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D E C I S I O N
of 28 March 2006

Case Number: T 0606/05 - 3.3.08

Application Number: 96106725.3

Publication Number: 0741140

IPC: C07H 15/04

Language of the proceedings: EN

Title of invention:
A process for manufacturing crystalline maltitol and crystalline mixture solid containing the same

Patentee:
TOWA CHEMICAL INDUSTRY CO., LTD.

Opponent:
Cerestar Holding B.V.

Headword:
Maltitol/TOWA

Relevant legal provisions:
EPC Art. 56, 83

Keyword:
"Main request: inventive step (yes)"
"Sufficiency of disclosure (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0606/05 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 28 March 2006

Appellant I: (Proprietor of the patent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 14 March 2005 concerning maintenance of European patent No. 0741140 in amended form.**

Composition of the Board:

Chairman: L. Galligani
Members: T. J. H. Mennessier
C. Rennie-Smith

Summary of Facts and Submissions

I. The Patentee (Appellant I) and Opponent 01 (Appellant II) each lodged an appeal against the interlocutory decision of 14 March 2005, whereby European patent No. 0 741 140, which had been granted on European application No. 96 106 725.3, was maintained on the basis of the third auxiliary request filed on 25 January 2005.

II. The main request (claims as granted) and the first and second auxiliary requests then on file had been refused by the Opposition Division for lack of inventive step (Article 56 EPC).

III. The patent had been opposed by two opponents on the grounds as set forth in Articles 100(a) and (b) EPC that the invention did not involve an inventive step (Article 56 EPC) and was not sufficiently disclosed (Article 83 EPC).

IV. Opponent 02, which had withdrawn its opposition on 28 January 2004, ie before the decision under appeal was taken, is not a party to the present appeal proceedings.

V. Both statements of grounds of appeal were filed, the one of Appellant I being accompanied by a main request, which was identical to the main request (claims as granted) as refused by the Opposition Division, and eight auxiliary requests (numbered 1 to 8).

VI. Each of the appellants submitted observations in reply to the statement of grounds of appeal of the other. The

observations of Appellant I were accompanied by an expert declaration. Those of Appellant II were directed in particular to the main request, the request as a whole being considered not to involve an inventive step (Article 56 EPC), and the invention of claim 3 being regarded as insufficiently disclosed (Article 83 EPC).

VII. A communication under Article 11(1) of the Rules of Procedure of the Boards of Appeal presenting some preliminary and non-binding views of the Board was then sent to the parties.

VIII. Oral proceedings took place on 28 March 2006.

IX. The main request (claims as granted) consisted of four claims.

Claims 1 to 3 read:

"1. A process for manufacturing crystalline maltitol and crystalline mixture solid containing the maltitol, **characterized in that** the process passes sequentially through the following processes:

1) the first step of hydrogenating syrup having a concentration of 30 to 75% by weight and a maltose content of 81 to 90% by weight in the solid component under the existence of catalyst to obtain corresponding syrup of sugar alcohol;
2) the second step of chromatographically separating said syrup of sugar alcohol by supplying said syrup of sugar alcohol to a column packed with cation-exchange resin to obtain high content maltitol syrup fraction

having a maltitol purity of 92 to 99.9% by weight in the solid component; and
3) the third step having a sub-step of crystallizing, in the presence of a seed crystal, a part of syrup resulting from condensation of said high content maltitol syrup fraction to collect crystalline maltitol, and another sub-step of spray-drying or cooling and kneading, in the presence of a seed crystal, remaining part to obtain crystalline mixture solid containing crystalline maltitol."

"2. A process for manufacturing crystalline maltitol and crystalline mixture solid containing the maltitol, **characterized in that** the process passes sequentially through the following processes:

1) the first step of hydrogenating syrup having a concentration of 30 to 75% by weight and a maltose content of 81 to 90% by weight in the solid component under the existence of catalyst to obtain corresponding syrup of sugar alcohol;
2) the second step of chromatographically separating said syrup of sugar alcohol by supplying said syrup of sugar alcohol to a column packed with cation-exchange resin to obtain high content maltitol syrup fraction having a maltitol purity of 92 to 99.9%, preferably 94 to 99.9%, by weight in the solid component;
3) the third step of crystallizing after a condensation of said high content syrup fraction and separating crystalline maltitol from mother liquor, whereby collecting crystalline maltitol; and
4) the forth step of adding said high content maltitol syrup fraction resulting from the second step to said mother liquor resulting from the third step, condensing

and spray-drying or cooling and kneading it in the presence of a seed crystal to obtain crystalline mixture solid containing crystalline maltitol."

"3. A process for manufacturing crystalline maltitol and crystalline mixture solid containing the maltitol, **characterized in that** the process passes sequentially through the following processes:

1) the first step of hydrogenating syrup having a concentration of 30 to 75% by weight and a maltose content of 81 to 90% by weight in the solid component under the existence of catalyst to obtain corresponding syrup of sugar alcohol;
2) the second step of chromatographically separating said syrup of sugar alcohol by supplying said syrup of sugar alcohol to a column packed with cation-exchange resin to obtain high content maltitol syrup fraction having a maltitol purity of 92 to 99.9%, preferably 94 to 99,9%, by weight in the solid component;
3) the third step of crystallizing after a condensation of said high content maltitol syrup fraction and separating crystalline maltitol from mother liquor, whereby collecting crystalline maltitol; and
4) the forth step of adding a seed crystal to said mother liquor resulting from the third step, and spray-drying or cooling and kneading to obtain crystalline mixture solid containing crystalline maltitol."

Claim 4 was dependent on claims 1 to 3 and was directed to particular embodiments thereof.

X. The following documents are referred to in the present decision:

(O1) US-A-4,846,139 (published on 11 July 1989)

(O2) EP-A-0 491 953 (published on 1 July 1992)

(O4) US-A-4,917,916 (published on 17 April 1990)

(O6) US-A-4,849,023 (published on 18 July 1989)

XI. The submissions made by Appellant I, insofar as they are relevant to the present decision, may be summarised as follows:

Main request

Inventive step (Article 56 EPC)

Claim 1

Starting from document O4, regarded as the closest prior art, the technical problem to be solved was the provision of a cost-effective process for manufacturing both crystalline maltitol and a crystalline mixture solid containing crystalline maltitol from the same raw material. The solution to that problem was a process which, as indicated in claim 1, provided as an intermediate product a high content maltitol syrup (obtained as the result of the chromatography separation step) that could be rapidly processed at the same time into crystalline maltitol and a crystalline mixture solid containing crystalline maltitol.

Document O4 did not describe a process for manufacturing at the same time and from the same raw material both crystalline maltitol and a crystalline mixture solid containing crystalline maltitol. The maltose syrup used in document O4 was a highly purified product (with maltose representing 99% by weight of the dry matter) obtained using an expensive enzyme system or as the result of a long saccharification process. Contrary to the process of document O4, in the process of claim 1, a less purified maltose syrup (81 to 90% by weight of the dry matter) was used and the maltitol purity increased during the chromatography so as to reach the level of 92 to 99% by weight of the dry matter.

Document O1 described a process for the preparation of crystalline maltitol with a purity lower than that of the crystalline maltitol as prepared using the process of the patent. It comprised a step of recycling the crystallisation mother liquor to the head of the chromatographic fractionation step. An almost quantitative extraction of the maltitol was achieved. The mother liquor was only used to prepare crystalline maltitol.

The person skilled in the art, facing the afore-mentioned technical problem, would not have introduced such a step of chromatographic fractionation because the purity of the maltitol syrup obtained after the hydrogenation step of the process of document O4 was already high enough.

Moreover, document O1 did not suggest the production of a crystalline mixture solid containing crystalline maltitol.

Document O6 described a process for the preparation of a syrup with a high content of maltitol. A maltose syrup with a low maltose concentration (50 to 80 % by weight of the dry matter) was used as the starting material. It was hydrogenated and then chromatographed. Two fractions, one with the maltitol syrup and one enriched with maltitriitol, were recovered.

Document O6 did not suggest the production of a crystalline mixture solid containing crystalline maltitol.

Therefore, the process according to claim 1 could not be deduced from a combination of the teachings of document O4 and of document O1 or document O6.

Claim 3

As the process of claim 3 differed from that of claim 1 only in that the crystalline mixture solid containing crystalline maltitol was prepared not from the maltitol syrup recovered from the chromatographic fractionation but from the crystallisation mother liquid, the reasons given for claim 1 applied *mutatis mutandis* to claim 3.

Claim 2

The process of claim 2 was the same as the process of claim 3, however, with the additional step of adding part of the maltitol syrup recovered from the

chromatographic fractionation to the crystallisation mother liquid before it was processed to produce a crystalline mixture solid containing crystalline maltitol. As the process of claim 3 as such was inventive, the process of claim 2 was also inventive.

Sufficiency of disclosure (Article 83 EPC)

No verifiable facts had been submitted by Appellant II in support of its objection raised against claim 3.

XII. The submissions made by Appellant II, insofar as they are relevant to the present decision, may be summarised as follows:

Main request

Inventive step (Article 56 EPC)

Claim 1

Document O4 was the closest prior art. It disclosed and taught that, starting from one and the same maltitol syrup containing at least 65% by weight of maltitol in the dry matter, for example, 85,4% as described in Example 3, both crystalline maltitol and a crystalline mixture solid containing crystalline maltitol could be obtained.

The process of claim 1 differed from the process of document O4 only in that it comprised an additional chromatographic separation step.

In view of document O4, the technical problem was the provision of an alternative process for the preparation of both maltitol crystals and a crystalline mixture solid containing crystalline maltitol.

As each of documents O1 and O6 taught the use of a chromatographic separation step in a process for the preparation of crystalline maltitol, the skilled person by combining the teaching of either of those documents with the teaching of document O4 would have arrived at the solution to the technical problem as proposed in claim 1.

The step which apparently provided the economic advantage alleged by Appellant I was deciding to split the maltitol syrup into two portions. Splitting a syrup into two portions could not provide an inventive step and could not be considered to solve any technical problems.

Claim 3

The process of claim 3 was analogous to the process of claim 1, as in both processes the crystalline mixture solid was prepared from a maltitol syrup (the mother liquor being such a syrup). Therefore, for the assessment of inventive step, the argument directed at claim 1 also applied to claim 3 which thus was not inventive.

Claim 2

Claim 2 differed from claim 3 only in that part of the maltitol syrup recovered after the chromatographic

separation was added directly to the mother liquor in order to prepare the crystalline mixture solid. As there were no data in the patent as to the relative amounts of maltitol syrup to be directly crystallised and to be added to the mother liquor, this step of adding maltitol syrup was to be regarded as arbitrary and should be ignored when assessing inventive step, with the result that claim 2 was to be assessed in the same way as claim 3. Therefore, the process of claim 2 was also not inventive.

Sufficiency of disclosure (Article 83 EPC)

From document O2 it was known that, if the maltitol content of the mother liquor was lower than 65% by weight of the dry matter, it was not possible to obtain a crystalline mixture solid. Since claim 3 encompassed embodiments in which the mother liquor had a lower maltitol content and since step 4 of claim 3 did not indicate a condensation step before spray-drying, the process of claim 3 was not sufficiently disclosed.

XIII. Appellant I (Patentee) requested that the decision under appeal be set aside and the patent be maintained as granted (main request) or on the basis of one of the auxiliary requests 1 to 8 filed with its statement of grounds of appeal.

XIV. Appellant II (Opponent 01) requested that the decision under appeal be set aside and the patent be revoked.

Reasons for the Decision

Inventive step

Claim 1

1. Claim 1 of the main request is directed to a process for manufacturing **from the same intermediate material**, namely a high content maltitol syrup (with maltitol representing 92 to 99,9% by weight of the dry matter), **and at the same time**, crystalline maltitol (crystals of maltitol) and a crystalline mixture solid containing crystalline maltitol. The maltitol syrup is recovered as an enriched fraction eluted from a cation-exchange chromatography column to which a maltitol syrup has been applied, the maltitol syrup being obtained upon hydrogenation of a maltose syrup with maltose representing from 81 to 90% by weight of the dry matter. The high content maltitol syrup is split into two parts. The crystalline mixture solid is recovered from one part by a process such as spray drying or cooling and kneading while the crystalline maltitol is recovered from the other part by crystallisation and separation from a mother liquor. Claim 1 is not drafted in an open way. It comprises a definite sequence of steps without any recycling of any of the intermediate or final products.

2. As agreed by the appellants and the Examining Division, document O4 is considered to represent the closest prior art. It describes a process for manufacturing **either** crystals of maltitol **or** a crystalline mixture solid containing crystalline maltitol from the massecuite obtained upon crystallisation of an aqueous

maltitol solution, prepared with a sugar alcohol mixture having a maltitol content of **at least 65%,** to give a concentration, preferably, of 65-95% (see column 4, lines 52 to 56). Upon addition of seed crystals, crystallisation occurs and a massecuite is obtained which can then be **either** separated into the anhydrous crystals of maltitol and mother liquor **or** processed into a crystalline mixture solid containing crystalline maltitol. The sugar alcohol mixture is prepared upon hydrogenation of a syrup in which maltose represents 99% of the dry matter.

3. The process of claim 1 differs from the process of document O4 in that (i) the maltose syrup used as the starting material has a lower maltose concentration (81 to 90% by weight of the dry matter to be compared with 99%), (ii) a chromatography separation step is used to recover maltitol as a highly concentrated syrup from the hydrogenated maltose syrup, (iii) the crystalline maltitol and the crystalline mixture solid are obtained at the same time from the same material, (iv) the material from which the crystalline maltitol and the crystalline mixture solid can be prepared is the maltitol syrup (whereas in the process of document O4 it is the massecuite obtained upon crystallisation of the maltitol syrup), and (v) the crystalline mixture solid is obtained upon the direct processing of the maltitol syrup (to be compared with the processing of the massecuite obtained upon crystallisation of the maltitol syrup in document O4).

4. In view of this prior art, the technical problem faced by the skilled person may be regarded as the provision of a further process for preparing crystals of maltitol

and a crystalline mixture solid containing crystalline maltitol. The solution to that problem is a process as featured in claim 1 in which a syrup with a high maltitol content is prepared which is then split into two parts, one being processed into a crystalline mixture solid and the other into crystals of maltitol.

5. The question to be answered is whether the skilled person would have found any incentive in the state of the art to modify the process according to document O4 so as to develop a process wherein **the simultaneous preparation of both crystals of maltitol and a crystalline mixture solid containing crystalline maltitol** takes place.

6. At the oral proceedings two prior art documents, namely documents O1 and O6, have been referred to by Appellant II in support of its position.

6.1 Document O1 describes a process for **the preparation of crystalline maltitol** comprising successively a step of catalytic hydrogenation of a saccharified starch milk, a step of chromatographic fractionation of the hydrogenated syrup, a step of crystallisation and separation of the maltitol crystals and a step of recycling of the crystallisation mother liquor to the head of the chromatographic fractionation step.

6.2 Document O6 describes a process for **the preparation of a syrup rich in maltitol**. A by-product rich in maltitriitol is also recovered.

7. As documents O1 and O6 are not dealing at all with **the preparation of a crystalline mixture solid containing**

crystalline maltitol, the skilled person would not have derived therefrom any suggestions to modify the process according to document O4 so as to prepare both crystals of maltitol and a crystalline mixture solid containing crystalline maltitol by a process as now claimed.

8. Therefore, and in the absence of any further relevant prior art document, the Board comes to the conclusion that claim 1 involves an inventive step.

Claim 3

9. The process of claim 3 of the main request differs from the process of claim 1 in that the crystalline mixture solid is not prepared directly from the maltitol syrup recovered as a fraction eluted from the chromatography column but from the massecuite obtained upon crystallisation of that maltitol syrup.

10. Again in this case, document O4 is considered to represent the closest state of the art. The process of claim 3 differs from the process of document O4 in that (i) the maltose syrup used as the starting material has a lower maltose content (81 to 90% by weight of the dry matter to be compared with 99%), (ii) a chromatography separation step is used to recover maltitol in the form of a highly concentrated syrup from the hydrogenated maltose syrup, and (iii) the crystalline maltitol and the crystalline mixture solid are obtained **sequentially** from the same intermediate material, namely the massecuite obtained upon crystallisation of the maltitol syrup, the crystals of maltitol being first recovered and the resulting mother liquor being

processed into the crystalline mixture solid containing crystalline maltitol.

11. In view of this prior art, the technical problem faced by the skilled person may be regarded - as for claim 1 - as being the provision of a further process **for preparing crystals of maltitol and a crystalline mixture solid containing crystalline maltitol**. The solution to that problem is a process as featured in claim 3 in which a syrup with a high maltitol content is prepared and crystallised, the crystals of maltitol contained therein being then recovered and the resulting mother liquor being processed into a crystalline mixture solid containing crystalline maltitol.

12. The question to be answered is whether the skilled person would have found any incentive in the state of the art to modify the process according to document O4 so as to develop a process as claimed wherein sequential preparation of crystals of maltitol and a crystalline mixture solid containing crystalline maltitol takes place.

13. As documents O1 and O6 are not dealing at all with the preparation of **a crystalline mixture solid containing crystalline maltitol** (see points 6.1 and 6.2 supra) a negative answer has to be given to that question.

14. Therefore, and in the absence of any further relevant prior art document, the Board comes to the conclusion that claim 3 involves an inventive step.

Claim 2

15. The process of claim 2 of the main request differs from the process of claim 3 in that part of the maltitol syrup recovered as a fraction eluted from the chromatography column is added to the mother liquor before it being processed into the crystalline mixture solid containing maltitol. Apart from this additional technical feature, the processes of claims 2 and 3 are the same. Therefore, the same reasoning as above (see points 9 to 14 supra) with respect to claim 3 also applies to claim 2.

16. Thus, the Board comes to the conclusion that claim 2 involves an inventive step.

Claim 4

17. As claim 4 is dependent on claims 1 to 3, it also involves an inventive step. Thus, the main request as a whole meets the requirements of Article 56 EPC.

Sufficiency of disclosure

18. Appellant II has submitted that, if the maltitol content of the mother liquor is below 65% by weight of the dry matter, according to the common general knowledge of the skilled person as evidenced, for example, in document O2 at page 3, lines 26 to 31, it is not possible to obtain a crystalline mixture solid containing crystalline maltitol by conventional processes such as spray drying or cooling and kneading. Appellant II has derived therefrom that since claim 3 encompasses embodiments of the process using mother

liquors with a maltitol content lower than 65% by weight of the dry matter, the patent does not disclose the invention as claimed in a manner sufficiently clear and complete for it to be carried out by a skilled person.

19. However, the Board notes that the afore-mentioned passage of document O2 only states that the method for producing a crystalline mixture solid containing crystalline maltitol described in a previously published patent application (which anyway, being neither a basic handbook nor a textbook, could not be considered as reflecting the common general knowledge of the skilled person) comprises dissolving maltitol having a purity of 65% or more into water to form an aqueous solution of maltitol having a concentration of about 65 - 95%, and forming a massecuite upon crystallisation. There is no indication in that passage that a maltitol concentration of at least 65% is a prerequisite for the method to be performed.

20. Moreover, Appellant II has not provided any evidence in the form of verifiable facts which would have permitted an accurate assessment of its submissions.

21. Therefore, the Board concludes that, in the absence of any evidence of the contrary, the subject-matter of claim 3 has to be considered as being sufficiently disclosed.

22. As lack of inventive step and insufficiency of disclosure are the only grounds on which the case for setting aside the decision under appeal is based, the

main request (claims as granted) is allowable, and consequently the patent can be maintained unamended.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained unamended.

The Registrar The Chairman

A. Wolinski L. Galligani