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Datasheet for the decision of 13 August 2012

Case Number: T 2033/09 - 3.3.09

Application Number: 01932104.1

Publication Number: 1284102

IPC: A23L 1/236, C07H 3/04, C07H 15/04

Language of the proceedings: EN

Title of invention:
Syrup containing compositions and process for producing the same

Patentee:
Ueno Fine Chemicals Industry, Ltd.

Opponents:
Cargill, Inc.
Südzucker Aktiengesellschaft Mannheim/Ochsenfurt

Headword:
-

Relevant legal provisions:
EPC Art. 54, 83, 111(1)

Keyword:
"Main request, Auxiliary requests 1, 2: Sufficiency of disclosure (yes), novelty (no)"
"Auxiliary request 3: admitted into the proceedings"
"Remittal"

Decisions cited:
T 0608/07

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 2033/09 **-** 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 13 August 2012

Appellant:
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 17 July 2009 revoking European patent No. 1284102 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman: W. Sieber
Members: W. Ehrenreich
W. Sekretaruk

Summary of Facts and Submissions

I. Mention of the grant of European patent No. 1 284 102 in respect of European patent application No. 01 932 104.1 filed on 17 May 2001 as PCT/JP2001/004101 in the name of ***Kabushiki Kaisha Ueno Seiyaku Oyo Kenkyusho,*** now ***Ueno Fine Chemicals Industry, Ltd.,*** was announced on 3 May 2006 in Bulletin 2006/18.

The patent was granted with 7 claims, claims 1 and 4 reading as follows:

"1. A crystalline mixture solid composition comprising α-D-glucopyranosyl-1,1-mannitol, α-D-glucopyranosyl-1,6-sorbitol and 0.01 to 1.99 wt% of α-D-glucopyranosyl-1,1-sorbitol (the above wt% is based on the total weight of the α-D-glucopyranosyl-1,1-mannitol, α-D-glucopyranosyl-1,6-sorbitol and α-D-glucopyranosyl-1,1-sorbitol)."

"4. A process for producing a crystalline mixture solid composition according to any one of claim 1 to 3, comprising the steps of supplying a composition comprising 50 to 80 wt% of α-D-glucopyranosyl-1,1-mannitol, 1 to 50 wt% of α-D-glucopyranosyl-1,6-sorbitol and 0.01 to 20 wt% of α-D-glucopyranosyl-1,1-sorbitol into a kneader to knead and cool it so as to produce a composition, mixing the composition with a hydrophilic solvent, and separating solid matter from the liquid (the above wt% is based on the total weight of the α-D-glucopyranosyl-1,1-mannitol, α-D-glucopyranosyl-1,6-sorbitol and α-D-glucopyranosyl-1,1-sorbitol)."

II. The following abbreviations are used in the subsequent text of the decision:

α-D-glucopyranosyl-1,1-mannitol = GPM-1;
α-D-glucopyranosyl-1,6-sorbitol = GPS-6;
α-D-glucopyranosyl-1,1-sorbitol = GPS-1.

III. An opposition against the patent was filed by

Opponent I - ***Cargill Incorporated*** on 1 February 2007

and

Opponent II - ***Südzucker Aktiengesellschaft Mannheim/Ochsenfurt*** on 30 January 2007.

The opponents requested revocation of the patent on the grounds of lack of novelty and inventive step (Article 100(a) EPC) and insufficiency of disclosure (Article 100(b) EPC).

In support of their objections the opponents cited a number of documents, including

A1 Amendment of GRAS Petition 6G0321: Isomalt, submitted by Südzucker AG in January 1996 to the US Food and Drug Administration (FDA) and publicly available under the Freedom of Information Act (FOIA);

A7 Declaration of Bernhard Johannes Lussem dated 4 January 2007;

A13 EP-A 1 172 370;

A20 Compendium of food additive specifications, Addendum 4 (1996), pages 79-83.

In the following, all references to A1 relate to the stamped page numbering on the top right-hand corner of this document.

IV. With its decision announced orally on 17 June 2009 and issued in writing on 17 July 2009 the opposition division revoked the patent. The decision was based on the claims as granted (main request), claims 1 to 5 according to auxiliary request 1 and claims 1 to 7 according to auxiliary request 2. Claim 1 of auxiliary request 1 was identical to granted claim 1, and in claim 1 of auxiliary request 2 the amount of GPS-1 was amended to 0.01 to 1.5 wt%.

V. The opposition division was of the opinion that the claimed invention was sufficiently disclosed and therefore complied with Article 83 EPC. However, novelty of the subject-matter of claim 1 of all requests was not acknowledged in view of the disclosure in document A1.

A1 was a signed statement to a governmental authority made more than four years before the priority date of the patent. This document related to compositional changes in a commercial product called "Isomalt" due to a change in the refining step, from crystallisation to enzymatic hydrolysis. The composition of the "former" Isomalt (obtained via crystallisation) was disclosed in table 1, middle column on page 64. Page 10 of A1 indicated only quantitative changes in the sugar composition of Isomalt due to the process change.

Furthermore, A1 referred at page 3 to Isomalt as a crystalline substance that could only be solid since it was soluble in water and contained only a maximum amount of 7% water.

VI. Notice of appeal against the decision of the opposition division was filed by the patent proprietor (hereinafter: appellant) on 16 September 2009. The prescribed fee was paid on the same day. The grounds of appeal were filed on 19 November 2009, including copies of the first to sixth auxiliary requests.

The appellant requested that (a) the appealed decision be set aside and (b) the case be remitted to the opposition division for consideration of issues not addressed in its decision. In the event that the board was not able to accept the main request (claims as granted), the case should be remitted to the opposition division on the basis of any of the first to sixth auxiliary requests.

VII. Opponents I and II (hereinafter: respondents I and II) filed replies by letters dated 1 April 2010 and 19 March 2010 respectively and ***inter alia*** reiterated their objections of lack of novelty, based on A1. Respondent I further provided arguments concerning the issues of inventive step and sufficiency of disclosure.

In letters dated 6 March 2012 (respondent II) and 12 July 2012 (respondent I) they requested, with reference to Article 12(4) of the Rules of Procedure of the Boards of Appeal (RPBA), that the third to sixth auxiliary requests not be admitted into the proceedings.

Respondent I further requested that the case be remitted to the opposition division in the event that novelty of the composition claimed in claim 1 of each of the main request and the first and second auxiliary requests over the contents of A1 were to be acknowledged or the third and fourth auxiliary requests came up for consideration.

VIII. Oral proceedings before the board were held on 13 August 2012. The issues of sufficiency of disclosure, novelty of the invention claimed in claim 1 of the main request and the first and second auxiliary requests, and admission of the third auxiliary request into the proceedings were discussed.

IX. The arguments of respondents I and II provided in writing and orally, as far as they are relevant for this decision, can be summarised as follows:

(a) Sufficiency of disclosure

Claim 1 requires the presence of 0.01 to 1.99 wt% of GPS-1, i.e. the end values of the claimed range are given to two decimal places. There is no teaching in the patent specification as to how the GPS-1 values can be determined with this accuracy or how GPS-1 can be separated from GPM-1 and GPS-6. In the examples of the patent (tables 1 to 3) GPS-1 values are only given with an accuracy of one decimal place without indicating the measuring method. According to A20, pages 82/83, the sugar alcohols GPS-6 and GPS-1, when passing the column of a gas chromatograph, have an almost equal retention time.

It should further be noted that document A13 discloses a crystalline mixture with a GPS-1 content of 2 to 25 wt%, which means that the numerical difference between the GPS-1 upper limit of 1.99 wt% according to the claimed composition and the lower limit of 2 wt% according to A13 is only 0.01. This difference, however, is below the standard deviation of 0.03 for the determination of GPD-1 via GC, as can be derived from the table at page 43 of A1. From the same table it follows that GPS-6 and GPS-1 cannot be separated by HPLC.

In the light of the above the skilled person cannot, without undue burden, determine the GPS-1 content in the claimed composition with an accuracy of two decimal places as required by claim 1.

(b) Novelty

Document A1 concerns the 1996 amendment of the GRAS Petition 6G0321 proposing a new production step for the commercial product Isomalt. In particular, the then current process using crystallisation as refining step is replaced by an alternative refining process involving enzymatic hydrolysis. Both refining processes are illustrated in the table at page 10. On page 3, under the heading "Proposed regulations", it is indicated under (a) that Isomalt is produced by the enzymatic rearrangement of sucrose followed by metal catalytic hydrogenation, and under (b) that the ingredients meet certain specifications for

substances of food quality. In the subsequent table it is mentioned that Isomalt is an odourless, white, sweet crystalline substance. Furthermore, it is apparent from page 11 that the use of the new refining step causes no qualitative change in the composition of the final product

According to Table 1 at page 10 of A1, Isomalt prepared according to the then current refining process contains 0.3 wt% GPS-1, which is within the range claimed in claim 1.

A1 therefore contains an unambiguous disclosure that Isomalt prepared according to the then current refining step is a commercially available, crystalline composition comprising 0.3 wt% GPS-1 and therefore anticipates the subject-matter of claim 1.

The appellant's argument that A1 is a non-enabling disclosure is irrelevant, because A1 describes a commercially available product which can be readily analysed, as demonstrated by A1 itself.

X. The arguments of the appellant provided in writing and orally, as far as they are relevant for this decision, can be summarised as follows:

(a) Sufficiency of disclosure

The teaching of the patent is directed to a skilled person with his common general knowledge. The skilled person would therefore be aware of the methods suitable for separating sugar alcohols and

determining their contents in a composition. He would consider A20, which is a publication of the Joint FAO/WHO Expert Committee and recommends on pages 82/83 the GC method for separating sugar alcohols, ***inter alia*** GPS-1, GPM-1 and GPS-6. GC is also recommended as a suitable method in A1, which indicates in table 1 at page 37 the GPS-1 amount of various Isomalt samples to two decimal places. This is confirmed in the declaration of Mr. Lussem, A7, wherein the amounts of GPS-1 in two Isomalt samples analysed by GC are also given to two decimal places.

(b) Novelty

According to page 3 of A1, Isomalt is referred to as being mainly a mixture of GPS-6 and GPM-1. The data in the subsequent table specifying Isomalt as a crystalline substance are, however, silent on GPS-1 and only indicate GPS-6 and GPM-1 in a broad range. A1 also fails to characterise Isomalt, prepared by using the then current refining step illustrated in figure 1 and containing 0.3 wt% GPS-1 according to table 1 at page 10, as a crystalline substance. There was therefore no clear and unambiguous disclosure in A1 that Isomalt containing GPS-1 in the claimed range was a crystalline substance.

Even if such an Isomalt were crystalline, there is no enabling disclosure in A1 as to how Isomalt can be prepared in crystalline form. That the preparation of a crystalline product containing GPM-1, GPS-6 and GPS-1 in the sense of the

invention is critical is shown by the experimental report A21, already submitted in the examining proceedings with the letter of 11 January 2005. This report shows that simple evaporation of the raw mixed GPS-1 containing solution does not lead to a crystalline product.

XI. The appellant requested that the decision under appeal be set aside and the case be remitted to the opposition division for consideration of issues not addressed in its decision on the basis of the claims as granted (main request), alternatively on the basis of one of the first to sixth auxiliary requests submitted with the letter dated 18 November 2010.

XII. The respondents requested that the appeal be dismissed. They further requested that the third to sixth auxiliary requests not be admitted into the proceedings. In the event that issues not dealt with in the opposition division's decision came up for consideration, they requested that the case be remitted to the opposition division for further prosecution.

Reasons for the Decision

1. The appeal is admissible.

2. Main request (claims as granted)

2.1 Sufficiency of disclosure

2.1.1 Respondent I argued that the range of 0.01 to 1.99 wt% of GPS-1, specified in claim 1 of the main request,

necessitated the use of a measuring method which is capable of measuring the GPS-1 content in the composition to at least a difference of 0.01%. This was particularly so in view of the fact that A5 and A13 taught GPS-1 contents of 2 wt% (based on GPM-1, GPS-6 and GPS-1) and in view of the fact that there were Isomalt products which contained no GPS-1. The patent in suit, however, contained no information regarding the method that was to be used to measure the GPS-1 content to such a degree of accuracy.

2.1.2 It is incontestable that a skilled person was able before the effective priority date to separate GPS-1 and to determine its amount in compositions containing GPS-1, GPS-6 and GPM-1. In accordance with the expert opinion A20, document A1 discloses on page 42, third paragraph under the heading "II. Validation results" that complete separation of GPS-6 and GPS-1 is possible by gas chromatography (GC) only. It further states that "Therefore, the GC method is the most accurate analytical method currently available for detailed analyses". Separate GPS-1- and GPS-6-peaks are clearly visible in the upper gas chromatogram at page 36 of A1. Furthermore, Table 1 at page 37 shows GPS-1 contents for Isomalt samples to two decimal places, for example 0.09, 0.03 and 0.04 wt% for Isomalt manufactured using crystallisation.

It might be true that the determination of the GPS-1 end values of 0.01 wt% and 1.99 wt% claimed in claim 1 with sufficient accuracy is critical, because the standard deviation for the GC-method, according to page 43 of A1, is 0.03. This however does not mean that the GPS-1 cannot be measured at the end values of the

claimed range. If at all, the reliability of the measuring method may lead to an ambiguity at the edges of the claimed ranges. Such an ambiguity at the edges of the claim which does not permeate the whole claim (this has never been alleged by the respondents) does, however, not amount to an insufficient disclosure (see for example T 608/07 of 27 April 2009, not published in the OJ EPO, point 2.5.2 of the reasons).

2.2 Novelty over A1

2.2.1 A1 relates to a 1996 amendment of the GRAS petition 6G0321 for Isomalt. In particular, it concerns an alternative method in the manufacture of Isomalt, wherein the then current refining step for the removal of sucrose via crystallisation is replaced by enzymatic hydrolysis (A1, page 7 under the heading "Information on the alternative method in the manufacture of ISOMALT"). Thus, the then "current" Isomalt is a commercial product and was therefore available to the public.

Under the heading "Proposed regulation" it is stated in A1 that Isomalt has to meet certain specifications for substances of food quality and that one requirement is crystallinity of the substance (page 3, middle column of the table setting out the Isomalt specification). Under point 4 "Revised Specification" (page 12) it is stated that "The implementation of the alternative refining method as described in point 3 results in a quantitative change of various components and therefore requires a revision of the ISOMALT specification". According to the subsequent table on page 13 of A1 headed "Specifications for Isomalt (Food Quality)" one

requirement is again crystallinity (second column from the left). It is furthermore stated on page 11, third paragraph that "components contained in ISOMALT manufactured using the alternative refining step are also contained in ISOMALT as currently manufactured. This shows that the use of the new refining step causes no qualitative change to the composition of the final product". From these passages in A1 it is unambiguously derivable that both the Isomalt refined with the then current method and the alternatively refined Isomalt are crystalline substances. It can therefore be concluded that Isomalt prepared according to the then current refining step as schematically illustrated in figure 1 on page 8 and having a GPS-1 content of 0.3 wt% according to table 1 at page 10 of A1 is a crystalline composition embraced by claim 1.

Since ISOMALT obtained via the then current refining step further comprises GPM-1 and GPS-6 (tables at pages 10 and 64 of A1) the commercial ISOMALT disclosed in A1 has all the features required in claim 1 as granted.

2.2.2 The appellant argued that A1 did not anticipate the claimed subject-matter because it does not describe a method for the preparation of Isomalt in crystalline form and was therefore not an enabling disclosure. This argument is, however, not relevant because the Isomalt prepared via the then current refining step is a commercial product, which was already available to the public before the effective priority date of the patent and could be readily analysed, as demonstrated by A1 itself.

2.2.3 From the above it follows that the subject-matter of claim 1 of the main request is not novel. The request is therefore not allowable.

3. First and second auxiliary requests

Since claim 1 of the first auxiliary request is identical to claim 1 of the main request, the first auxiliary request is also not allowable.

In claim 1 of the second auxiliary request the GPS-1 content has been merely limited to 0.01 to 1.5 wt%. Thus, commercial ISOMALT having a GPS-1 content of 0.3 wt% as disclosed in A1 is still novelty-destroying for the subject-matter of claim 1 of this request.

4. Admission of the third auxiliary request 3 into the proceedings

The respondents requested, with reference to Article 12(4) of the RPBA, that the third to sixth auxiliary requests not be admitted into the proceedings. It was argued that these requests could have been presented in the opposition proceedings and were partly inadmissible because they either created new issues arising out of the introduction of a new lower limit for the GPS-1 content (third and fourth auxiliary requests) or concerned solely process claims (fifth and sixth auxiliary requests) which were not discussed during the oral proceedings before the opposition division.

Claim 1 of auxiliary request 3, in which the lower limit for the GPS-1 content is increased to 1.0 wt%,

overcomes the reasons which led to the revocation of the patent by the opposition division. The board considers the appellant's filing of the third auxiliary request 3 with the grounds of appeal as a *bona-fide* attempt to overcome the novelty objection with respect to A1. Nor does the board see in the present case any abuse of procedure in the filing of this new auxiliary request in the appeal proceedings. Therefore the third auxiliary request is admitted into the proceedings.

5. Remittal

In contrast to the previous requests, the Isomalt product prepared according to the "current" refining step as described in A1 no longer anticipates the composition of claim 1 of the third auxiliary request, since the lower limit of the GPS-1 content is now 1.0 wt%.

Since the third auxiliary request has not been considered by the opposition division (*inter alia* added subject-matter with regard to the new GPS-1 lower limit or novelty and inventive step with regard to other documents cited in the opposition and appeal proceedings), the board exercises its discretion under Article 111(1) EPC and remits the case to the opposition division.

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 for further prosecution.

The Registrar | The Chairman

M. Canueto Carbajo | W. Sieber