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**Datasheet for the decision
of 30 January 2007**

Case Number: T 0115/05 - 3.3.06

Application Number: 95939264.8

Publication Number: 0804532

IPC: C11D 3/386

Language of the proceedings: EN

Title of invention:
Coated enzyme granules

Patentee:
GENENCOR INTERNATIONAL, INC.

Opponents:
HENKEL KGaA
NOVOZYMES A/S

Headword:
Unctuous mixture coating/GENENCOR

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (main request, auxiliary requests 1 to 9): no"

Decisions cited:
-

Catchword:
-



Case Number: T 0115/05 - 3.3.06

D E C I S I O N
of the Technical Board of Appeal 3.3.06
of 30 January 2007

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Decision under appeal:

Interlocutory decision of the Opposition
Division of the European Patent Office posted
8 December 2004 concerning maintenance of
European patent No. 0804532 in amended form.

Composition of the Board:

Chairman: P.-P. Bracke
Members: G. Raths
A. Pignatelli

Summary of Facts and Submissions

I. This appeal is from the interlocutory decision of the Opposition Division concerning maintenance in amended form of European patent No. 0 804 532.

II. Claim 1 of the patent as granted read:

"1. A method of preparing coated enzyme granules including the steps of
(i) contacting enzyme granules comprising a core material to which an enzyme containing layer is applied, with a coating material; and
(ii) contacting the granules formed in step (i) with an anti-caking agent so as to obtain free-flowing granules; characterized in that the coating material is either
(a) a non-aqueous liquid or aqueous emulsion thereof, or
(b) an unctuous mixture comprising at least one liquid as in (a) having dissolved therein a second component having a melting point in the range of 30 to 90°C,

said contacting being carried out so as to provide a substantially uniform coating on said granules of said coating material at less than 25 wt%, and said coated enzyme granules, having a dust figure of less than 2 µg as determined by the Heubach attrition test."

III. Two notices of opposition were filed against the granted patent, wherein both opponents sought revocation of the patent on the grounds of Article 100(b) EPC for lack of sufficiency of disclosure (Article 83 EPC) and on the grounds of

Article 100(a) EPC for lack of novelty and inventive step (Articles 52(1), 54 and 56 EPC).

IV. Inter alia, the following documents were cited during the opposition proceedings:

- (1) WO-A-83/07263;
- (16) WO-A-90/09 428 and
- (20) US-A-4 242 219.

V. During opposition proceedings, with letter of 31 August 2004, the proprietor had filed a main request and several auxiliary requests of which only auxiliary requests 1 to 3 are relevant for the present decision.

Claim 1 of the main request differed from Claim 1 as granted in that the passage

"either

(a) a non-aqueous liquid or aqueous emulsion thereof, or

(b) an unctuous mixture comprising at least one liquid as in (a) having dissolved therein a second component having a melting point in the range of 30 to 90°C,"

was replaced by

"an unctuous mixture comprising at least one non-aqueous liquid or aqueous emulsion thereof, having dissolved therein a second component having a melting point in the range of 30 to 90°C,"

Claim 1 of the first auxiliary request differed from the main request in that the passage

"by smearing over or blending onto the core material"

was inserted between

"carried out" and "so as to provide".

Claim 1 of the second auxiliary request differed from Claim 1 of the main request in that

"(i) contacting enzyme granules comprising a core material to which an enzyme containing layer is applied with a coating material; and
(ii) contacting the granules formed in step (i) with an anti-caking agent so as to obtain free-flowing granules;"

was replaced by

"(i) coating a core material with an enzyme layer in a fluidized bed to provide enzyme granules;
(ii) contacting said enzyme granules with a coating material; and
(iii) contacting the granules formed in step (ii) with an anti-caking agent so as to obtain free-flowing granules;"

Claim 1 of the third auxiliary request differed from Claim 1 of the second request in that

"at less than 25 wt% "

was replaced by

"of from 5 to 20 wt%".

VI. In its decision the Opposition Division held that the set of twelve claims of the third auxiliary request met the requirements of Articles 54, 56, 83 and 123 EPC.

In particular, in regard of inventive step, the reasoning was as follows:

Main request

The object of document (1) was to provide coated enzyme granules having low dust formation. The problem underlying the patent in suit in the light of document (1) would be to obtain a further method of preparing coated enzyme granules.

Two features would be of importance: the dust value and the unctuous mixture.

Since there was no procedural step allowing to obtain a dust value of less than 2 µg of the granules, said value could only be considered as a desideratum. Further, the problem would not be solved over the whole scope of Claim 1 since a too small amount of unctuous mixture could not lead to a dust figure of less than 2 µg.

Therefore the subject-matter of Claim 1 of the main request did not involve an inventive step.

1st and 2nd auxiliary requests

The feature regarding the contacting of the coating material with the anti-caking agent by smearing over or blending onto the core material was the essential difference between the subject-matter of Claim 1 of the main request and that of the first auxiliary request. This feature was considered by the Opposition Division as not implying inventive merit.

The subject-matter of Claim 1 of the second auxiliary request differed in essence from that of the main request in the coating step. However, the coating of a core material with an enzyme layer in a fluidized bed was - as explained by the proprietor during oral proceedings before the Opposition Division - part of the state of the art.

Hence, the subject-matter of Claim 1 of the second auxiliary request did not involve an inventive step.

3rd auxiliary request

Claim 1 of the third auxiliary request differed from that of the second auxiliary request in that "at less than 25 wt%" was replaced by "5 to 20 wt%". The amount of 5 to 20 wt% of a coating used according to Claim 1 of the third auxiliary request would provide a method which solved the problem of providing enzyme granules having a dust figure of less than 2 µg in the Heubach test.

Document (1) would teach to use 1 to 20 wt% of a coating, but would not give an incentive to the skilled person to apply this teaching to document (20) which disclosed an unctuous mixture. In order to arrive at the claimed subject-matter the skilled person would have to combine selected passages of document (1) (page 14, lines 3 to 4, examples, page 11, last paragraph) with selected passages of document (20) namely those disclosing the specific preparation according to example 2. Further, there would be no evidence that the results of the elutriation test of document (20) were correlated to those obtained in the Heubach test.

Therefore, the subject-matter of Claim 1 of the 3rd auxiliary request would involve an inventive step.

VII. This decision was appealed by opponent 02 (hereinafter the appellant/opponent) and by the patent proprietor (hereinafter the appellant/proprietor).

VIII. The appellant/opponent raised objections under Articles 56, 83 and 123(2)(3) EPC.

In particular, in regard of inventive step, it argued that document (1) relating to enzyme granule compositions would teach to use 1 to 20 wt% of a coating material and document (20) would direct the skilled person to use 5 wt% of a coating material.

Applying the coating at a level of from 5 to 20 wt% would not involve an inventive step because coatings at this level were already disclosed by documents (1) and (20).

The description of the state of the art in the patent in suit would deal with matrix granules as described in document (20) as well as with layered granules as described in document (1) (patent in suit, paragraphs [009] and [008]).

Further, document (16) would disclose processes for making enzyme granules that combine fluidised bed (also called fluid bed) coating methods with methods used to prepare matrix granules. For instance, a granulate previously produced in a Lödiger mixer was coated in a fluid bed (page 8, line 5).

Also, document (1) would disclose the interchangeability of the fluid bed process with other coating processes (page 7, last full paragraph, last sentence).

Document (20) would disclose that enzyme granules having a coating of a mixture of paraffin oil and glycerol monostearate reduced dust formation, the elutriation test giving values of 10, 18 and 32 Delft Units (DU) (example 2, table, column 6, lines 45 to 63) whereas particles without such a coating resulted in elutriation test values of 45 (paraffin oil only as coating) and 80 (coating comprising only an anti-caking agent). This testing would refer only to dust formation, and not to moisture.

Therefore, the subject-matter of Claim 1 as maintained by the Opposition Division would lack an inventive step.

IX. The appellant/proprietor filed by letter of 18 April 2005 a main request and auxiliary requests 1 to 3.

Claim 1 of the main request was identical to that before the Opposition Division (see point V).

Claim 1 of the first auxiliary request differed from Claim 1 of the main request in that "less than 25 wt%" was replaced with "from 1% to less than 25 wt%".

Claim 1 of the second auxiliary request differed from Claim 1 of the first auxiliary request in that

"(i) contacting enzyme granules comprising a core material to which an enzyme containing layer is applied, with a coating material; and
(ii) contacting the granules formed in step (i) with an anti-caking agent so as to obtain free-flowing granules;"

was replaced by

"(i) coating a core material with a an enzyme layer in a fluidized bed to provide enzyme granules;
(ii) contacting said granules with a coating material; and
(iii) contacting the granules formed in step (ii) with an anti-caking agent so as to obtain free-flowing granules;"

and

"by smearing over or blending onto the core material"

was inserted between

"carried out" and "so as to".

Claim 1 of the third auxiliary request differed from Claim 1 of the third auxiliary request as maintained by the Opposition Division, in that "of from 5 to 20 wt%" was replaced by "at from 5 to 20 wt%".

In respect of inventive step, the appellant/proprietor argued as follows:

In essence, the difference between document (1) and the patent in suit would be that the enzyme-coated core according to document (1) was coated with a layer of polyvinyl alcohol (PVA) in a fluid bed reactor instead with an unctuous mixture according to the invention.

The appellant/proprietor did not agree with the decision of the Opposition Division for the following reasons: The Opposition Division would have taken two approaches. According to a first approach the problem underlying the patent in suit in the light of document (1) was to provide an alternative coating process.

The Opposition Division had objected that an unctuous mixture used at a too low amount would not lead to a dust figure of less than 2 μg and, hence, not solve the technical problem in the lower range of the concentration of the unctuous mixture, the concentration range being defined in Claim 1 of the

main request as "at less than 25 wt%". This objection would not be acceptable because the Opposition Division ignored the requirement to obtain a low dust figure. Said requirement would be linked to the coating amount which should be sufficient to keep the dust figure below 2 µg.

Therefore, the amount of unctuous mixture would be a function of the make up of the unctuous coat. The patent in suit would teach a wide variety of combinations and provide guidance as to the proportions of solid and liquid components of the coat (see paragraph [0043]).

The Opposition Division would be wrong in finding the alternative process obvious. Merely pointing to an alternative process would not justify a lack of inventive step because an alternative process could also involve an inventive step.

The second approach of the Opposition Division started again with defining the problem to be solved as the provision of an alternative method of preparing coated enzyme granules to the one according to document (1). But according to the second approach, there would be a pointer in document (20) to replace the coating of document (1) with a coating disclosed by document (20).

According to example 2 of document (20) the coating was made up of a mixture of paraffin and glycerol monostearate. Table 2 (column 6, lines 50 to 58) would disclose low results of dust expressed in DU in the elutriation test when a paraffin oil: glycerol monostearate mixture was used as a coating. Hence,

according to the Opposition Division, a skilled person would replace the coating according to document (1) with said coating according to example 2 of document (20) and thus arrive at the technical solution proposed in the patent in suit.

According to the appellant/proprietor the result obtained in the elutriation test would be a function of all the ingredients and not only of the coating. The paraffin-stearate coating would not be responsible per se for the low dust figure, because the lowest dust figure (10 DU) was obtained with a coating comprising only 0.5 wt% paraffin oil and 0.5 wt% glycerol monostearate whereas the concentrations of 2.5 wt% for both components in the coating led to higher dust figures, namely 18 and 32 DU respectively, although the amount of the coating was increased (namely from 0.5 wt% for paraffin oil as for glycerol monostearate).

Hence, the variation in DU values would not be due to the barrier coating itself but to the contents of the matrix particle.

Consequently, the low dust elutriation value of the particles according to example 2 of document (20) would not be an incentive for the skilled person to use the same coating according to example 2 of document (20) on a particle which was enzyme coated according to document (1).

The particles according to document (20) would contain an equal concentration of enzyme throughout the entire cross section of the granule. A layered particle according to document (1) however would consist of

discrete layers applied to a core in successive steps. These layers would be composed of individual or mixture of components. In contrast to particles according to document (20), the enzyme according to document (1) would not be homogenously distributed throughout the particle but highly concentrated in one layer.

Because of their different constructions, the particles according to document (1) would behave differently from those according to document (20).

As a result, these two types of particles would behave differently in the Heubach test and in the elutriation test measurements.

In the case of an elutriator, each type of particle releasing dust associated with the surface of the particle would not dust from within the particle. Both matrix and core-coated layered particles would behave similarly in the elutriation test.

A Heubach test would introduce shear and crush forces that have the tendency to release dust contained within the particles as granules break.

If a matrix particle breaks in the Heubach test, the surface of the broken particle would release a low concentration of enzyme, all the enzyme being distributed homogeneously throughout the particle.

If a layered particle breaks in the Heubach test a concentrated layer of enzyme would release a high amount of enzyme dust.

If in an elutriation test matrix and layered particles would result in low dust levels this would not necessarily mean that low dust levels are obtained in a Heubach test.

Heubach attrition test results would be different from those of the elutriation tests.

It would follow therefrom that, since documents (1) and (20) were technically incompatible, a skilled person would not combine the teachings of both documents. Also the objective of document (20) was to prevent loss of moisture, whereas the objective of the patent in suit was to manufacture granules having reduced enzyme dust figures.

Consequently, the subject-matter of Claim 1 of the main request would be inventive.

Should the Board not allow the main request because the problem would not be solved over the whole scope of Claim 1, the indication of a lower limit of 1 wt% of Claim 1 of the first auxiliary request would redress this flaw; a coating of from 1 to 25 wt% according to the invention would lead to a sufficient reduction of dust release so as to meet the requirement of less than 2 µg.

The second auxiliary request would comprise the process step of smearing the coating material over the core material or of blending it onto the core material. Starting from document (1) the Opposition Division would have failed to analyse why the skilled person would be motivated to carry out such a process step.

- X. With letter of 26 August 2005 the appellant/opponent, in respect of inventive step, refuted the appellant's/proprietor's arguments, in essence, as follows:

The dust figure of lower than 2 µg would be a desideratum and would therefore have to be disregarded.

The appellant's/proprietor's distinction between fluid bed coating and methods for preparing matrix granules would not prevent the skilled person from combining the teaching of document (1) relating to a fluid bed process with that of document (20) relating to matrix granules. Evidence for the purpose of combining documents (1) and (20) would be document (16) disclosing processes for making enzyme granules which combine fluid bed coating methods with methods of preparing matrix granules.

When pointing to the objective of preventing loss of moisture according to document (20), the appellant/proprietor overlooked the document's other objective, namely that of manufacturing dust free particles.

The specification of the lower limit of 1 wt% would not contribute inventive step. The process step of smearing over or blending onto would not distinguish over the process steps disclosed by document (20).

- XI. With letter of 8 February 2006 the appellant/proprietor replaced auxiliary request 3 with a new auxiliary request 3 and it also filed auxiliary request 4. During

the oral proceedings which took place on 30 January 2006, it filed auxiliary requests 5 to 9 which contained amendments announced in its letter dated 31 October 2006.

New Auxiliary request 3 filed with letter dated
8 February 2006

Claim 1 of the new auxiliary request 3 was identical to Claim 1 of auxiliary request 3 filed with letter dated 18 April 2005.

Auxiliary request 4

Claim 1 of auxiliary request 4 differed from Claim 1 of auxiliary request 3 in that the passage "said contacting being carried out" was replaced by

"wherein the coating material and optionally the anti-caking agent are applied to the granules in a mixing unit or a blending unit, and wherein said contacting is carried out".

Auxiliary requests 5 to 9

Claim 1 of auxiliary requests 5 to 9 differed from Claim 1 of the main request and auxiliary requests 1 to 4, respectively, in that the words "or aqueous emulsion thereof" were deleted.

The appellant/proprietor argued that the appellant/opponent failed to indicate a reason why the skilled person **would** rely on document (20) when starting from document (1).

XII. The appellant/opponent requested that the decision under appeal be set aside and the European patent No. 0 804 532 be revoked.

The appellant/proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or one of the first and second auxiliary requests filed on 18 April 2005, or one of the third or fourth auxiliary requests filed on 8 February 2006 or of one of the fifth to ninth auxiliary requests filed during oral proceedings.

Reasons for the Decision

1. Main request

1.1 Inventive step

1.1.1 An objective of the patent in suit was to provide improved coated enzyme granulates having reduced enzyme dust figures compared with enzyme granules known in the art, and without the need for extensive use of a fluid bed coating apparatus.

Besides this enzyme dust reduction, the coating used in accordance with the present invention provides the possibility of incorporating additives which change functional features of granules such as colour, stability, solvability and antistatic properties. In particular, an object of the invention was to provide a process wherein the amount of the outer

coating layer material needed to provide a dust figure of less than 2 μg is less than 25 wt%. Also, the time for producing the coating layer in a fluid bed apparatus is reduced by 50 % or more compared with previously known processes (page 2, lines 46 to 54).

- 1.1.2 The Board concurs with the parties' point of view that document (1) is a reasonable starting point for evaluating inventive step because it relates to the provision of low dust, low residue, delayed release enzyme granules, increased stability and processes and enzyme granule compositions which afford the formation of such improved granules in much lower processing time, thus reducing the cost of the granular product (page 2, line 25 to page 3, line 3).

In the light of document (1), the problem as defined in the patent in suit has not to be redefined since the main objective is the same: formation of low amounts of dust. This was not contested.

- 1.1.3 According to the patent in suit the technical problem is solved by the method as defined in Claim 1 of the main request, and in particular, by the use of an unctuous coating material which is applied on the granules so as to provide a substantially uniform coating on said granules of said coating material at less than 25 wt% and said coated enzyme granules have a dust figure of less than 2 μg as determined by the Heubach attrition test.

Having regard to the data displayed in table 1 of the patent in suit, the granules coated according to the invention have considerably lower dust figures than

those which comprise only a fluid bed coating. The invention examples have a dust figure of 1.2 and <1 µg, respectively, i.e. lower than 2 µg as required by Claim 1.

In particular, the granule according to the example in line 1 of said table comprised 5.4 wt% of a coating (i.e. 30 g of an unctuous mixture of paraffin oil: glycerol monostearate (3:1) and 24 g of Aerosil, which is the anti-caking agent) on 1000 g of uncoated Maxacal (i.e. Protease enzymes) fluid bed granules. This invention example had a dust figure of 1.2 µg.

Further, the granule according to the example in line 2 of said table comprises 5.4 wt% of a coating (as defined above for the coating in line 1) together with a 5 wt% fluid bed coating. This invention example had a dust figure of <1 µg.

Both examples had a dust figure lower than 2 µg as required by Claim 1.

The comparison granules having a 10 wt% and 20 wt% fluid bed coating had dust figures of 186 and 3.5 µg, respectively, i.e. higher than 2 µg and thus fell outside Claim 1.

Therefore, the Board is satisfied that the claimed method plausibly solves the existing technical problem.

- 1.1.4 The question now is whether the cited prior art would have suggested to a person skilled in the art to solve the above-indicated technical problem in the proposed way.

- 1.1.5 The teaching of document (1) differs from that according to the patent in suit in that the coating surrounding the enzyme layer comprised a vinyl (co)polymer, usually PVA (document (1), page 3, lines 10 to 17; page 4, lines 7 to 10) whereas the patent in suit taught to surround the core with an unctuous mixture.
- 1.1.6 The question is whether the skilled person had an incentive to rely on another document disclosing the unctuous mixture as defined in Claim 1.
- 1.1.7 The objective of document (20) was, inter alia, to provide a process for the preparation of dust-free enzyme containing particles (column 1, lines 45 to 48; lines 54 to 56; column 4, lines 50 to 53).

The table of example 2 of document (20) displayed results of the elutriation test when various coatings were applied to enzyme containing particles. It is of relevance that the coatings are unctuous mixtures as in the patent in suit.

In particular, a coating comprising 2.5 wt% of paraffin oil and 2.5 wt% of glycerol monostearate as well as 2 wt% Aerosil (as anti-caking agent) led to a value of 32 DU; a coating comprising 2.5 wt% of paraffin oil and 2.5 wt% of glycerol monostearate comprising 3 wt% of corn starch as anti-caking agent led to a value of 18 DU and a coating of 0.5 wt% of paraffin oil and 0.5 wt% of glycerol monostearate and 1 wt% Aerosil (as anti-caking agent) to a value of 10 DU.

In the same table, for comparison purposes, the elutriation test gave 80 DU when the coating comprised only 1 wt% of Aerosil and 45 DU when the coating comprised 0.5 wt% of paraffin oil and 3 wt% of corn starch (as anti-caking agent).

Hence, the skilled person was taught that a coating comprising a 1:1 mixture of a paraffin oil and glycerol monostearate led to reduced DU values in the elutriation test. In other words, it was possible to reduce the dust level when surrounding the enzyme-containing particles with such a coating.

The Board points to the unctuous mixtures according to examples 1, 2 and 3 of the patent in suit which consist of paraffin oil: glycerol monostearate in a ratio of 3:1. In other words, the components of the unctuous mixtures used according to the examples of the patent in suit are the same as those used according to the coating mixture of example 2 of document (20). The difference in ratio i.e. 3:1 according to the patent in suit and 1:1 according to the example 2 of document (20), is not relevant since the ratio is not a feature of Claim 1.

Starting from paraffin oil disclosed by document (20) and extending this specific example to the general term of non-aqueous liquids does not require inventive skill. The same holds for glycerol monostearate which was extended to the general term of a solid having a melting point of 30 to 90°C which should dissolve in the non-aqueous liquid upon melting.

Having regard to the teaching of example 2 of document (20), it was obvious to replace the PVA coating according to document (1) by unctuous mixtures according to document (20).

- 1.1.8 The appellant/proprietor argued that the skilled person would not combine the teachings of documents (1) and (20) since the manufacturing techniques of the enzyme containing granule portion were different.

For the Board this argument fails because of the following reasons:

Document (16) disclosed processes for making enzyme granules that combined fluidised bed coating methods with methods used to prepare matrix granules. For instance, a granulate previously produced in a Lödiger mixer was coated in a fluid bed (page 8, line 5).

Also, document (1) disclosed the interchangeability of the fluid bed process with other coating processes (page 7, last full paragraph, last sentence).

The matrix as well as the core-coated layered particles behave similarly in the elutriation test (proprietor's letter dated 18 April 2005, statement of grounds of appeal, point 6.14.).

Therefore in spite of the fact that document (20) dealt with matrix granules whereas document (1) with layered granules, for the skilled person it was routine to combine both techniques.

1.1.9 The appellant/proprietor also argued that the objective of document (20) would be to prevent loss of moisture (column 2, lines 1 to 2). Thus, there would have been no incentive for a person skilled in the art looking for low dust particles to turn to document (20).

For the Board, however, the numerous direct and indirect references to dust free particles or to low elutriation test values (column 1, lines 46 and 56, column 4, lines 50 to 53, lines 59 to 61; column 6, lines 20 to 21; table of example 2; column 6, lines 64 to 65; column 9, line 5) do not hide the fact that the provision of particles having low dust figures is an issue in document (20).

Furthermore, the patent in suit clearly refers also to the aspect of moisture. Thus, it is said that the advantage of introducing a solid into the liquid is an increase of the moisture barrier effect of the coating (page 4, lines 55 to 56) and the liquid or unctuous coating material may provide a water impermeable layer (page 5, line 9). It can thus be concluded that the appropriate moisture content of the granules was also taken into consideration in the patent in suit.

The argument of the appellant/proprietor that the skilled person would not turn to document (20) is therefore not accepted.

1.1.10 A further argument of the appellant/proprietor to disregard document (20) was the plastification of the mixture (column 3, lines 49 to 65).

However, for the Board, plastification depends on the ingredients of the mixture (lubricating agents, moisture-regulating agents, other ingredients; document (20), column 3, lines 10 to 65) and is not a compulsory feature of the process disclosed by document (20) (see Claim 1). Also, plastification does not occur in the process according to example 2 of document (20). By the way, according to the patent in suit, plasticizers may be added to the enzyme containing liquid (page 3, line 56). Therefore, the appellant's/proprietor's argument to disregard document (20) because of the plastification issue fails.

1.1.11 In conclusion, the Board finds that the method of preparing coated enzyme granules according to Claim 1 of the patent in suit does not involve an inventive step in the sense of Article 56 EPC.

2. Auxiliary request 1

Claim 1 of the auxiliary request 1 differed from Claim 1 of the main request in that "at less than 25 wt%" was replaced with "from 1% to less than 25 wt%".

The problem underlying the patent in suit in the light of document (1) is the same as defined under point 1.1.2 and the Board is satisfied that this problem was solved in the range of 1 to 25 wt%.

The reasoning as outlined under points 1.1.3 to 1.1.11 for the main request applies mutatis mutandis to auxiliary request 1.

Consequently, Claim 1 of auxiliary request 1 does not involve an inventive step.

3. Auxiliary request 2

Claim 1 of auxiliary request 2 (see above point X) now defines that the enzyme layer is coated in a fluidized bed and that the unctuous coating is contacted to the resulting core by smearing it over or blending it onto the core material.

The reasoning as outlined under points 1.1.3 to 1.1.11 for the main request applies mutatis mutandis to the auxiliary request 2 since document (1) dealt with fluid bed manufactured cores (page 7, line 22) and document (20) with techniques involving coating in a mixing unit (column 4, line 26).

Consequently, Claim 1 of auxiliary request 2 does not involve an inventive step.

4. Auxiliary request 3

Claim 1 of auxiliary request 3 (see points IX and XI) differed from Claim 1 of the second auxiliary request in that

"at less than 25 wt%"

was replaced by

"of from 5 to 20 wt%".

It has to be determined whether there is evidence that the problem underlying the patent in suit is solved at concentrations above 5 wt%.

In particular, the granule according to the example in line 1 of table 1 of the patent in suit (page 6, lines 1 to 10) comprised 5.4 wt% of a coating. This amount of 5.4 wt% results from 30 g of an unctuous mixture of paraffin oil: glycerol monostearate (3:1) and 24 g of Aerosil (which is the anti-caking agent) on 1000 g of uncoated Maxacal (i.e. Protease enzymes) fluid bed granules. This invention example had a dust figure of 1.2 µg.

Further, the granule according to the example in line 2 of said table comprised 5.4 wt% of a coating (as defined above for the coating in line 1) and 5 wt% fluid bed coating. This invention example had a dust figure of <1 µg.

However, the coating according to Claim 1 consists of an unctuous mixture which does not comprise an anti-caking agent.

Since the anti-caking agent is present in an amount of 24 g, this amount cannot be taken into consideration when assessing the percentage concentration of the unctuous mixture which amounts only to 30 g. Hence, the concentrations of the coatings consisting of paraffin oil and glycerol monostearate (namely 30 g based on 1000 g uncoated fluid bed granules) according to the examples in lines 1 and 2 of table 1 of the patent in suit fall outside the range of 5 to 20 wt%.

Therefore, there are no data proving that the problem underlying the patent in suit is solved at concentrations above 5 wt% and thus said problem has to be reformulated as the provision of a further method for surrounding the enzyme containing core material.

Said less ambitious problem is plausibly solved by the method according to Claim 1 which comprised an unctuous mixture. Starting from document (1) the question is whether the skilled person would rely on another document for arriving at a method comprising "an unctuous mixture comprising at least one non-aqueous liquid or aqueous emulsion thereof, having dissolved therein a second component having a melting point in the range of 30 to 90°C".

According to the method disclosed by document (1), the enzyme containing core is manufactured by a fluid bed process and example 2 of document (20) teaches to surround the core material with an unctuous coating.

The reasoning why the skilled person would combine the teachings of both documents and why the claimed subject-matter is not inventive is outlined in points 1.1.7 to 1.1.11 and applies mutatis mutandis to Claim 1 of auxiliary request 3.

Consequently, the subject-matter of Claim 1 of the third auxiliary request does not involve an inventive step.

5. Auxiliary request 4

Claim 1 of auxiliary request 4 (see point XI) differed from Claim 1 of auxiliary request 3 in that the passage "said contacting being carried out" was replaced by

"wherein the coating material and optionally the anti-caking agent are applied to the granules in a mixing unit or a blending unit, and wherein said contacting is carried out".

The reasoning outlined under auxiliary request 3 applies mutatis mutandis to auxiliary request 4 since Claim 1 of auxiliary request 4 can be treated as if the feature regarding the addition of the caking agent would not be present, this feature being optional. As to the mixing or blending unit, document (20) related to techniques involving coating in a mixing unit (column 4, line 26).

Consequently, the subject-matter of Claim 1 of the fourth auxiliary request does not involve an inventive step.

6. Auxiliary requests 5 to 9

Claim 1 of auxiliary requests 5 to 9 differed from Claim 1 of the main request and of auxiliary requests 1 to 4 in that the feature "aqueous emulsion thereof" was deleted (see point XI). The coating surrounding the enzyme containing core is now an unctuous mixture comprising no more an emulsion but at least one liquid having dissolved therein a second component having a melting point in the range of 30 to 90°C.

This amendment does not affect the reasoning of the problem-solution approach as outlined for the main request under points 1.1.1 to 1.1.11 which applies mutatis mutandis to auxiliary request 5. The same holds for auxiliary requests 6 to 9 in connection with auxiliary requests 1 to 4. In particular, an object of the invention was to provide a process wherein the amount of the outer coating layer material, needed to provide a dust figure of less than 2 μg , is less than 25 wt%. Also, the time for producing the coating layer in a fluid bed apparatus is reduced by 50 % or more compared with previously known processes (page 2, lines 46 to 54).

According to the subject-matter of Claim 1 of auxiliary requests 5 to 9 the technical solution to this problem still comprises at least one liquid having dissolved therein a second component having a melting point in the range of 30 to 90°C. The reasoning by the Board under points 1.1.1. to 1.1.11 in combination with points 2 to 5 (regarding auxiliary requests 1 to 4) applies mutatis mutandis to Claim 1 of the auxiliary requests 5 to 9.

Consequently, the subject-matter of Claim 1 of auxiliary requests 5 to 9 does not involve an inventive step.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is revoked.

The Registrar

The Chairman

G. Rauh

P.-P. Bracke