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**Datasheet for the decision
of 13 December 2013**

Case Number: T 1167/09 - 3.3.02

Application Number: 01985674.9

Publication Number: 1320375

IPC: A61K31/736, A61K31/733,
A61K31/732, A61K31/731,
A61K31/718, A61K31/717,
A61P31/04

Language of the proceedings: EN

Title of invention:
INHIBITION OF SYSTEMIC INFECTIONS IN HUMANS AND VERTEBRATES BY
DIETARY FIBERS

Patent Proprietor:
Mississippi State University
Tiense Suikerraffinaderij N.V.

Opponents:
CARGILL, INCORPORATED
N.V. Nutricia

Headword:
Dietary fructooligosaccharides/Mississippi State University

Relevant legal provisions:
EPC Art. 56, 111
RPBA Art. 13

Keyword:

Late-filed auxiliary requests - partly admitted (response to objections of the board; rest not admitted - objections not cleared)

Inventive step - auxiliary request 4A (no) obvious modification

Decisions cited:

Catchword:

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**Beschwerdekammern
Boards of Appeal
Chambres de recours**

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 1167/09 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 13 December 2013

Appellant: Mississippi State University
(Patent Proprietor 1) P.O. Box 5282
Mississippi State, MS 39762 (US)

Appellant: Tiense Suikerraffinaderij N.V.
(Patent Proprietor 2) Tervurenlaan 182
1150 Brussel (BE)

Representative: Nollen, Maarten Dirk-Johan
Arnold & Siedma
Sweelinckplein 1
2517 GK Den Haag (NL)

Respondent 01: CARGILL, INCORPORATED
(Opponent 1) 15407 McGinty Road West
Wayzata, MN 55391-5624 (US)

Representative: Gowshall, Jonathan Vallance
Forresters
Skygarden
Erika-Mann-Strasse 11
80636 München (DE)

Respondent 02: N.V. Nutricia
(Opponent 2) 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 Opposition Division of the
European Patent Office posted on 2 April 2009
revoking European patent No. 1320375 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
R. Cramer

Summary of Facts and Submissions

- I. European application No. 01 985 674.9 was granted as European patent No. 1 320 375 with eight claims, based on international application No. PCT/EP2001/011198, published as WO 2002/026242.

Independent claim 1 as granted read as follows:

"Use of a dietary fiber or mixture of dietary fibers for the manufacture of a composition for oral administration or for tube feeding for the treatment of systemic infections in humans and in vertebrates caused by pathogenic bacteria."

- II. Oppositions were filed against the granted patent under Article 100(a) EPC (novelty and inventive step) and Article 100(b) EPC (sufficiency of disclosure).

The documents cited during the proceedings before the opposition division and the board of appeal include the following:

(D3) US-A-5 260 279

(E2) Campbell, J. et al., "Selected indigestible oligosaccharides affect large bowel mass, cecal and fecal short-chain fatty acids, pH and microflora in rats", Journal of Nutrition, 1997, 130-136

(E7) Gibson, G. et al., "Dietary modulation of the human colonic microbiota: introducing the concept of prebiotics", Journal of Nutrition, 1995, 1401-1412

(F1) Yano, T. et al., "Polysaccharide-induced protection of carp, *Cyprinus carpio* L., against bacterial infection", J. Fish diseases, 1991, vol. 14, 577-582

III. By its decision posted on 2 April 2009, the opposition division revoked the patent under Article 101(3)(b) EPC.

The opposition division held that the subject-matter of the main request and the first auxiliary request (as single auxiliary request) was anticipated by the teaching of document (D3) and that it was obvious over the combination of documents (E2) and (E7).

IV. An appeal was lodged against that decision and grounds of appeal were filed together with a request that the patent be maintained according to the main request or one of auxiliary requests A1 to A5.

V. In a communication dated 1 August 2013, the board expressed concerns of added subject-matter and lack of novelty with respect to all requests except auxiliary request A5 (Articles 123(2) and 54 EPC). Documents (D3) and (E7) were indicated to be relevant for assessing novelty.

As far as inventive step (Article 56 EPC) was concerned, in particular documents (D3), (E7) and (F1) were to be taken into account with respect to all requests.

VI. The appellants filed arguments with respect to the considerations in the board's communication, together with auxiliary requests 1A to 9A replacing the requests

on file; no explicit main request remained formally on file. Auxiliary request 4A was identical to former auxiliary request A5 filed together with the statement of grounds of appeal.

In addition, the appellants filed a declaration from one of the inventors, together with further documents.

Claims 1 of the current auxiliary requests 1A to 3A are based on claim 1 as granted and still relate to the treatment of humans and vertebrates; the use of inulin, oligofructose and mixtures thereof is particularly specified. The manufacture of a pharmaceutical being omitted, additionally, the claim is restricted to the manufacture of a functional food composition or a functional feed composition.

Claim 1 of auxiliary request 4A reads (amendments compared to claim 1 as granted marked):

"Use of a dietary fiber or mixture of dietary fibers for the manufacture of a composition for oral administration ~~or for tube feeding~~ for the treatment of systemic infections in fish ~~in humans and in vertebrates~~ caused by pathogenic bacteria, wherein the dietary fiber or mixture of dietary fibers is selected from the group consisting of inulin, oligofructose, and mixtures thereof."

Claims 1 of the further auxiliary requests 5A to 9A relate to treatment of fish, using inulin, oligofructose and mixtures thereof for the manufacture of a functional feed.

VII. On 13 December 2013, oral proceedings took place before the board.

During the oral proceedings, respondent 01 requested that auxiliary requests 1A, 2A, 3A and 5A to 9A not be admitted into the proceedings because they were late filed.

The board did not admit auxiliary requests 1A, 2A and 3A.

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

The objections of the board were no longer relevant for the new requests. The new requests were a direct response to the board's communication. Therefore, they should be admitted into the proceedings.

Regarding the claims on file, with a mind willing to understand, the person skilled in the art would take into account the experiments in the application as originally filed and read the claim in this sense. The result was that the teaching of the claims on file became clear as a mixture of prevention and treatment, namely administering the active substances both before and during the infection.

Starting from document (F1), firstly inulin was only present as one polysaccharide in a long list and, according to the results of the experiments, was not the preferred substance for the treatment of bacterial infection. Additionally, in document (F1) the polysaccharides were administered intraperitoneally and, thus, the effects resulted from unfermented polysaccharides being present in fish beyond the mucosa of the gut. In contrast, at the time of the priority of the patent in suit, the skilled person would have been sure that no complete and unfermented polysaccharide

would enter the body to be treated, starting from the gastrointestinal pathway after feeding.

Regarding the overall content of document (E7), infections were all contemplated under the proviso that they had entered the body through the gastrointestinal tract, even when these infections were called systemic and their etiology comprised implantation of parasites or extensive burn injury. Moreover, all the statements with respect to probiotics, prebiotics and synbiotics were speculative and even most of those made with regard to bifidobacteria as a probiotic, which was not subject-matter of the patent in suit.

Thus, the disclosure of document (E7) was limited to prevention of translocation of bacteria by fructooligosaccharides and could not render the teaching of the patent in suit obvious in combination with document (F1), the latter differing in the administration route of the active substance.

IX. The respondents' arguments may be summarised as follows:

Amended auxiliary requests 1A, 2A and 3A should not be admitted because they were late filed and *prima facie* still suffered from the deficiencies set out in the communication of the board with regard to the main request and auxiliary requests A1 to A4 filed together with the grounds of appeal. The further new auxiliary requests 5A to 9A should have been filed earlier and could not be considered as response to the communication of the board since the problems addressed were already known from the responses of the opponents to the statement of grounds of appeal.

Document (F1) as closest prior art disclosed all the features of claim 1 of auxiliary request 4A apart from oral administration. Oral administration, however, was known from the related document (E7) for the same active substance, namely inulin. Moreover, document (E7) related to immunostimulation, a further issue common to document (F1).

- X. The appellants (patent proprietors) requested that the decision under appeal be set aside and the patent be maintained in amended form on the basis of one of the auxiliary requests 1A to 9A filed with the letter of 4 November 2013.

- XI. The respondents (opponents) requested that the appeal be dismissed.

Reasons for the Decision

- 1. The appeal is admissible.

- 2. *Admissibility of auxiliary requests 1A, 2A and 3A*

The amended claims filed as auxiliary requests 1A, 2A and 3A in response to the communication of the board relate to the subject-matter of the main request and auxiliary requests A1 to A4 as filed with the grounds of appeal and as commented on by the board with respect to Article 123(2) EPC. *Prima facie*, the problems set out by the board were not solved and new problems were generated. Therefore, auxiliary requests 1A, 2A and 3A are not admitted into the proceedings.

3. *Claim 1 of auxiliary request 4A; Articles 123(2) and 56 EPC*

3.1 *Claim 1 of auxiliary request 4A; Article 123(2) EPC*

3.1.1 The subject-matter of claim 1 of auxiliary request 4A relates to

- the use of inulin, oligofructose and mixtures thereof for the manufacture of a composition
- for oral administration
- for the treatment of systemic infections caused by pathogenic bacteria
- in fish.

3.1.2 The disclosure of the subject-matter of this claim is based on a combination of claims 1, 3, 5 and 8 from the application as originally filed, together with page 5, line 30 to page 6, line 3 and page 9, lines 5 to 6 and lines 9 to 20.

These claims, together with the cited passages of the description as originally filed, teach

- the use of inulin, oligofructose and mixtures thereof (original claim 5 together with claim 4 and claim 1 and citations on page 9 of the description) for the manufacture of a composition (original claim 1)
- for oral administration ~~or for tube feeding or for rectal administration~~ (original claim 8 together with original claim 3)
- for ~~the prevention, the inhibition and/or~~ the treatment of systemic infections caused by pathogenic bacteria (original claim 1)

- in ~~humans and in vertebrates~~ fish (original claim 8 together with the citations of the original description).

The current claim 1 of auxiliary request 4A differs from this originally disclosed teaching in that the passages put in strikethrough (by the board) have been deleted or replaced. Additionally, since the features of original claim 8 are included in this claim 1 and since original claim 8 refers to "any one of claims 1 to 7", claim 1 *prima facie* should contain the restrictions of all the original claims 1 to 7. But, compared to the combined teaching of original claims 1 to 8, the restrictions of original claims 2, 4, 6 and 7 do not exist in the teaching of claim 1 of auxiliary request 4A.

However, the alternatives mentioned in claim 2 are only illustrative examples of what the manufactured composition could be, and putting them as new claim 2 after the new claim 1 results in a generalisation of the subject-matter of this claim 1 that can be accepted in this case.

The selection of the features of original claim 5 from possible alternatives in claims 4, 6 and 7 can be derived from the text passages on page 9 as cited.

The restriction to oral administration is mandatorily connected to the "patient group" fish in original claim 8 and on page 9 of the original description and therefore both features, the "treatment of fish" and "oral administration" are directly and unambiguously based on this claim.

Under these circumstances, only the restriction from **"the prevention, the inhibition and/or the treatment"** to "treatment" remains, which consequently is in line with the provisions of Article 123(2) EPC.

3.2 *Claim 1 of auxiliary request 4A; Article 56 EPC
(document (F1) as closest state of the art)*

3.2.1 The subject-matter of claim 1 of auxiliary request 4A relates to

- the use of inulin, oligofructose and mixtures thereof for the manufacture of a composition
- for oral administration
- for the treatment of systemic infections caused by pathogenic bacteria
- in fish.

3.2.2 The subject-matter of document (F1) relates to

- the use of inulin for the manufacture of a composition
- for the treatment of systemic infections caused by pathogenic bacteria
- in fish

- for intraperitoneal administration.

(see page 578, experimental procedure and table 1)

The use of any particular polysaccharide from the list in table 1, for instance inulin, for the manufacture of a composition ... is directly and unambiguously disclosed in document (F1) since all other features are disclosed in context and to be combined with table 1.

"Systemic infections" according to document (F1) are in conformity with the patent in suit because the same methods are applied to trigger the infection and to observe the results.

Treatment, according to the experiment in document (F1), is administration of the polysaccharide in advance of the infection (see page 578, experimental procedure). Taking into account that in the examples on file the inulin or oligofructose is fed during a 6-week period before the infection, there is no difference in the meaning of the term treatment in document (F1) and in claim 1 of auxiliary request 4A. An indication that treatment as claimed would include continued treatment after having triggered the infection and that there is a particular effect to be derived from this difference can be seen neither from the teaching as claimed nor from the experiments currently on file.

Particularly under these conditions, the board cannot of its own motion consider the teaching represented by the current claims as being restricted by elements from the experiments as long as these elements are not contained in the wording of the claims.

- 3.2.3 The problem to be solved is to provide an improvement in the use of inulin for the production of a composition for the treatment of systemic infection by pathogenic bacteria in fish.
- 3.2.4 The proposed solution according to the features of claim 1 of auxiliary request 4A is oral application.
- 3.2.5 Based on the "Results of salmon trials" filed with the grounds of appeal (appendix A), and because oral administration is less cumbersome than intraperitoneal

administration, the board is satisfied that the problem is solved.

3.2.6 The skilled person in the field of the use of polysaccharides in the treatment of bacterial disease knowing document (F1) also knows document (E7), all the more so since document (F1) is not principally restricted to fish (see the first two paragraphs of the introduction and page 582 at the beginning of the second paragraph, where promotion of resistance in mice by way of application of polysaccharides is indicated). Accordingly, both documents relate to inulin, both of them relate to vertebrates (namely fish and mice in document (F1) and humans based on experiments involving rats (see e.g. table 2 on page 1409) in document (E7)) and both of them deal with immunostimulation and inhibitory effects on the growth of harmful bacteria (see (F1), title and page 577, second paragraph under "Introduction" and (E7), page 1409, left-hand column, last paragraph, lines 11 to 13 together with lines 19 to 25).

Document (E7), a review article on inulin and fructooligosaccharides as prebiotics, discloses that fructooligosaccharides (see page 1407, left-hand column, first full paragraph, lines 17 to 21) may be used to produce compositions for the treatment (in particular prevention) of colonic and also systemic disorders by promoting inhibitory effects on the growth of harmful bacteria **by oral administration** (see title and page 1409, right-hand column, last paragraph including the rest of the last sentence on page 1410).

3.2.7 Therefore, the teaching of claim 1 of auxiliary request 4A lacks inventive step with respect to document (F1) in combination with document (E7).

4. Under these circumstances the appellants' further arguments on file cannot succeed:

The conclusions of the author of document (E7) are not "speculation" in a negative sense, i.e. blind and lacking any sound basis, and they do not relate to translocation only:

Under the heading "conclusions and perspectives" results from all the considerations in the review article are described, in particular concerning pharmaceutical applications *inter alia* with regard to systemic disorders. These systemic disorders are gut-origin disorders but also e.g. "multiple organ failure syndrome" which is not "gut origin" *per se*. "Implantation of parasites" and "extensive burn injury" are mentioned as "major factors in the etiology of these (the systemic; annotation of the board) disorders, which are often (not always; annotation of the board) associated with bacterial translocation due to intestinal barrier failure.

Therefore, the teaching of document (E7) also deals with systemic infection independent of translocation.

However, applying the problem-solution approach in the present case and under the given conditions it is sufficient that document (E7) at least does not exclude treatment of systemic infections whether or not based on translocation. Consequently, there is no obstacle to combining it with document (F1) for assessing inventive step.

With respect to systemic infection in the sense of the claimed teaching it is sufficient that document (F1) as

the closest prior art includes this feature because the solution to the problem is focussed on oral administration only.

Accordingly, and independently of any considerations about the mechanism on which immunostimulating effects are based in document (F1) or in document (E7), both of them observe effects to combat bacterial infections, the first of them by intraperitoneal application of e.g. inulin and the second by oral application. Therefore, the argument that, orally administered, no intact fructooligosaccharide will appear beyond the gut in the organism of the vertebrate to be treated is also of no significance.

5. *Admissibility of auxiliary requests 5A to 9A*

The filing of auxiliary requests 5A to 9A is a *bona fide* attempt to respond to the arguments set out in the communication of the board concerning auxiliary request A5 and relating to inventive step only, particularly in view of documents (D3), (E7) and (F1). The amended auxiliary requests relate to oral feeding of fish by the use of inulin, oligofructose and mixtures thereof for the manufacture of a functional feed. The effort of the appellants to streamline the teaching to be claimed in reaction to the objections of the board is recognised, and the auxiliary requests 5A to 9A are therefore admitted into the proceedings.

6. *Remittal*

The subject-matter of these further auxiliary requests has never been commented on during the written proceedings, and an investigation as to whether they

meet the requirements of the Convention (including Articles 123 and 84 EPC) is necessary.

Because the subject-matter of original claim 2 was introduced into claim 1 of these requests and the alternative "pharmaceutical" was deleted, the question may also arise whether a functional feed composition may be allowed to be the subject of a second-medical-use-type claim.

Even in the knowledge that the problem of allowability of second-medical-use-type requests for functional food or functional feed would necessarily become an issue in the appeal proceedings, in advance of the oral proceedings the respondents commented neither on their admissibility nor on their allowability.

Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party may be given an opportunity for two readings of the important elements of a case.

For these reasons, the subject-matter of the further auxiliary requests is to be regarded as a fresh case. It should now be examined on its own merits.

Thus, the board exercises its discretion and remits the case to the first instance for further prosecution (Article 111(1) EPC).

7. To conclude: The board takes the view that the subject-matter of auxiliary request 4A lacks inventive step. Since the further auxiliary requests which have been filed have not yet been examined as to their allowability, the case is remitted.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution.

The Registrar:

The Chairman:



N. Maslin

U. Oswald

Decision electronically authenticated