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**Datasheet for the decision
of 10 February 2023**

Case Number: T 0179/20 - 3.3.07

Application Number: 10797669.8

Publication Number: 2451462

IPC: A61K31/702, A61K31/7016,
A61K35/20, A61P1/04, A61P29/00

Language of the proceedings: EN

Title of invention:

INHIBITING INFLAMMATION WITH MILK OLIGOSACCHARIDES

Patent Proprietor:

Children's Hospital Medical Center
The General Hospital Corporation
Instituto Nacional De Ciencias Medicas Y Nutricion

Opponents:

N.V. Nutricia
Grünecker Patent- und Rechtsanwälte
PartG mbB

Headword:

2'-Fucosyllactose/CHILDREN'S HOSPITAL

Relevant legal provisions:

EPC Art. 123(2)

Keyword:

Amendments - allowable (no) - undisclosed combination of features

Decisions cited:

G 0001/16



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Case Number: T 0179/20 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 10 February 2023

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 28 November
2019 revoking European patent No. 2451462
pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairman A. Uselli
Members: J. Molina de Alba
 Y. Podbielski

Summary of Facts and Submissions

- I. The decision under appeal is the opposition division's decision revoking European patent No. 2 451 462.

The decision was based on the claims of a main request and four auxiliary requests. The opposition division concluded, among other things, that the amendments of the main request were allowable and that the claimed subject-matter was sufficiently disclosed and novel but did not involve an inventive step. The subject-matter of auxiliary requests 1 to 3 did not involve an inventive step either. Auxiliary request 4 was admitted, but its amendments were unallowable and the claimed subject-matter was also not inventive.

- II. The patent proprietors (appellants) filed an appeal against the opposition division's decision. With their statement of grounds of appeal, the appellants filed five sets of claims as their main request and auxiliary requests 1 to 4. The requests were identical to the main request and auxiliary requests 1 to 4 on which the decision under appeal was based.

Claim 1 of the main request reads as follows:

"1. A milk-derived oligosaccharide-for use in treating ulcerative colitis, Crohn's disease or irritable bowel syndrome, wherein the milk-derived oligosaccharide is 2'-fucosyllactose, or a variant thereof, the variant being identical to 2'-fucosyllactose except that the reducing end is N-acetylglucosamine instead of glucose."

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the milk-derived oligosaccharide has been limited to 2'-fucosyllactose.

Claim 1 of auxiliary request 2 differs from claim 1 of auxiliary request 1 in that the expression "*an inflammatory disease selected from the group consisting of*" has been inserted before the recited diseases.

Claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 1 in that the diseases have been limited to "*ulcerative colitis, Crohn's disease*".

Claim 1 of auxiliary request 4 differs from claim 1 of auxiliary request 3 in that the diseases have been limited to "*ulcerative colitis or Crohn's disease*" (emphasis added by the board).

- III. In their replies to the statement of grounds of appeal, opponents 1 and 2 (respondents 1 and 2) requested that the appeal be dismissed.
- IV. The board scheduled oral proceedings in line with the parties' requests and issued a communication drawing attention to salient issues that might be debated at the oral proceedings.
- V. With a letter dated 7 December 2022, respondent 2 announced that it would not be attending the oral proceedings.
- VI. Oral proceedings were held by videoconference on 10 February 2023 in the absence of respondent 2. At the end of the oral proceedings, the board announced its decision.

VII. The appellants' arguments relevant to the present decision can be summarised as follows.

Applying the gold standard, claim 1 of the main request did not add subject-matter. A reading of the application as a whole made the link between 2'-fucosyllactose (2'-FL) and the diseases ulcerative colitis, Crohn's disease and irritable bowel syndrome clear and unambiguous.

The claim was based on a limitation of claim 1 as filed by incorporating 2'-FL (and its N-acetylglucosamine variant) from claim 3 and the inflammatory diseases ulcerative colitis, Crohn's disease and irritable bowel syndrome from claim 21. The amendment did not provide any new technical teaching and involved a single selection. The compound 2'-FL was selected from among the preferred milk-derived oligosaccharides, but no additional selection was made when indicating the treated diseases. Indeed, it was obvious from the dependency of claim 21 on claim 20 that the diseases in claim 1 were the most preferred ones.

Additional support could be found in the description on page 4 in Table 1, on page 6, lines 20 to 23, and on page 8, lines 24 to 26. Claim 1 was also consistent with the examples in the application as filed, in which a fraction of human-milk oligosaccharides containing 2'-FL was isolated and tested for its ability to inhibit intestinal inflammation.

VIII. The respondents' arguments relevant to the present decision can be summarised as follows.

Claim 1 of the main request added subject-matter. There was no clear and unambiguous link between 2'-FL and

ulcerative colitis, Crohn's disease and irritable bowel syndrome in the application as filed. The features had not been disclosed in combination, the compound 2'-FL was not the most preferred milk-derived oligosaccharide and nor were ulcerative colitis, Crohn's disease and irritable bowel syndrome the most preferred diseases.

There was no direct dependency between claims 3 and 21 as filed. The compounds of claim 3 had the same level of preference as those listed in claims 6 to 8, 10, 12, 15 and 17. As to claim 21, its dependency on claim 20 was obviously wrong. Both claims 20 and 21 were actually dependent on claim 19, and each of them disclosed a different and equally preferred group of diseases. This was confirmed by the description on page 8, lines 17 to 26. The examples in the application as filed did not support the appellants' case, since they related to a mixture of human-milk oligosaccharides and were silent as regards the presence of 2'-FL or the claimed selection of treated diseases in claim 1.

IX. The parties' final requests relevant to the present decision are the following.

- The appellants requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the main request or, alternatively, on the basis of one of auxiliary requests 1 to 4, all filed with the statement of grounds of appeal.
- The respondents requested that the appeal be dismissed.

Reasons for the Decision

1. Amendments (Article 123(2) EPC) - main request

1.1 The board agrees with the appellants that the standard of disclosure to be applied for assessing whether amendments add subject-matter beyond the content of the application as filed is the gold standard, as last confirmed by the Enlarged Board of Appeal in decision G 1/16 (Reasons 17 to 20). This standard is defined as:

"what a skilled person would derive directly and unambiguously, using common general knowledge and seen objectively and relative to the date of filing, from the whole of these documents as filed".

1.2 On this issue, the main point of dispute between the parties was whether the application as filed directly and unambiguously disclosed a link between the milk-derived oligosaccharide 2'-FL and the treatment of the diseases ulcerative colitis, Crohn's disease and irritable bowel syndrome.

According to the appellants, a basis for this combination of features in the application as filed could be found in the limitation of claim 1 by incorporating features from claims 3 and 21. Although claims 3 and 21 were not directly linked, they were both (indirectly) dependent on claim 1. The combination of claims 3 and 21 involved a single selection, namely the choice of 2'-FL from among the preferred milk-derived oligosaccharides. The limitation to the

diseases of claim 21 did not involve a selection, because the diseases were the most preferred ones.

1.3 Claim 1 as filed reads as follows:

"1. A method of inhibiting inflammation, comprising administering to a subject in need thereof an effective amount of a composition containing at least a milk-derived oligosaccharide or a glycoconjugate containing the oligosaccharide, the oligosaccharide including a first sugar unit and a second sugar unit, wherein the first sugar unit, located at a first non-reducing end, is fucose, galactose, mannose, or sialic acid and the second sugar unit, linked to the first sugar unit, is galactose, glucose, mannose, or N-acetylglucosamine."

1.4 Limitation to 2'-FL as the milk-derived oligosaccharide

The respondents argued that the application as filed did not disclose 2'-FL as being the most preferred milk-derived oligosaccharide but just one of those preferred. This was not contested by the appellants, which conceded, at the oral proceedings before the board, that the limitation of the milk-derived oligosaccharide to 2'-FL involved a selection.

The board agrees. The claims as filed disclose three groups of equally preferred milk-derived oligosaccharides according to claim 1, namely those in which:

- the first sugar unit of the oligosaccharide is fucose (claim 2),
- the oligosaccharide includes a second non-reducing end (claim 4), and

- the first sugar unit of the oligosaccharide is sialic acid (claim 11).

Preferred oligosaccharides within each of these groups are disclosed in claims 3, 6, 8, 10, 12, 15 and 17. The compound 2'-FL is one of the embodiments in claim 3 as filed.

Other elements of the application as filed cited by the parties in this context were the first entry of Table 1 on page 4, and the passage on page 6, lines 20 to 23. These elements mention 2'-FL but do not state that it has a higher preference than other preferred milk-derived oligosaccharides. Table 1 discloses 2'-FL as one compound within a list of fucosyl oligosaccharides that naturally occur in human milk according to cited prior-art documents. The passage on page 6, lines 20 to 23, refers to 2'-FL as one among several examples of milk-derived oligosaccharides that can be used for forming glycoconjugates via a reducing sugar.

Therefore, 2'-FL is just one of the numerous preferred milk-derived oligosaccharides disclosed in the application as filed.

- 1.5 Limitation to ulcerative colitis, Crohn's disease and irritable bowel syndrome as the diseases to be treated

Claims 19 to 21 as filed disclose the diseases that may be treated by the method of claim 1. The claims read as follows:

"19. The method of claim 1, wherein the subject suffers from or is at risk for an inflammatory disease of the digestive tract."

"20. The method of claim 19, wherein the inflammatory disease of the digestive tract is selected from the group consisting of oesophagitis, gastroenteritis, colitis, cholangitis, and appendicitis."

"21. The method of claim 20, wherein the inflammatory disease of the digestive tract is ulcerative colitis, Crohn's disease, or irritable bowel syndrome."

It is clear to the skilled reader that the diseases recited in claim 21 do not constitute a sub-group of the diseases in claim 20 but are, instead, a different group of inflammatory diseases of the digestive tract. The skilled person would have realised that the reference by claim 21 to claim 20 was obviously a mistake and that claim 21 should refer back to claim 19.

This view is confirmed by the passage on page 8, lines 6 to 26 of the application as filed, which discloses the same two groups of inflammatory diseases of the digestive tract separately and at the same level of preference. The passage states that the method of the invention is particularly effective in treating inflammatory diseases of the digestive tract, including oesophagitis, gastroenteritis, colitis, cholangitis and appendicitis. In the next sentence, the passage adds that inflammatory diseases of the digestive tract also include inflammatory bowel disease (e.g. Crohn's disease and ulcerative colitis) and irritable bowel syndrome.

On page 2, lines 19 to 22, the application recites the two groups of diseases within a single list - at the same level of preference - as examples of diseases of the digestive tract.

Thus, inflammatory diseases of the digestive tract are preferred in the application as filed, but the sub-group consisting of ulcerative colitis, Crohn's disease and irritable bowel syndrome is not the most preferred sub-group. It represents a selection equivalent to that of the sub-group consisting of oesophagitis, gastroenteritis, colitis, cholangitis and appendicitis.

1.6 The appellants cited the examples in the application as filed as additional support for the claimed subject-matter. However, the examples do not help since they merely disclose the *in-vitro* effect of a fraction of human-milk oligosaccharides of undetermined composition in inhibiting intestinal inflammation. The examples are silent as to both the presence of 2'-FL in the isolated oligosaccharide fraction and the treatment of ulcerative colitis, Crohn's disease and irritable bowel syndrome.

1.7 It follows from points 1.4 to 1.6 above that the application as filed does not disclose a clear and unambiguous link between 2'-FL and ulcerative colitis, Crohn's disease and irritable bowel syndrome. Thus, the skilled person could not clearly and unambiguously derive from the application as filed that the invention concerned the use of 2'-FL for treating the three specific diseases.

Therefore, claim 1 of the main request adds subject-matter and does not comply with the requirements of Article 123(2) EPC.

2. *Amendments (Article 123(2) EPC) - auxiliary requests*

Claim 1 of auxiliary requests 1 and 2 contains the combination of 2'-FL with the treatment of ulcerative colitis, Crohn's disease and irritable bowel syndrome. In claim 1 of auxiliary requests 3 and 4, the compound 2'-FL is combined with ulcerative colitis and Crohn's disease.

Therefore, for the reasons explained in relation to the main request, claim 1 of each of auxiliary requests 1 to 4 also adds subject-matter.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated