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Datasheet for the decision of 16 July 2013

Case Number: T 1766/09 - 3.3.08

Application Number: 98964823.3

Publication Number: 1037968

IPC: C12N 9/98

Language of the proceedings: EN

Title of invention:
Matrix granule

Patentee:
GENENCOR INTERNATIONAL, INC.

Opponent:
NOVOZYMES A/S

Headword:
Layered granule/GENENCOR

Relevant legal provisions:
EPC Art. 54, 56, 83, 123(2)
RPBA Art. 12(4), 13(1)

Keyword:
"Main request - requirements of the EPC met (yes)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1766/09 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 16 July 2013

Appellant: (Opponent)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 22 July 2009 concerning maintenance of European Patent No. 1037968 in amended form.

Composition of the Board:

Chairman: M. Wieser
Members: B. Stolz
J. Geschwind

Summary of Facts and Submissions

I. The appeal lies against the decision of the opposition division, dated 22 July 2009, to maintain European patent No. 1037968 in amended form on the basis of the main request filed on 20 October 2008.

II. With its grounds of appeal, filed on 20 November 2009, the opponent (appellant) filed new documents D30 to D34. On 24 November 2013, it filed new document D35.

III. With its response, filed on 10 June 2010, the patent proprietor (respondent) filed auxiliary requests 1 and 2.

IV. In a letter, dated 22 October 2010, the appellant filed further arguments and new documents D1D, and D36 to D39.

V. In a communication pursuant to Article 15(1) RPBA, annexed to the summons to oral proceedings, to be held on 16 July 2013, the board informed of its preliminary, non-binding opinion on some of the issues to be discussed at the upcoming oral proceedings.

VI. In a letter dated 14 June 2013, the appellant made further submissions and filed new documents D40 to D43.

VII. In a letter dated 16 June 2013, the respondent made further submissions, filed experimental reports and two additional auxiliary requests as auxiliary requests 2 and 4, and renumbered previous auxiliary request 2 as auxiliary request 3.

VIII. In response to appellant's filing of document D40, the respondent made additional submissions, filed auxiliary requests 5 to 8, and filed new document D44.

IX. In a letter dated 12 July 2013, the respondent filed a new main request, and auxiliary requests 1 to 6, replacing all requests previously on file.

X. Oral proceedings were held on 16 July 2013.

XI. Claim 1, the only claim of the main request reads:

"1. A layered granule having a single seed particle, layers of the layered granule comprising:

a) a protein matrix layered over the seed particle wherein said matrix comprises a mixture of a protein and a combination of a sugar or sugar alcohol and a polysaccharide structuring agent; and

b) a barrier layer coated over the protein matrix or a coating layer.

XII. The following documents are cited in this decision:

D1: "Enzymes in Detergency", Editors Jan H van Ee et al, Marcel Dekker, Inc., 1997, ISBN 0-8247-9995-x

D2: WO 97/12958 (Genencor International, Inc.)

D4: WO 97/23606 (Genencor International, Inc.)

D27: Kellor R.L. (1974), J. Am. Oil Chemist's Soc., Vol. 51, 77A

D35: "Repetition by Novozymes A/S of Example 9 in WO97/12958", prepared by appellant, received on 24 November 2009.

Annex to respondent's submission of 16 June 2013, "Experimental Report, Repetition of WO97/12958 (D2) Example 9"

XIII. The arguments of the appellant, as far as relevant for the present decision, can be summarized as follows:

Article 123(2) EPC

Individual features of claim 1 were disclosed in claims 1, 2, 7, 8 and 12, as originally filed. Claims 2, 7 and 8 were however not linked by cross references. There was therefore no disclosure of granules comprising a polysaccharide and a barrier layer coated over the protein matrix. The relevant paragraphs on pages 3 and 5 of the description referred to two alternative structuring agents, a polysaccharide or a polypeptide, and to a barrier layer layered over the protein matrix or, also in the alternative, to a barrier material included in the protein matrix.
The term "single seed particle" was not used in the application as filed, and the disclosure at page 5, that the ratio of seed particles to granules is 1:1 provided no basis for this feature. The disclosure on page 5 was in relation to the overall population of granules and it said nothing concrete about individual granules.

Article 83 EPC

The claims contemplated carrying out the invention with any sugar or any sugar alcohol in combination with any polysaccharide and yet the patent only contained examples that employed a combination of sucrose as sugar and starch as polysaccharide. The skilled person could not reasonably expect to get the alleged invention to work with all possible combinations of materials.
In paragraph [0039], the patent specified a variety of methods of forming the layered granule, having a single seed particle, and yet all of the examples used a fluid bed coater. The skilled person was not taught how to carry out the invention with each of the methods described.

Article 87 EPC

The first priority document was almost identical to the application as originally filed and all passages of the originally filed application, upon which the claimed subject matter was based, could be found in the priority document. The claimed subject matter was not entitled to the first priority date for the same reasons as put forward in connection with added matter.

Article 54 EPC

Document D2 disclosed low dusting granules having a majority of the particle size within 20 to 400 microns. Preferred compositions comprised an active enzyme bound to a soy flour carrier by a modified starch binder in combination with a sugar and a film-forming polymer. The enzyme binder blend was sprayed on the carrier.

Example 9 of document D2 disclosed the preparation of layered granules, and contained a statement that the enzyme binder solution was sprayed on the soy flour at a rate as not to cause formation of aggregates.
The term "aggregates" used in Example 9 and the term agglomerates used in other places of document D2 were used synonymously. Therefore, Example 9 clearly disclosed layered granules according to claim 1.
Document D35 disclosed the results of a reproduction of Example 9 by the appellant. The experiments were carried out with a reactor having similar properties to those of the reactor used in Example 9. The pictures clearly showed single seed layered particles with a diameter of about 80 microns.
According to document D27, soy flour particles had a wide size distribution. The experimental data submitted by the respondent showed agglomerated granules but a fraction of the particles had to comprise a single seed.

Article 56 EPC

Document D2 disclosed the production of low dusting micro granules by fluid bed spraying. A preferred composition comprised an active enzyme, a soy flour carrier, a modified starch binder to bind the enzyme to the carrier, and a film forming polymer. The chemical composition of the granules in document D2 was the same as that of the claimed granules. The technical problem was the provision of alternative low dusting micro granules. The patent did not disclose any benefit of the claimed layered granules in comparison with the granules of document D2. The provision of single seed layered particles was merely an obvious alternative in view of

the common general knowledge as shown on page 317 of document D1.
Document D4 disclosed the manufacture of low dusting microgranules with increased enzyme stability. According to page 7, line 10, the enzymes were typically coated from relatively impure solutions comprising other suspended solids such as carbohydrates. The binder in the enzyme matrix of the layered granules of Example 3 was PVA. The technical problem starting from document D4 was the provision of an alternative binder in the production of low dusting micro granules. The solution to this problem, the use of starch and sugar as an alternative binder, was obvious in view of document D2.

XIV. The arguments of the respondent, as far as relevant for the present decision, can be summarized as follows:

Article 123(2) EPC

Page 4, lines 23 to 29, as well as all examples of the published patent application provided basis for polysaccharides as a preferred structuring agent. The two options for the barrier layer were also preferred throughout the application. Basis for the "single seed" feature could be found on page 5, lines 23 to 24.

Article 83 EPC

The Patent included several examples which described different ways of carrying out the invention. They described in detail that the fluid-bed spray-coating technique could be used for producing the claimed granules and detailed the particular fluid-bed coater used, the amounts of the individual granule components

employed, and all essential process parameters. In addition, the description provided further instructions with regard to the composition of the seed particle, the protein matrix (i.e. the protein, the sugar or sugar alcohol, and the polysaccharide structuring agent), the barrier layer and the coating layer. Thus, the Patent contained sufficient information to allow the person skilled in the art, using his common general knowledge, to perform the invention over the entire scope of the claims.

The appellant did not show and did not give any well founded reasons that a particular combination of a sugar or sugar alcohol and a polysaccharide structuring agent could not be used to get the claimed invention to work.

Article 87 EPC

The content of he first priority document (US 08/995,457) was almost identical to the content of the application as originally filed and all passages, upon which the claimed subject-matter was based, could also be found in the first priority document. Accordingly, the effective filing date was 20 December 1997.

Article 54 EPC

Document D2 described the preparation of enzyme micro granules useful in food or feed applications. The granules were however prepared by fluid bed agglomeration. As stated in [0009] of the opposed patent, fluid bed coaters could be used to produce granules by agglomeration or by spray coating. The type of granules produced depended on the settings of the apparatus and

the components used. Aggregation was favoured by the use of small seeds, the use of sticky binders, fast spray rates and slow dry rates. Document D2 as a whole, e.g. page 2, line 4, page 3, paragraph 2, and page 5, paragraph 2, taught the production of micro granules by agglomeration. The soy flour used in Example 9 was a fine powder, the corn syrup/starch binder was sticky and the spray rate according to Table 1 was rather high, all of which favoured the formation of agglomerated granules. The statement in Example 9 that "enzyme binder solution was sprayed ... onto the soy flour at a rate as not to cause formation of aggregates" referred to the avoidance of the formation of excessively large lumps of material, and the term agglomerates should not be confused with the term aggregates. The reproduction of Example 9 in document D35 was based on the use of large soy flour particles and a different fluid bed granulator. The results obtained in document D35 were not in line with the results obtained in respondent's own reproduction of Example 9.

Article 56 EPC

Document D4 disclosed methods for the production of stable, low dusting enzyme granules with a controlled size distribution and represented the closest prior art. Example 3 of document D4 disclosed layered granules comprising an enzyme PVA matrix. The technical problem consisted of providing a further layered enzyme granule having a single seed particle with low dusting properties and high stability. Sugars were known to stabilize enzyme compositions but they were also known to favour agglomeration of seed particles.

Document D2 suggested the use of sugar/starch matrices but the granules obtained using this matrix were agglomerated. The claimed solution was not obvious because no prior art document suggested the use of sugar containing matrix solutions for the formation of single seed layered granules.

XV. The appellant requested that the decision under appeal be set aside and the patent be revoked.

XVI. The respondent requested that the decision under appeal be set aside and that the patent be maintained on the basis of the sole claim of the main request filed with letter of 12 July 2013.

Reasons for the decision

Admissibility of the main request

1. The main request, filed four days before oral proceedings, consists of a single claim. The claim is identical with claim 1 of the main request which was found allowable by the opposition division. The board, exercising its discretion under Article 13(1) RPBA, decided to admit it into the proceedings.

Admissibility of late filed documents

2. With its grounds of appeal, filed on 20 November 2009, the appellant introduced new documents D30 to D34, and with letter of 24 November 2009, it introduced experimental test results D35.

In further submissions dated 22 October 2010 and 14 June 2013, the appellant submitted documents D36 to D39, and D40 to D43, respectively.

3. The respondent filed an experimental test report, attached to its submissions of 16 June 2013. In response to appellant's filing of document D40, it filed document D44.

4. According to Article 12(4) of the Rules of Procedure of the Boards of Appeal (RPBA), the board has the discretionary power to hold inadmissible facts, evidence or requests which could have been presented in the first instance proceedings.

5. Appellant introduced Documents D30, D33 and D34 as further evidence for the alleged lack of an inventive step. Documents D31 and D32 were introduced as evidence for the chemical nature of Maltrin, mentioned in document D30.

Documents D30 to D34 represent new evidence for fresh inventive step objections. These objections could and should have been raised in the first instance proceedings. Moreover, the board considers these documents of no more technical relevance than the documents already on file. Exercising its discretion under Article 12(4) RPBA, the board therefore decided not to admit documents D30 to D34 into the appeal proceedings.

6. Document D35 is an experimental report describing a reproduction of Example 9 of document D2. It was filed in response to the position taken by the opposition

division that, based on the then available evidence, Example 9 did not affect the novelty of the claimed subject matter. It was filed four days after the statement of the grounds of appeal on appellant's own motion and not in response to a submission of the respondent. This document was of high relevance for the assessment of the disclosure of document D2. The board therefore decided to admit it into the proceedings.

7. Since document D35 was admitted into the proceedings and the experimental data attached to respondents submissions of 16 June 2013 were filed in direct response to the introduction of document D35, the board decided to also admit this report into the proceedings.

8. During oral proceedings, the parties indicated that they had no intention to rely on documents D36 to D39. The board therefore saw no need to decide on their admission into the proceedings.

9. Documents D40 to D43 were submitted one month before the date of the oral proceedings. The appellant argued that document D40 disclosed subject matter falling within the scope of claim 1 and that it should be admitted into the proceedings. Documents D41 to D43 were submitted to document the chemical nature of certain compounds mentioned in document D40. The respondent submitted document D44 to disprove appellant's submissions that document D40 disclosed layered granules having a single seed particle. The respondent also requested remittal to the first instance, should document D40 be admitted into the proceedings.

10. Document D40 was published in 1992, as a divisional application of an earlier European patent application published in 1988. Its subject matter was therefore in the public domain for almost ten years before the application of the patent in suit was filed, and its introduction represents a fresh case to attack novelty. The assessment of the technical relevance of document D40 raises complex issues and its admission at this stage of the proceedings would unavoidably lead to procedural delays at a late stage of the appeal proceedings. Therefore, exercising its discretion under Article 13(1) RPBA, the board decided not to admit any of documents D40 to D44.

Article 123(2) EPC

11. The layered granule of claim 1 is characterized by a single seed particle and a protein matrix layered over the seed particle. The protein matrix comprises a combination of a sugar or sugar alcohol and a polysaccharide structuring agent. The granule comprises furthermore a barrier layer coated over the matrix or a coating layer.

12. All but one of the technical features of claim 1 can be found in a single paragraph of the application as originally filed (page 3, lines 18 to 24 of the published international patent application). This paragraph discloses granules including "a protein matrix layered over a seed particle" where the protein matrix "includes a protein mixed together with a combination of a sugar or a sugar alcohol and a structuring agent". Furthermore, "the structuring agent is a polysaccharide or a polypeptide", and "Optionally a barrier layer can

be layered over the protein core or a barrier material can be included in the protein core". As a further option, "a coating can be applied over the seed particle, the protein matrix and/or the barrier layer", basically anywhere in or on the granule.

13. The granules of claim 1 comprise only matrices with a polysaccharide structuring agent. The limitation to polysaccharides as the structuring agent can be regarded as a selection from one of two possible embodiments. According to page 7, line 29, the granules of the invention can further or optionally comprise a barrier layer which in the case of a layer can be coated over the protein (page 7, lines 31-32). As a further option according to the paragraph recited from page 3, a coating layer can be added. Including these two optional features into claim 1 as independent alternatives does not lead to an unallowable combination of features.

14. Regarding the feature "having a single seed particle", the patent application discloses the following (page 5, lines 23 to 24): "In the granules of the present invention, if a seed particle is used then the ratio of seed particles to granules is 1:1".

This general statement refers to any of the disclosed granules comprising a seed particle, i.e. also to the layered granules described on page 3 of the application document. A ratio of one seed particle per granule clearly implies (on average) a single seed particle per granule, irrespective of whether that single seed particle itself is an agglomerated particle or not.

15. The board is therefore satisfied that claim 1 meets the requirements of Article 123(2) EPC.

Article 83 EPC

16. The appellant argued that the patent did not describe the invention in sufficient detail to allow it to be repeated across the entire scope of the claim. It argued in particular that (a) the skilled person would not expect the invention to work with the combination of any sugar and any structuring polysaccharide, and that (b) the majority of methods disclosed on page 9, second paragraph, of the patent application as filed were unsuitable for producing the claimed particles.

17. Regarding objection (a), the board notes that there is no evidence on file to show that combinations of certain sugars with certain polysaccharides are unsuitable to produce the claimed particles. Regarding objection (b), the board notes that the claims are directed to products with specific features and that the patent (Examples 2, 4-7, 9, 10) discloses methods for obtaining them. Whether further methods are available for obtaining the claimed products or not is therefore irrelevant for the purpose of Article 83 EPC.

18. The board is therefore satisfied that the main request meets the requirements of Article 83 EPC.

Article 87 EPC

19. Page 4, lines 1 to 7, and page 6, lines 7 and 8, of the priority document US 08/995457 provide literally

identical paragraphs to those cited above in points 12 and 14, respectively.

The claimed subject matter is thus disclosed in this priority document, and the relevant date for the assessment of novelty is December 20, 1997.

20. Documents D16 and D17, submitted as evidence of prior use of granules falling within the scope of claim 1 before June 1998, are therefore irrelevant for the assessment of novelty.

Article 54 EPC

21. Example 9 of document D2 discloses a fluid bed granulation process using soy flour as the seed particle onto which a mixture of enzyme, corn syrup solids (sugars) and Miragel (hydrolyzed starch) was sprayed. The resulting granules were then coated with Keltone.

22. The respondent submitted that the granules described in Example 9 of document D2 did not have a protein matrix layered on a single seed but rather consisted of agglomerated particles with each particle coated with a protein matrix.

23. According to document D2 (page 2), an object of the underlying invention is to provide an agglomeration process utilizing fluid bed spraying. The detailed description of document D2 refers to the use of binders which "either alone or in combination with sugars ... act to bind the enzyme to the carrier material, thus forming agglomerates" (page 3, 2nd paragraph). It also mentions that the micro granules obtained are made by

agglomeration (page 5, 2nd paragraph). Thus, the disclosure in D2 provides arguments supporting respondent's position that it refers to the production of agglomerated particles but not to the production of layered particles according to claim 1.

24. On the other hand, Example 9 comprises an explicit statement that "enzyme binder solution was sprayed ... onto the soy flour at a rate as not to cause formation of aggregates". The appellant submitted that this was clear evidence for a layered structure according to claim 1. The respondent on the other hand submitted that this statement referred to the avoidance of the formation of excessively large lumps of material, and that the term agglomerates should not be confused with the term aggregates.

25. Both parties submitted supplementary experimental data to support their position. The results of these experiments are contradicting, although both parties submitted that they were carried out according to Example 9.

Appellant's document D35 comprises electron micrographs showing the soy flour used as a starting material as well as individual granules. According to the appellant the individual granules shown in figures 3 and 4 of document D35 represent granules within the scope of claim 1.

Attached to its letter of 16 June 2013, the respondent submitted its own experimental report. The figures show soy flour particles used as the staring material and agglomerated particles comprising multiple seed

particles. The respondent noticed that the appellant had not used the same fluid bed granulator as in Example 9 and submitted that this could explain the different results.

The supplementary experimental evidence is therefore ambiguous and inconclusive.

26. The respondent also submitted that the operating conditions of the granulators as described in document D2 favoured agglomeration rather than spray coating.

27. According to document D1 (page 317, 2nd full paragraph), spray rate, bed temperature and atomization air pressure in a fluid bed granulation process have to be balanced to favour the formation of layered granules and minimize agglomeration. Low temperatures in combination with low air pressure tend to favour overwetting and agglomeration of the suspended particles.

A comparison of the parameters used to operate the fluidized bed granulator of the patent under appeal and of D2 shows that different parameters for operating the same type of granulator (Vector FL1) were used. D2 (table 1 and page 5, paragraph 3) discloses a bed and exhaust air temperature of 42-45°C, a spray rate of 20-25 ml/min and an atomization air pressure of 20-22 psi. In the patent under appeal (cf. e.g. Examples 1 and 2), higher bed and exhaust temperatures of about 55-60°C, a similar spray rate of about 20 ml/min (18g/min), and higher atomization air pressures of 50-56 psi were used to produce the layered granules. Respondent's argument that the conditions used in D2 favoured the formation of aggregates can therefore not be dismissed.

28. In case of an alleged lack of novelty, the burden of proof lies invariably with the party raising the objection (Case law of the Board's of appeal, 6th edition, I.C.1.9.1), and the proof has to be beyond doubt, ruling out a decision on likelihood.

In view of the facts that the supplementary experimental evidence submitted by the parties is inconclusive (cf. point 25, above), and that the disclosure of document D2 provides no evidence, neither explicit nor implicit, for the production of layered granules but rather for the production of agglomerated granules, the board decided that the subject matter disclosed in document D2 does not fall within the scope of claim 1.

Article 56 EPC

29. The subject matter of claim 1 is a low dusting layered protein granule having low residue properties and increased stability.

30. Document D4 discloses layered granules comprising a core, i.e. a single seed particle, a layer comprising an enzyme and a vinyl polymer, and an outer coating (e.g. claim 1, Figure 1). An object of the invention disclosed in document D4 is the provision of low dusting, low residue enzyme granules having increased stability (page 2, lines 7-8). The use of polyvinyl alcohol has a protecting, i.e. stabilizing, effect on the enzyme (p. 13, lines 2 and 15) and reduces dusting (page 12, Table).

Document D2 discloses methods for the production of enzyme micro granules which are dispersible in food,

rapidly disintegrate in an aqueous environment and have low dusting properties (page 2, lines 1-5). There is however no evidence that the granules possess a single seed particle. Rather, they consist of agglomerated particles (cf. points 22-28, above).

31. Only document D4 discloses methods serving the same purpose as the patent under appeal, and the micro granules disclosed therein have the same layered structure as the micro granules of claim 1. In line with established case law (Case law of the Boards of Appeal, I.D.3.2), in view of the fact that document D4 is directed to the same purpose and requires the least structural modifications, it represents the closest prior art.

32. Starting from document D4, the technical problem underlying the present invention is seen in the provision of alternative enzyme granules with low dust properties and good stability.

33. For the solution of this problem, the patent proposes the enzyme layered granules of claim 1. The results of Example 3 show that the layered granules have low dust properties and good stability. The board is therefore satisfied that the above mentioned problem has been solved.

34. It remains to be established if the claimed solution involves an inventive step.

35. The appellant submitted that the claimed solution was obvious in view of document D4 in combination with document D2.

36. Document D4 specifically focuses on the use of vinyl polymers to bind the enzyme to the core particle and stabilize it. Document D4 provides no incentive to use an alternative binder, let alone a binder comprising a sugar and a polysaccharide, in order to achieve the goal of the invention. Although sugars and starch were generally known to have binding properties (cf. e.g. Document D1, page 314, 3rd paragraph) and sugars were also known to have a stabilizing effect on enzymes (e.g. document D6, page 2, lines 33-35), the board sees no reason why the skilled person addressing the above mentioned problem, in the absence of any incentive or pointer in document D4, should have turned to document D2. This all the more as document D2 disclosed the use of polysaccharides and sugars to agglomerate the granules (cf. points 22-28, above). In order to arrive at the claimed solution by combining the teachings of documents D4 and D2, the skilled person would not only have had to modify the chemical composition of the granules disclosed in document D4 but he would additionally have had to modify the parameters of the production process of document D2. This was however not obvious from document D2.

The board therefore concludes that the skilled person, starting from document D4, would not have arrived at the claimed solution in an obvious way.

37. The board therefore decides that the main request meets the requirements of Article 56 EPC.

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:

   pages 2, 6 to 11, and 13 of the description of the patent as granted,

   amended pages 3 to 5 and 12 of the description as filed during the oral proceedings, and

   the sole claim of the main request filed with letter of 12 July 2013.

The Registrar: The Chairman:

A. Wolinski M. Wieser