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Datasheet for the decision of 9 March 2022

Case Number: T 1289/19 - 3.3.03

Application Number: 06765408.7

Publication Number: 1858930

IPC: C08B37/00, C07H1/00, C07F15/02, A61K31/715, A61K31/70

Language of the proceedings: EN

Title of invention:
PROCESS FOR THE PREPARATION OF TRIVALENT IRON COMPLEXES WITH MONO-, DI- AND POLYSACCHARIDE SUGARS

Patent Proprietor:
Biofer S.p.A.

Opponent:
Vifor(International)AG

Relevant legal provisions:
RPBA Art. 12(4)
EPC Art. 54, 56

Keyword:
Experimental report submitted with statement of grounds of appeal (partly admitted)
Product-by-process-claim - novelty (no)
Process claim - inventive step (yes)

Decisions cited:
G 0002/12, T 0815/93, T 0179/03

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Case Number: T 1289/19 - 3.3.03

D E C I S I O N
of Technical Board of Appeal 3.3.03
of 9 March 2022

Appellant: (Patent Proprietor)	Biofer S.p.A. Via Canina 2 41036 Medolla (IT)
Representative:	Modiano, Micaela Nadia Modiano & Partners Via Meravigli, 16 20123 Milano (IT)
Respondent: (Opponent)	Vifor(International)AG Rechenstrasse 37 9001 St.Gallen (CH)
Representative:	Gille Hrabal Partnerschaftsgesellschaft mbB Patentanwälte Brucknerstraße 20 40593 Düsseldorf (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 20 February 2019 revoking European patent No. 1858930 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	D. Semino
Members:	F. Rousseau
	R. Cramer

Summary of Facts and Submissions

I. The present appeal lies from the decision of the opposition division to revoke European patent No. 1 858 930. The decision was based on a main request and auxiliary requests 1 to 5, all submitted with letter of 23 November 2018 and auxiliary request 6 submitted during the oral proceedings on 24 January 2019.

II. In a first appealed decision, the opposition division revoked the patent on the ground that all pending requests extended beyond the content of the application as filed. The Board found in decision T 1318/14 that the opponent's objections under Article 123(2) and (3) EPC against the main request did not convince. The decision under appeal was therefore set aside and the case remitted to the opposition division for further prosecution.

III. The opposition proceedings were based among others on the following items of evidence:

D5: Besemer et al., The Catalytic Effect of Bromide in the Hypochlorite Oxidation of Linear Dextrins and Inulin, starch/stärke 46(1994) Nr. 3, pages 101-106
D9: WO 2004/037865 A1
D17: Experimental report with enclosures D17a-D17e submitted with letter of 8 February 2013
D21: Experimental report with enclosures D21a-D21b submitted with letter of 14 January 2014
D22: Experimental report with enclosures D22a-D22b submitted with letter of 14 January 2014

D23: Experimental report with enclosures D23 2a1 to 2a3 MDP, D23 2a5 surnat MDP and D23 2c MDP submitted with letter of 14 January 2014
D24: Experimental report with enclosures D24 2b1 to 2b3 Glu and D24 2c Glu submitted with letter of 14 January 2014
D26: Menachem Lewin, Bleaching and Oxidation of Cellulose by Hypobromite and Hypochlorite-Bromide Solutions, Tappi, Vol. 48, No. 6, June 1965, pages 333-343
D28: Experimental data and annexes D28A to D28C submitted with letter of 23 November 2018
(D28A: GPC curves of oxidized maltodextrins obtained at pH 7, 8, 9 and 10
D28B: ^{1}H NMR spectra of oxidized maltodextrins obtained at pH 7, 8, 9 and 10
D28C: Zoom in of the ^{1}H NMR spectra of D28B)
D30: "Enclosure B" filed with letter of 21 August 2014 during the first appeal procedure
D31: "Enclosure 2" filed with letter of 16 March 2009 during Examination procedure

IV. According to the reasons for the contested decision which are pertinent for the appeal proceedings:

(a) Auxiliary requests 3 and 6 were admitted into the proceedings, while auxiliary requests 1, 2, 4 and 5 were not.

(b) D30 was admitted into the proceedings.

(c) The invention was sufficiently disclosed.

(d) Product claim 2 defining the Fe(III)-activated sugar complex obtainable by the preparation process according to claim 1 of the main request lacked

novelty over the Fe(III)-activated sugar complexes disclosed in D9, since based on the whole set of evidence submitted, i.e. D17, D21, D28 and D31, no coherent link between the process features distinguishing the process of claim 1 from the process used in D9 and "*any specific structural characteristic of the products according to the invention*" could be identified.

(e) The same held true for auxiliary request 3 since the definition of the sugar had been limited to maltodextrin also used in D9.

(f) The process defined in auxiliary request 6 lacked an inventive step over D9 taken as the closest prior art.

(g) The patent was therefore revoked.

V. An appeal against that decision was lodged by the patent proprietor (appellant).

VI. The appellant submitted with the statement of grounds of appeal the following documents:

D32: "Non-Biological Complex Drugs - The Science and the Regulatory Landscape", edited by Springer (ISBN 978-3-319-16241-6), 2015, pages 149-167
D33: Jahn et al. European Journal of Pharmaceutics and Biopharmaceutics 78 (2011) 480-491,
D34: Experimental Report, Iron Polymaltose - Maltodextrin (with sub-enclosures 1-3)
D35: Experimental Report, Iron Polymaltose - Complex
D36: Pages 6 to 8 from chapter 2 and page 2 from chapter 15 of the manual of the Zetasizer Nano ZS DLS employed in D35 (Malvern Instruments, manual retrieved

at http://www.biophysics.bioc.cam.ac.uk/wp-content/uploads/2011/02/zetasizer nanozs manual.pdf)

VII. The opponent (respondent) replied to the statement of grounds of appeal and submitted with the rejoinder the following document:

D37: Frequently asked question, "Can The MW Be measured With Dynamic Light Scattering?", technical information from Malvern Instruments.

VIII. After issuance of the summons to oral proceedings, the respondent submitted the following document:

D38: Thaburet et al., TEMPO-mediated oxidation of maltodextrins and D-glucose: effect of pH on the selectivity and sequestering ability of the resulting polycarboxylates, Carbohydrate Research 330 (2001) 21-29.

IX. Oral proceedings before the Board were held on 9 March 2022.

X. The appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the claims of the main request, or alternatively in this order on the basis of the claims of any of auxiliary requests 3, 6, 1, 2, 4 or 5, all submitted with letter of 23 November 2018, with the exception of auxiliary request 6 that was submitted during the oral proceedings on 24 January 2019.

XI. The respondent requested that the appeal be dismissed.

XII. Claims 1 and 2 of the main request read as follows:

"1. Process for the preparation of an activated sugar iron complex comprising the step of reacting a sugar having an aldehyde end group with bromine in a solution at a pH between 7,0 and 9,0, wherein

i) said sugar is selected from the group consisting of glucose, maltose, lactose, maltodextrins, dextrins and dextrans and wherein

ii) said bromine is produced *in situ* through the addition of a hypochlorite of an alkaline or earth alkaline metal to said solution comprising said sugar to be activated and a bromide of an alkaline or earth alkaline metal, said hypochlorite being added in stoichiometric quantities with respect to the aldehyde end groups, wherein said hypochlorite is added instant by instant, such that an excess of hypochlorite in solution is never present,

where, in a following step, a water soluble Fe(III} salt, which salt is iron trichloride hexahydrate, is added to the solution containing the activated sugar in a weight ratio of iron to sugar from 1:0.5 to 1:4 to react with said activated sugar to form a Fe(III)-activated sugar complex,

wherein after the addition of the iron salt to the solution containing the activated sugar, the pH of the solution is controlled at a value from 2.3 to 2.7 by adding a sodium hydrogencarbonate solution containing 15% w/v sodium hydrogencarbonate in a time between 1 and 6 hours,

wherein the pH of the solution is subsequently brought to a value between 8 and 12, through the addition of a sodium hydroxide so1ution, to give a solution containing the Fe(III)-activated sugar complex,

wherein the Fe(III)-activated sugar complex is subjected to purification by ultrafiltration, with a membrane having a cut-off between 3000 and 5000 Daltons for the mono- and disaccharide sugars, such as glucose, maltose and lactose, and a cut-off between 400 and 50.000 Daltons for the polysaccharide sugars, such as dextrins and dextran,

wherein said complex is stabilized by heating of the solution containing the same at a temperature between 75° C and 95° C for a period between 1 and 4 hours at a pH between 9.0 and 12.0.

2. Fe(III) and activated sugar complex obtainable according to a preparation process according to claim 1."

XIII. Compared to the main request, the claims of auxiliary request 3 are restricted by defining that the sugar is to be selected from the group consisting of maltodextrins, the membrane being accordingly defined in claim 1 to have a "*cut-off between 400 and 50.000 Daltons for the polysaccharide sugars*".

XIV. Auxiliary request 6 consists of claim 1 of auxiliary request 3.

XV. The appellant's submissions, in so far as they are pertinent, may be derived from the reasons for the decision below. They are essentially as follows:

(a) D32 to D36 should be admitted into the proceedings.

(b) Having regard to experimental reports D21, D31, D34 and D35 the products of claim 2 of both the main request and auxiliary request 3 differ from those described in D9.

(c) The process of claim 1 of auxiliary request 6 is inventive over D9 taken as the closest prior art.

XVI. The respondent's submissions, in so far as they are pertinent, may be derived from the reasons for the decision below. They are essentially as follows:

(a) D32 to D36 should not be admitted into the proceedings.

(b) The products according to claim 2 of the main request and auxiliary request 3 lack novelty over D9.

(c) The process of claim 1 of auxiliary request 6 lacks an inventive step over D9 taken as the closest prior art.

Reasons for the Decision

Main request

Novelty of claim 2

1. Claim 2 of the present main request, i.e. the main request underlying the contested decision, concerns complexes of an activated sugar with Fe(III) obtainable

according to a preparation process as defined in claim 1. Sugar activation means transformation of the aldehyde end group of the sugar molecule, such as maltodextrin, into a carboxyl group in order to form in a subsequent step a complex between said modified sugar molecules and Fe(III) (paragraph [0014] of the patent). Whereas it is undisputed that the process of claim 1 of the main request is novel over that described with examples 3 to 8 of D9, the parties disagree as to whether the same is valid for the product resulting from the process of operative claim 1 compared to the products obtained with said processes exemplified in D9.

2. Examples 3 to 8 on pages 11 to 16 of D9 which are alleged by the respondent to anticipate the product defined in operative claim 2 also concern a process for the preparation of Fe(III) activated sugar complexes, the sugar being a maltodextrin. The sole parametric or structural features explicitly described for the complexes prepared in those examples are their iron content and molecular weight. Additional information about the complexes obtained in these examples can be derived from the description of the process steps used for their preparation, i.e. the process steps employed in a first phase of the process for activating the maltodextrin(s) and in second phase for complexing Fe(III) with said activated maltodextrin(s). The analysis of the technical information provided by these examples has to be made having regard to the overall context of D9.

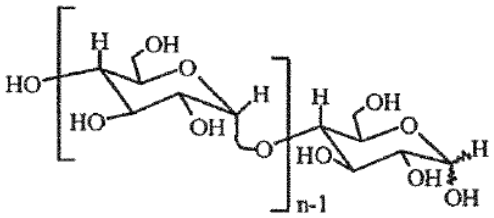
3. Pursuant to the established case law of the Boards of Appeal a process feature can only contribute to the novelty of a product claimed insofar as it gives rise to a distinct and identifiable characteristic of the

product (see e.g. decision T 0815/93, Reasons, points 4.3 and 4.3.1 and decision T 0179/03, Reasons, points 3.7 to 3.9). The specific process needed to obtain the claimed product should make it possible to distinguish the inevitable product of the product-by-process claim over the prior-art (see decision G 2/12, OJ EPO 2016, 27, Reasons, point IV.(5)).

4. The peculiarity of the present case is that both the definition of the subject-matter of product claim 2 and the disclosure of D9 alleged to anticipate said claimed product essentially rely on an enumeration of process steps. Nevertheless, the same principle applies. The process features defined in claim 1 can only contribute to the novelty of the product claim 2 to which claim 1 refers insofar as they give rise to a distinct and identifiable characteristic of the product over the products disclosed with examples 3 to 8 of D9.

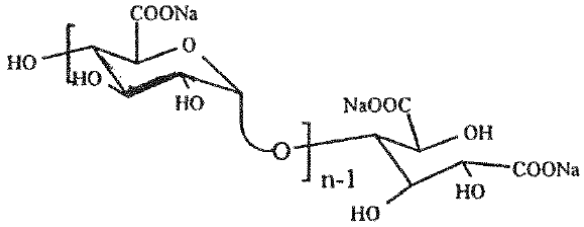
5. In this respect the respondent submits that the activation process defined in operative claim 2 achieves in comparison to the process used for examples 3 to 8 of D9 a more selective oxidation of the aldehyde end groups of the maltodextrin, which structural difference would be carried over when complexing the modified sugar molecules and Fe(III).

6. As indicated by the appellant (points 3.7 and 3.8 in the statement of grounds) the structure of the polymeric sugar chains prevailing in aqueous solution consists of n-1 glucose units connected by alpha 1-4 glycosidic linkage. The terminal glucose unit (unit n) bears a terminal hemiacetal linkage which is in equilibrium with a ring-opened form having an aldehyde group at C-1 and a C-5 hydroxyl group:

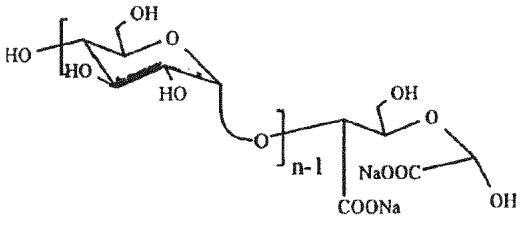


The terminal hemiacetal group is the target of the "activation" reaction, i.e. of selective oxidation. While it is sought to leave the sugar chain unaffected by the oxidation reaction, numerous side reactions are in practice prone to occur, depending on the oxidant employed and on the reaction conditions applied. These side reactions competing with the oxidation of the terminal hemiacetal unit include *inter alia* :

(a) oxidation of primary alcohols (along the chain and eventually on the terminal unit) further to the oxidation of the terminal hemiacetal function:

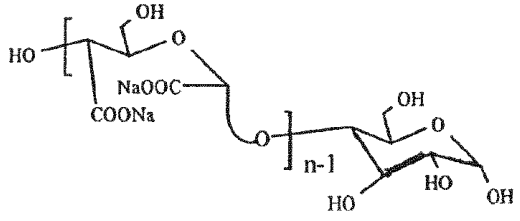


(b) oxidative cleavage of the C-2-C-3 carbon bond on the terminal ring, and



(c) oxidative cleavage of C-2-C-3 carbon bonds on the glucose units of the chain, eventually resulting in turn in chain breakage (depolymerization) in a next step, due to subsequent opening of the hemiacetalic

sugar bond [not shown in the Figure below], brought about by the loss of ring closure effect.



Notably, with increasing chain length of the polymeric sugar substrate, the relative concentration of the terminal hemiacetal function (and of the terminal ring number "n" bearing the same) decreases - statistically speaking - with respect to the growing number of chain moieties prone to side reactions, thus favouring increasingly the occurrence of side reactions along the growing chain.

7. The respondent does not dispute those explanations concerning the need to achieve a selective oxidation of the terminal aldehyde group of the maltodextrin molecules and to avoid the occurrence of said mentioned side reactions, but disputes that the process defined in present claim 1 has been shown to be more appropriate for this purpose than the process disclosed in D9. The respondent also disputes that structural chemical differences resulting from different activation steps would necessarily be carried over into the subsequent complexation step.

8. The existence of a link between the process features distinguishing the process of claim 1 from the process used in D9 and "*any specific structural characteristic of the products according to the invention*" had been at the core of the debate during the oral proceedings before the opposition division. The emphasis was put on the role of the pH range of 7 to 9 for the activation

step defined in operative claim 1 vs. a pH 10 used in all examples of D9.

Whereas before the opposition division the patentee had essentially based its submissions concerning maltodextrin on experimental reports D17, D21 and D31, alleged to demonstrate the effect of using a pH in the range of 7.0 to 9.0 for the activation step, that party, now appellant, is referring in addition to D21 and D31 to new evidence D32 to D36, whose admittance is challenged by the respondent.

9. The respondent argues that D32 to D36 should not be admitted as they are late filed and not *prima facie* highly relevant. The respondent points out that the patentee had ample time to provide any evidence before the present statement setting out the grounds of appeal, and that it had already done so with various experimental reports, reference being made to D17, D18, D21 to D24 and D31.

The question of the admittance to the proceedings of D32 to D36 submitted with the statement of grounds of appeal is regulated by the provisions of Article 12(4) RPBA 2007 (Article 25(2) RPBA 2020).

Admittance of documents D32 and D33

9.1 D32 is an excerpt of a book addressing in general terms polynuclear Fe(III)-oxyhydroxide - carbohydrate complexes. According to the appellant, D32 indicates that said complexes cannot be fully characterized, their structure being highly dependent on a well-controlled manufacturing process. The submissions made on the basis of D32, however, do not address the link between the process features distinguishing the process

of operative claim 1 from those used in D9 and any structural features meant to distinguish the complexes obtainable with the patent in suit from those disclosed in D9.

D33 is a scientific article showing according to the appellant that GPC and zeta potential measurements can be used to characterize iron complexes, including ferric carboxy maltose. As for D32, D33 does not address the link between the process features distinguishing the process of operative claim 1 from those used in D9 and the structural features meant to distinguish the complexes obtainable with the patent in suit from those disclosed in D9.

On that basis the submissions based on D32 and D33 cannot be held to have been triggered by the course of events before the opposition division. These documents if they were to be considered could and should have been submitted before the opposition division. Accordingly, D32 and D33 are held inadmissible pursuant to Article 12(4) RPBA 2007.

Admittance of documents D34 to D36

10. According to the contested decision (points 5.3.2 and 5.3.3 of the reasons) novelty of the complexes over those obtained in D9 was denied, since the whole set of experimental evidence did not allow to identify a coherent link between the features distinguishing the process of claim 1 from the one disclosed in D9 and structural characteristics of the obtained complex.

10.1 The experimental data submitted before the opposition division concern the influence of the pH value used for the activation step of the claimed process on (i) the

molecular weight of the activated sugar and its polydispersity (via GPC measurements in D17, D18, D21, D22 and D23) and (ii) the carbon atoms oxidised in the sugar chain (via ^{13}C measurements in D18 and ^{1}H NMR measurements in D28B and D28C). D31 concerns the influence of the amount of oxidant (hypochlorite) and the manner of adding it on the molecular weight of the activated sugar and the ability to prepare an homogeneous complex (via GPC measurements).

The pertinence of the experimental evidence D17, D18, D21, D22 and D23 in relation to novelty over D9 was addressed for the first time by the opponent in its written submission of 23 November 2018, i.e. two months before the second oral proceedings before the opposition division. D28 and its Annexes D28A to D28C as well as D31, which concerned experimental data filed during examination procedure, were filed by the opponent with the same letter.

10.2 D34 is an experimental report which addresses the influence of lowering the pH of the activation step from a value of 10 as used in the Examples of D9 to a value of 8, which is in the middle of the pH range defined in operative claim 1, on the structure of the activated (oxidized) sugar. The structure of the activated sugars is made by determining their Dextrose Equivalent (DE) and performing GPC and UV-VIS measurements, as well as ^{13}C and ^{1}H NMR analysis.

D35 is an additional experimental report which addresses both the influence of lowering the pH from a value of 10 to a value of 8 (comparison of samples P087 and P085) and the effect of replacing an isolation step of the iron complex by precipitation with ethanol, as done in Example 5 of D9, by an isolation step using

ultrafiltration as defined in operative claim 1. The iron complexes are analysed then by GPC and Dynamic Light Scattering in order to determine their size and polydispersity. The Zeta potential of said samples are also reported.

10.3 Having regard to the appellant's submissions on pages 13 and 14 of the statement of grounds of appeal, section 1 on page 2/24 of D34 and section 1 on page 2/8 of D35 in which the preparation of the materials to be tested is explained, experimental reports D34 and D35 are meant to demonstrate a link between features identified by the appellant as distinguishing features of the claimed process, i.e. the same process as underlying the contested decision, from that disclosed in D9, and the existence of a resulting structural characteristic of the obtained complex alleged by the appellant to impart novelty over D9. Those alleged distinguishing structural characteristics resulting from the use of a pH in the range of 7 to 9 concerns as before the opposition division for the activated sugar its MW, its polydispersity and the extent of oxidization which did not involve oxidation of the aldehyde end groups, which distinguishing features according to the appellant would be carried over in the complexation step.

Having regard to the fact that an exchange of submissions between the parties in relation to novelty and inventive step over D9 in the light of experimental evidence D17, D18, D21 to D24, D28 and D31 started shortly before the second oral proceedings before the opposition division, the submissions based on D34 and D35, as far as they concern alleged structural differences of the activated sugar and complexes in terms of size, MW, polydispersity and extent of

oxidization which did not involve aldehyde end groups, represent timely and appropriate submissions in response to the contested decision. In other words, the submission of D34 and D35 as far as the above alleged distinguishing features are concerned are the result of normal developments in the opposition appeal proceedings so that the Board has no reason to make use of its discretionary power under Article 12(4) RPBA 2007 to hold documents D34 and D35 inadmissible insofar they concern the above mentioned features.

10.4 D36 addresses the meaning of Zeta potential. The measurements of Zeta potential or the stability of the claimed complexes at physiological pH values which is addressed in D35 were not subject of any debate before the opposition division. Accordingly, D36 and the submissions in relation to Zeta potential in D35 should have been submitted already before the opposition division with the consequence that the Board holds them inadmissible pursuant to Article 12(4) RPBA 2007.

Admittance of documents D37 and D38

10.5 D37 was submitted by the respondent with the rejoinder. It addresses the relationship between MW and size of the hydrodymanic radius. Its filing is in direct response to the measurement of hydrodynamic radius in D35. Having regard to the Board's decision concerning the admittance of D35 in relation to the size of the activated sugar and complexes and the absence of objection by the respondent to its admittance the Board has no reason to hold document D37 inadmissible (Article 12(4) RPBA 2007). The respondent also submitted D38 in reaction to the Board's communication sent in preparation for oral proceedings. While document D38 was also admitted into the proceedings

pursuant to Article 13(2) RPBA 2020, it is not necessary to address this issue any further, since the content of that document or the parties' submissions made on its basis are of no relevance for the present decision.

11. Having regard to the experimental evidence admitted in the proceedings, the following sections address whether the process features defined in claim 1 can contribute to the novelty of the product of claim 2 over the products disclosed in examples 3 to 8 of D9.

Activation reaction

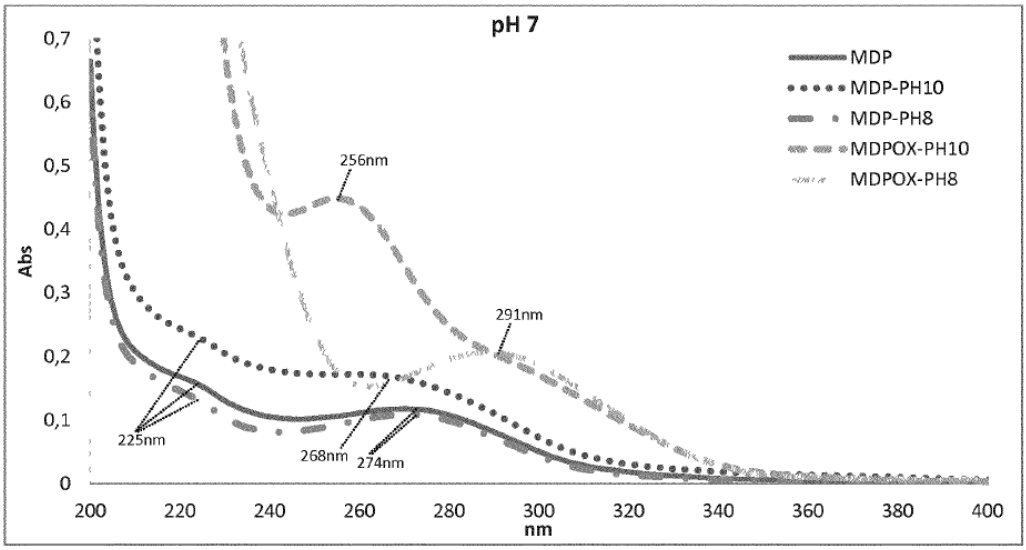
12. As already mentioned above, the respondent disputes that the process of operative claim 1 results in less side reactions during the activation reaction of the sugar and accordingly a higher selectivity towards oxidation of the terminal aldehyde groups, contrary to the appellant who submits that said higher selectivity of the oxidation reaction is the result of selecting (i) a pH value in the range of 7.0 to 9.0, (ii) the presence of bromine, (iii) the use of a stoichiometric quantity of hypochlorite with respect to the aldehyde end groups and (iv) the addition of hypochlorite instant by instant, such that an excess of hypochlorite in solution is never present. The influence of these measures on the selectivity of the activation of maltodextrin, used in examples 3 to 8 of D9, is addressed in the following sections.

pH value in the range of 7.0 to 9.0

13. According to the appellant, the advantage of selecting a pH value in the range from 7.0 to 9.0 for the activation step compared to 10.0 used in examples 3 to

8 of D9 would be demonstrated by experimental report D34 in which the structure of maltodextrins activated at pH 8.0 and 10.0 was investigated using Gel Permeation Chromatography (GPC), UV-VIS spectroscopy, bidimensional ^{1}H ^{13}C NMR and Dextrose Equivalent (DE) analysis. Whereas the appellant acknowledges based on the results shown in D34 that using a pH of 8.0 vs a pH of 10.0 does not lead to significant differences concerning the molecular distribution of the activated maltodextrin observed by GPC, it is submitted that structural differences are proven when comparing the UV-VIS absorption profiles, the bidimensional ^{1}H ^{13}C NMR spectra and the Dextrose Equivalent (DE) values obtained at these pH values.

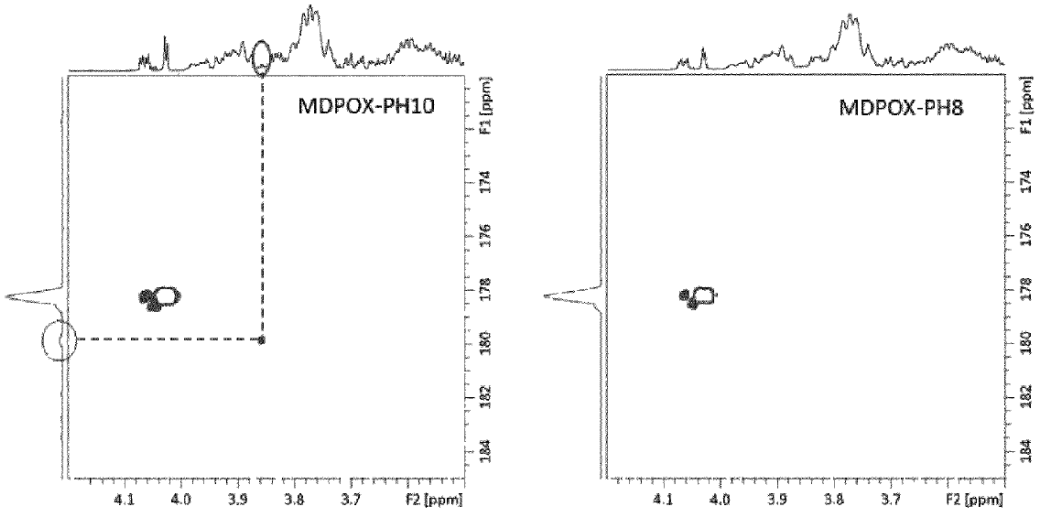
13.1 The five spectra obtained by UV-VIS spectroscopy for the untreated maltodextrin, the maltodextrin treated at pH 8 and pH 10 and the maltodextrins activated at pH 8 and pH 10 are shown below:



According to the appellant, the untreated maltodextrin (MDP) and the maltodextrin treated at pH 8 without oxidant (MDP-PH8) share absorption curves with a

maximum close to 274 nm, while for the maltodextrin treated at pH 10 without oxidant (MDP-PH10) the maximum is slightly shifted towards 268 nm. The two activated maltodextrins at pH 8 and pH 10 (MDPOX-PH8 and MDPOX-PH10, respectively) show different spectra, as they display a maximum around 291 nm (MDPOX-PH8) and around 256 nm (MDPOX-PH10), respectively. The appellant submits that the maltodextrins activated at pH 8 and 10 which clearly exhibit different absorption maxima due to the occurrence of different chemical species upon oxidation are definitely different from each other. The argument of the appellant cannot, however, be considered as conclusive as they did not explain to which chemical bonds, in particular to which putative side reactions, these peaks would correspond.

13.2 According to the appellant one dimensional ^{1}H NMR and ^{13}C NMR spectra of MDPOX-PH8 and MDPOX-PH10 shown in D34 confirm the oxidation of the reducing end of the maltodextrin, a new protonic signal appearing at about 4 ppm and a new ^{13}C signal being detected at about 178.2 which is attributed by the appellant to a carboxy moiety. The appellant, however, explained that no difference can be detected between the one dimensional spectra obtained, although for these experiments care had been taken to eliminate the solvent peak, contrary to what had been done in experimental report D28 submitted by the respondent. According to the appellant, a difference in the oxidation behaviour can, however, be detected using bidimensional ^{1}H ^{13}C NMR spectroscopy (Heteronuclear Multiple Bond Correlation referred to as HMBC) as reported in D34, the results of which are shown below for MDPOX-PH8 and MDPOX-PH10. The comparison is made based on an amplification of the spectra in the carboxylic region of the ^{13}C spectrum.



According to the appellant, the HMBC spectrum of MDPOX-PH10 shows an additional cross-peak between protons at 3.85 ppm (^{1}H) and a carbon at 179.8 ppm (^{13}C), which would be ascribable to the presence of an additional carboxylic moiety in the MDPOX-PH10 sample, whereas this additional cross-peak could not be found for the maltodextrin activated at pH 8 MDPOX-PH8. Having regard to the high relaxation times for this additional ^{13}C signal, it could not be detected as indicated above by direct acquisition as having a very low and broad signal, due to the variable set applied.

Having regard to the low intensity of the signals detected the Board is, however, not in the position to determine wether the difference noted by the appellant between MDPOX-PH10 and MDPOX-PH8 when using bidimensional HMBC is significant. Moreover, the appellant did not explain which carbon atom whose chemical shift is observed at 198.8 ppm would correlate with the proton observed at 3.85 ppm, let alone indicated which carbon atom of the maltodextrin would be oxidized instead of the C atom of the terminal hemiacetal group. Furthermore, as addressed in the next section, the question arises whether the comparison

made by the appellant using bidimensional ^{1}H ^{13}C NMR spectroscopy is appropriate.

13.3 Experimental report D34 shows that the DE value of the activated maltodextrin activated at pH 10 is 0.60, i.e. a value which is much lower than the value of 2.34 obtained for an activation at pH 8. This would appear to be in line with experimental report D28 in which it is indicated, although no values are indicated, that oxidized maltodextrins have a DE at pH 10 which is lower than at pH 8. Since the DE value is a measure of the terminal aldehyde groups of the maltodextrin, this would indicate as submitted by the respondent that a lower degree of terminal aldehyde groups is oxidized at pH 8. This could be due to the fact that less side reactions take place at pH 10 which would be in contradiction with the appellant's submissions based on bidimensional ^{1}H ^{13}C NMR spectroscopy, or as submitted by the respondent that the oxidation at pH 8 is slower than at pH 10 explaining why the conversion of aldehyde end groups in the experiments presented in D34 is higher at pH 10.

In the latter case, the comparison submitted by the appellant with D34 would not be appropriate, since as noted by the appellant the risk of side reactions increases approaching 100% conversion of the aldehyde end groups. In other words, there is no indication that carrying out the activation for a longer time at pH 8 in order to obtain a similar DE value as that obtained for sample MDPOX-PH10, which possibility is covered by the process of operative claim 1, would not also lead to the occurrence of side reactions. The same remark is also valid for the comparison of the UV-VIS spectra made in D34.

In other words, although the experiments shown in D34 or in D28 in relation to the DE value might to the benefit of the appellant show the influence of the pH on the activation of maltodextrin, all other conditions being equal, they cannot demonstrate that the group of products obtainable by the process of present claim 1 does not overlap to a great extent with the products obtained by the process disclosed in D9, since in agreement with the respondent's position operative claim 1 does not contain any limitation concerning the proportion of oxidized aldehyde end groups of the maltodextrin or DE values of the maltodextrin after the activation step.

The appellant submitted during the oral proceedings that the lower DE observed in D34 when activating the maltodextrin at pH 10 could be explained by a disproportion (Cannizzarro) reaction between the aldehyde end groups which reaction would be known to take place at basic pH. Reference was made in this respect to paragraph [0018] of the patent in suit. This, however, does not convince, since this paragraph of the patent in suit refers to complex formation in a basic environment at high temperature, but not an activation reaction, let alone under the conditions used in D34, i.e. room temperature and pH 10. The fact that the dismutation reaction of the aldehyde end group in form of hemiacetal to the corresponding acid and alcohol requires strong heating in addition to a basic environment is also indicated in paragraph [0026] of the specification. It is also confirmed in paragraph [0027], which reports as conditions used for dismutating low molecular weight dextrin, maltose or glucose a pH in the range from 11 to 14 and a temperature of 90°C, which represent conditions much

more drastic than those employed in D34 for activating maltodextrin.

13.4 The effect of changing the pH from 10 to 8 for the activation step is also addressed in experimental report D35 having regard to the comparison made between samples P087 and P085 using for the activation step a pH of 10 and pH 8, respectively.

D35 does not provide a characterization of the two activated sugars prepared, but only of the Fe(III) complexes obtained therewith by GPC (determination of molecular weight and polydispersity) and Dynamic Light Scattering (DSL) (measures of the hydrodynamic radius and the polydispersity index). The small decrease of both the molecular weight measured by GPC (-5%) and the hydrodynamic radius (correlated to the molecular weight, as known from D37) of the complexes observed in D35 is in the Board's opinion not significant. The same applies for the polydispersity values based on GPC and DSL measurements, which even show a different trend, i.e. a slight decrease according to GPC measurement, but a slight increase based on DSL measurement.

On that basis, the results of E35 alone are inconclusive. They cannot demonstrate any influence of a decrease of the pH of the solution used for the activation step from 10 to 8 on the properties of the Fe(III) complex obtained with the activated maltodextrin.

In the absence of convincing evidence concerning the influence of a lower pH value for the activation step on the properties of the Fe(III) activated maltodextrin complex, it cannot be indirectly concluded either that a maltodextrin activated at pH 8 is necessarily

structurally different from a maltodextrin activated at pH 10.

13.5 D21 is an additional experimental report alleged by the appellant to demonstrate the influence of using a pH value of 8 for the sugar activation instead of a pH of 10. Like for D35, D21 does not report any characterization of the activated sugars prepared at pH 8 and 10, but the molecular weight and the polydispersity of the complexes obtained with the activated sugars, both determined by GPC analysis.

The experiments of D21, like those presented in D35, differ only by the use of a different pH for the activation step of the maltodextrin. The experiments reported in D35 and D21 are almost identical. The GPC analytical system operates with the same gel columns in both D21 and D35.

Despite the fact that the experiments reported in D21 and D35 marginally differ from each other (a maltodextrin with a DE of 18 is used in E35 instead of a maltodextrin with a DE of 19 in D21), E21 would show that a reduction of the pH from 10 to 8 for the activation step leads to a reduction of 37% of the molecular weight (against a 5% reduction observed in E35) and 31% for the polydispersity (against a 15% reduction observed in E35). Should the decrease of molecular weight and polydispersity observed in E21 be considered to be significant for this type of measurement, one would have to conclude that the experiments of E21 and those of E35 are contradictory.

Under these conditions, the experiments of E21 lack significance either on their own or in the light of contradicting evidence E35. Consequently, E21 cannot

demonstrate any influence of a decrease of the pH of the solution used for the activation step from 10 to 8 on the properties of the Fe(III) complex obtained with the activated maltodextrin. Accordingly, it cannot be indirectly concluded on the basis of E21 either that a maltodextrin activated at pH 8 is necessarily structurally different from a maltodextrin activated at pH 10.

13.6 Accordingly, in view on the available experimental evidence D34, D21 and D35 the Board is not in the position to conclude that an activation of the maltodextrin at pH 8 in accordance with operative claim 1 leads to less side reactions in comparison to the process disclosed with examples 3 to 8 of D9 using a pH 10 for the activation step. This is *a fortiori* true for an activation step carried out at a pH value above 8, in particular for pH values up to 9 also within the ambit of operative claim 1 and which are closer to the pH value used in examples 3 to 8 of D9, as submitted by the respondent.

Presence of bromine

14. The respondent's objection that the claimed invention lacked sufficiency of disclosure since the oxidizing agent contrary to what was indicated in operative claim 1 could not be bromine over the whole pH range of 7 to 9, but rather hypobromite, reference being made to D5, D26 and D28, was withdrawn during the oral proceedings. As shown in experimental report D30 and illustrated by D5 and D26 the *in situ* formation of bromine is the direct consequence of (i) using sodium bromide, which is not only employed in the examples 3 to 8 of D9, but also in the experiments of D34, and (ii) adding sodium hypochlorite (also present in the examples of D9) to

the solution used for the activation step whose pH as been adjusted in the range of 7 to 9. As already mentioned in point 4 of the Reasons for the first appeal decision T 1318/14 (see also paragraph [0046] of the patent in suit) bromine is produced *in situ* by addition of the alkaline or alkaline earth hypochlorite, which is used in a stoichiometric quantity with respect to the number of end aldehydes according to the reactions:

1) $NaClO + 2NaBr + H_2O \rightarrow Br_2 + NaCl + 2NaOH$
2) $Br_2 + R\text{-}CHO + 3NaOH \rightarrow 2NaBr + R\text{-}COONa + 2H_2O$.

Accordingly, the finding in above points 13 to 13.6 concerning the influence of pH range of 7 to 9 on the selective oxidation of the terminal aldehyde group and side reactions already takes into account the influence of the presence of bromine.

Use of a stoichiometric quantity of hypochlorite with respect to the aldehyde end groups

15. The appellant submits that the opponent has shown with the calculations provided in the notice of opposition that the examples of D9 do not use an exact stoichiometric amount of hypochlorite with respect to the aldehyde end groups. These calculations would demonstrate that the activation carried out in examples 3 and 7 employ amounts of hypochlorite from close to stoichiometric quantities up to amounts in excess of about 27%, whereas examples 4-6 and 8 employ amounts of hypochlorite in a range spanning from a small defect of about 8% to a small excess of about 17%. The appellant therefore argues that a stoichiometric amount of hypochlorite with respect to the aldehyde end groups

defined in operative claim 1 represents a distinguishing feature over the disclosure of D9.

16. The broad range of hypochlorite concentration relative to the amount of hypochlorite used in D9 which has been computed by the opponent, now respondent, is in part due to the fact that the solution of sodium hypochlorite used for activation of the maltodextrine is defined in the examples of D9 to contain 13 to 16% by weight of active chlorine. According to the respondent's submissions at the oral proceedings, this range of concentrations defined for a specific solution reflects the technical reality according to which solutions of sodium hypochlorite lack stability, especially at these concentrations, which explains why a range of concentration of active chlorine was defined in D9, whose applicant is the present respondent. This was not disputed by the appellant.

Furthermore, as pointed out by the respondent the patent in suit itself, although it defines in claim 1 the use of a stoichiometric quantity of hypochlorite with respect to the aldehyde end groups employs in its examples 3 to 8, all concerning the activation of maltodextrin, amounts of hypochlorite also ranging from a defect of -5% (example 3) to an excess of 14% (examples 4) in deviation of an exact stoichiometry, although the text of both examples indicates that an amount of sodium hypochlorite corresponding with the stoichiometric quantity with respect to the aldehyde end groups was added. It must therefore be concluded that the expression "*stoichiometric quantities with respect to the aldehyde end groups*" present in claim 1 is not to be interpreted as to mean an exact stoichiometric quantity either.

Accordingly, having regard to a technical sensible reading of both the patent in suit and D9, it can only be concluded that the feature that hypochlorite is added in stoichiometric quantities with respect to the aldehyde end groups does not constitute a distinguishing feature of the process of operative claim 1 over the process disclosed in examples 3 to 8 of D9. On that basis, that process feature cannot result in a feature distinguishing the product of operative claim 2 from the products obtained in the examples of D9 either.

Instant by instant addition of hypochlorite, such that an excess of hypochlorite in solution is never present

17. The instant-by-instant addition of hypochlorite is as indicated in points 5.2.2 and 5.2.3 of the Reasons of the first appeal decision T 1318/14 in the present opposition case to be understood as a gradual or step by step addition of that compound. As pointed out in point 5.2.2 of the Reasons of T 1318/14 that expression does not aim at quantifying the amount of hypochlorite in the solution at a certain time, but rather expresses in the context of operative claim 1 the idea that the amount of hypochlorite gradually added should not exceed that which can be consumed for the production of bromine. Taking into account that claim 1 does not contain any limitation concerning the amount of bromide of an alkaline or earth alkaline metal present in solution and that reaction 2) mentioned in point 14 above is the limiting step of the activation reaction (point 5.2.4 of the Reasons of T 1318/14), it cannot be held that claim 1 quantifies the maximum amount of bromine, i.e. the maximum amount of oxidant, present in solution, even when approaching 100% conversion of the

aldehyde end groups, which according to appellant increases the risk of side reactions.

18. The appellant's argument that the applicant would have found that by employing the appearance of bromine as an indicator at pH 7 to 9, it would be possible to "titrate" the aldehyde end groups using an instant by instant addition of hypochlorite, employing thus the oxidant in stoichiometric amount, is not relevant in so far as the patent in suit is concerned. Whereas such method would appear to be useful for activating maltodextrins, as is apparent from experimental report D30 relied on by the appellant, this argument cannot be accepted in relation to operative claim 1 for the following reasons. First of all, claim 1 does not concern the use of a true stoichiometric amount of hypochlorite, as shown in above sections 15 and 16. Moreover, claim 1 does not mention or imply, nor does the entire specification, a titration based on the appearance of bromine as an indicator or any measure of the absorbance of bromine, let alone any threshold for the bromine absorbance at which hypochlorite should be added again.

19. There was consensus among the parties at the oral proceedings that the skilled person is aware that a careful addition of hypochlorite compound is needed to avoid side reactions during the activation reaction. The text passages of the examples 3 to 8 of D9 do not specify the mode of addition of the hypochlorite compound. However, having regard to the general teaching on page 3, lines 19-23 of D9 according to which the degree of depolymerization of the maltodextrins used is kept to a minimum and the oxidation is believed to occur predominantly at the terminal aldehyde group of the maltodextrin molecules,

the skilled person would understand that this also necessary applies to examples 3 to 8 of D9. In the Board's conviction, the skilled person would therefore understand that the products obtained in examples 3 to 8 of D9 are not prepared by adding at once, but stepwise the hypochlorite compound in order to avoid side reactions and oxidize terminal aldehyde end groups of the maltodextrin molecules. This would be realized, if not immediately, at the latest when seeking to reproduce the teaching of examples 3 to 8 of D9, in which case the skilled person would necessarily find out with little experimentation that the hypochlorite compound is to be added stepwise, i.e. in the same manner as specified in operative claim 1.

20. It is therefore concluded that the instant by instant addition of hypochlorite as defined in operative process claim 1 does not result in the product obtainable by that process to be distinguished from those disclosed with examples 3 to 8 of D9.

21. It is also noted that part (I) "Activation tests on maltodextrins" of experimental report D31 is not pertinent for establishing the existence of structural features distinguishing the activated sugars or the complexes obtainable by the process of claim 1 from those obtained with the examples 3 to 8 of D9, since part (I) of D21 provides a comparison with a process in which hypochlorite is added at once, i.e. a process which does not correspond to those described in the examples of D9.

Conclusion concerning the activation step

22. Based on the above, the activation process as defined in operative claim 1 has not been shown to result in

different activated maltrodextrins that those obtained in examples 3 to 8 of D9.

Under these circumstances the appellant's argument that features distinguishing the activated maltodextrins obtainable with the process of operative claim 1 from those obtained in examples 3 to 8 of D9 would be carried over in the subsequent process steps defined in operative claim 1 is not relevant and needs not to be answered.

Nevertheless, the question whether the steps following the activation step defined in operative claim 1, namely complexation of the activated sugar with ferric hydroxide generated in solution, purification of the complex obtained and its stabilization, would lead to a different product from those obtained in examples 3 to 8 of D9 remains to be addressed.

Process steps following the activation step

23. According to the process of operative claim 1, the following steps referred to as (a1) to (a5) by the Board are performed after the sugar activation step:

(a1) addition of iron trichloride hexahydrate to the solution containing the activated sugar in a weight ratio of iron to sugar from 1:0.5 to 1:4 to react with said activated sugar to form a Fe(III)-activated sugar complex,

(a2) after the addition of the iron salt to the solution containing the activated sugar, control of the pH of the solution at a value from 2.3 to 2.7 by adding a sodium hydrogencarbonate solution containing 15% w/v

sodium hydrogencarbonate in a time between 1 and 6 hours,

(a3) bringing subsequently the pH of the solution to a value between 8 and 12 through the addition of a sodium hydroxide solution to give a solution containing the Fe(III)-activated sugar complex,

(a4) followed by purification of the Fe(III)-activated sugar complex by ultrafiltration, with a membrane having a cut-off between 3000 and 5000 Daltons for the mono- and disaccharide sugars, such as glucose, maltose and lactose, and a cut-off between 400 and 50 000 Daltons for the polysaccharide sugars, which polysaccharide sugars include maltodextrins

(a5) followed by a stabilization step of the complex by heating the solution comprising the complex at a temperature between 75° C and 95° C for a period between 1 and 4 hours at a pH between 9.0 and 12.0.

Steps (a1) to (a3) are referred to in paragraph [0055] of the specification as a complexation step of the activated sugar with ferric hydroxide generated in solution, while steps (a4) and (a5) are designated in this paragraph as purification of the ferric hydroxide/ sugar complex still not stabilized and stabilization of the ferric hydroxide/sugar complex, respectively.

23.1 Whereas examples 3 to 8 of D9 describe steps (a1) and (a3) according to operative claim 1, they do not describe as an intermediate step the addition of a solution of sodium hydrogencarbonate over a period between 1 and 6 hours according to step (a2), but instead the addition of a sodium carbonate solution.

23.2 Furthermore, the processes disclosed in examples 3 to 8 of D9 do not comprise a stabilization step as defined in step (a5) of operative claim 1, let alone after the purification step, which purification step is carried out in these examples of D9 by precipitation with ethanol and not like in step (a4) of present claim 1 by ultrafiltration. In this respect, it is undisputed that the precipitation with ethanol is also considered as a purification step. Reference is made to experimental report D35 and document D27 (page 2, lines 6-12 and 18-20).

24. The experimental reports which concern a full preparation of Fe(III) complexes and which are relied upon by the appellant in order to demonstrate that some of the process steps of operative claim 1 following the activation step result in products which are distinguishable from those obtained with examples 3 to 8 of D9 are D31 and D35.

25. Part (II) of D31 "Complete Analysis (Activation and complex formation)" provides a comparison between two processes for the preparation of a Fe(III) activated maltodextrin complex. While the second process corresponds to that of operative claim 1, the first process to which it is compared concerns a maltodextrin activated by addition at once of the hypochlorite. That comparison offered with D31 therefore does not concern the products prepared with examples 3 to 8 of D9. Accordingly, D31 which does not provide further experiments concerning the formation of the complex is not suitable to demonstrate that the product obtainable with the process of operative claim 1 differs from those prepared in examples 3 to 8 of D9.

26. The appellant's submissions in relation to experimental report D35 are based on a comparison of sample P086 (according to the invention) and P085 (comparative) which differ from each other in that precipitation with ethanol used as a final step before freeze drying is replaced by an ultrafiltration step using a membrane with a 30KDa cut-off, which is however undertaken before the thermal treatment at pH 10.8 and a temperature of 92°C for 3 hours (which treatment is carried out in P085 before the precipitation with ethanol). In that report sample P086 (according to the invention) is also compared with sample P092 meant to reproduce the teaching of example 5 of D9. An additional comparison between sample P092 and sample P087 (also comparative) which differ from each other in the thermal treatment applied is also available in D35. D35 is considered by the appellant to demonstrate that the product obtainable by operative claim 1 displays a more symmetrical molecular weight distribution, lower medium molecular weight and polydispersity values than the product obtained according to example 5 of D9.

26.1 As outlined by the respondent sample P092 was not prepared in accordance with the teaching of example 5 of D9, reference being made in particular to the iron maltodextrin ratio and the DE of the maltodextrin to be activated. Accordingly, the complex prepared with sample P092 cannot be considered to represent that obtained with example 5 of D9.

26.2 As to the question whether the comparisons provided convincingly demonstrate that the products obtained by the process of claim 1 are novel over those obtained with examples 3 to 8 of D9, the respondent submits that the only thing demonstrated in D35 is that changes of the process steps used for forming the complexes will

lead to different analytical data in respect of the complexes formed, i.e. that varying process conditions in accordance with operative claim 1 for the preparation of a specific complex whose preparation is similar to that described in example 5 of D9 will lead to structural changes of said specific complex.

26.3 In that respect, the question to be answered in relation to novelty of operative claim 1 over examples 3 to 8 of D9 is not only whether some process features of operative claim 1 might be shown by suitable experimental evidence to have an impact on the structure of the complex obtained. Although this might contribute in some cases to establish novelty, the question to be answered in the present case is a more fundamental one, namely whether the whole group of complexes obtainable by the process generally defined in operative claim 1 can be distinguished from the specific products obtained in examples 3 to 8 of D9, i.e. does not not cover the products obtained in said examples. Therefore, it needs to be answered whether the process features of operative claim 1 according to their general definition give rise to a distinct and identifiable characteristic of the product obtainable by said process over the specific products obtained with examples 3 to 8 of D9.

26.4 In that respect, it can be taken from paragraph [0067] of the specification that the ultrafiltration with a membrane with a cut-off of 30 000 Daltons employed for the preparation of sample P086 in D35 removes low molecular weight compounds. Although it is immediately evident that such measure has an impact on the molecular weight distribution of the complex, operative claim 1 is not limited to the use of an ultrafiltration membrane with a cut-off of 30 000 Daltons, but also

encompasses any of those having a cut-off as low as 400 Daltons which will not be able to provide the same result.

Moreover, the molecular weight of the complex obtained by the process of claim 1 and its molecular distribution is obviously highly dependent on the selection of the maltodextrin to be activated. This is illustrated by the examples of D9. However, claim 1 does not contain any restriction for the non activated maltodextrin, in particular in respect of its molecular weight distribution, being for example the result of using a mixture of maltodextrins, which possibility is not purely theoretical, as illustrated by D9.

26.5 On that basis, there is no reason to believe that the molecular weight distribution and the corresponding average molecular weight and polydispersity of the complexes obtainable by the process of operative claim 1 is different from those obtained in examples 3 to 8 of D9.

Conclusion concerning novelty of claim 2 over examples 3 to 8 of D9

27. Having regard to above points 11 to 22 concerning the activation step defined in operative claim 1 and above points 23 to 26.5 concerning subsequent steps (a1) to (a5) in the production of the activated sugar iron complex defined in said claim, it is concluded that none of those steps has been shown to give rise to a distinct and identifiable characteristic of the products obtainable by said process over those obtained in examples 3 to 8 of D9. In line with the established case law of the Boards of Appeal, the Fe(III) and activated sugar complexes obtainable according to the

preparation process defined in claim 1 lack novelty over those obtained in examples 3 to 8 of D9, contrary to the requirements of Article 54 EPC. The main request is therefore not allowable.

Auxiliary request 3

28. Compared to the main request, the claims of auxiliary request 3 are restricted by defining that the sugar is to be selected from the group consisting of maltodextrins. Accordingly, claim 2 of auxiliary request 3 is also directed to a complex of Fe(III) and an activated sugar which is obtainable according to the preparation process of claim 1. The amendment in claim 1 consisting in defining that the sugar is a maltodextrin does not introduce any distinguishing feature over the disclosure of examples 3 to 8 of D9 which also concern the preparation of complexes of Fe(III) with an activated maltodextrin. Accordingly, the reasons and conclusion provided in relation to claim 2 of the main request equally apply to claim 2 of auxiliary request 3. Auxiliary request 3 is therefore not allowable either.

Auxiliary request 6

29. Auxiliary request 6 consists of process claim 1 of auxiliary request 3. The sole issue in dispute concerns inventive step.

Closest prior art

29.1 In is a matter of consensus among the parties that the closest prior art can be represented by the processes described in examples 3 to 8 of D9.

Distinguishing features

29.2 It is also undisputed that the subject-matter of claim 1 differs from the closest prior art at least in that use is made of (i) a purification step by ultrafiltration with a membrane having a cut-off between 400 and 50 000 Daltons and (ii) a stabilization step of the complex by heating the solution comprising the complex at a temperature between 75° C and 95° C for a period between 1 and 4 hours at a pH between 9.0 and 12.0.

Problem successfully solved

29.3 Having regard to the finding concerning novelty of the products obtainable by the process of claim 1 of auxiliary request 3, identical to claim 1 of the present request, over the products obtained in examples 3 to 8 of D9, it is also undisputed that the problem successfully solved over the closest prior art by the process of claim 1 can only be defined as the provision of a further process for the preparation of complexes of Fe(III) and activated maltodextrin.

Obviousness of the solution

29.4 It remains to be decided whether the skilled person desiring to solve the problem identified above would, in view of the disclosure of D9, possibly in combination with other prior art documents or with common general knowledge, have modified the process of examples 3 to 8 of D9 in such a way as to arrive at the process of operative claim 1. The additional prior art document referred to by the respondent concerning obviousness of the claimed solution is D27.

As point out by the respondent D27 describes for the preparation of iron dextran complexes the use of a purification step with an ultrafiltration membrane which may have a molecular weight cut-off between 5 000 and 50 000 (example 1, pages 3 and 4). This purification method may be used instead of alcohol precipitation (D27, page 2, lines 18-20).

However, even if to the benefit of the respondent, it were agreed that the use of a purification step with an ultrafiltration membrane would be obvious for the preparation of iron sugar complexes other than those prepared in examples 3 to 8 of D9, although it was not shown that the complexes prepared in D27 contain dextran in an activated form, the skilled person replacing the purification method by ethanol precipitation used at the end of the process of examples 3 to 8 of D9 by an ultrafiltration step, would not arrive at the subject-matter of operative claim 1, since the stabilization or heating step used in the examples of D9 precedes the purification step contrary to the process of operative claim 1.

Moreover, D9 does not describe a stabilization step in accordance with claim 1, namely heating for a period between 1 and 4 hours at a temperature between 75° C and 95° C and a pH between 9.0 and 12.0.

29.5 On that basis the subject-matter of process claim 1 has not been shown to lack an inventive step over D9.

30. In the absence of additional objections against the subject-matter of claim 1, auxiliary request 6 is deemed to be allowable.

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 with the order to maintain the patent on the basis of the claim of auxiliary request 6 filed during oral proceedings before the opposition division on 24 January 2019, after any necessary consequential amendment of the description.

The Registrar: The Chairman:

B. ter Heijden D. Semino

Decision electronically authenticated