit (see paragraph [0002]), the use of the compositions according to the patent in suit for stimulating the colonisation of the gut by a beneficial *Bifidobacterium* strain has prophylactic effects - in particular, colon cancer prevention as well as the protection against certain infections by pathogenic bacteria.

3.6 In the decision under appeal (reasons: 19), the opposition division came to the conclusion that the

stimulation of the colonisation of the gut by the beneficial *Bifidobacterium* strains as defined in claim 11 of the former main request is inextricably associated with prophylactic therapeutic effects.

3.7 The board agrees with the entire chain of reasoning set out in point 19 of the decision under appeal. As mentioned above (see point XI), claim 11 of the main request considered by the opposition division is identical to claim 10 of the present main request A.

3.8 It is irrelevant for this assessment whether the composition to be administered is labeled or marketed as a food or feed product. Since the therapeutic effect in question is prophylactic, it is also irrelevant that the subject to whom the composition is administered may be a healthy subject.

3.9 As a consequence, the subject-matter of claim 10 of the main request A and auxiliary request 1A covers a prophylactic use and is not patentable pursuant to Article 53(c) EPC. The same conclusion applies to claim 10 of each of auxiliary requests 2A, 3A, 4A and 5A, since the amendments made in each of these claims (see point XI above) do not affect the reasoning with regard to the requirements of Article 53(c) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated