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Datasheet for the decision of 8 February 2017

Case Number: T 0754/10 - 3.3.02

Application Number: 00962260.6

Publication Number: 1224273

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Title of invention:
Enzyme granulate

Patent Proprietor:
Novozymes A/S

Opponents:
Henkel AG & Co. KGaA
Danisco US Inc.
BASF SE

Headword:
Enzyme Granulate/NOVOZYMES

Relevant legal provisions:
EPC Art. 54(2), 56

Keyword:
Novelty (no)
Inventive step (no)

Decisions cited:
T 1329/04, T 0124/87

Catchword:

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Case Number: T 0754/10 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 8 February 2017

Appellant: (Patent Proprietor)	Novozymes A/S Krogshøjvej 36 2880 Bagsvaerd (DK)
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Respondent: (Opponent 1)	Henkel AG & Co. KGaA CLI Patents Z01 40191 Düsseldorf (DE)
Respondent: (Opponent 2)	Danisco US Inc. 925 Page Mill Road Palo Alto CA 94304-1013 (US)
Representative:	Forrest, Graham Robert Mewburn Ellis LLP City Tower 40 Basinghall Street London EC2V 5DE (GB)
Respondent: (Opponent 3)	BASF SE 67056 Ludwigshafen (DE)
Representative:	Schweiger, Georg Patentanwälte Reitstötter, Kinzebach & Partner (GbR) Sternwartstrasse 4 81679 München (DE)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 9 February 2010 revoking European patent No. 1224273 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman A. Lindner
Members: T. Sommerfeld
L. Bühler

Summary of Facts and Submissions

I. European patent No. 1224273, based on application No. 00962260.6, entitled "Enzyme granulate" and published as international application WO 01/25412, was granted with 39 claims.

II. Three oppositions were filed against the granted patent, all opponents requesting revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Articles 54 and 56 EPC and Article 100(a) EPC). Lack of sufficiency of disclosure (Articles 83 and 100(b) EPC) was also raised by opponent 2, and added subject-matter (Articles 123(2) and 100(c) EPC) by opponent 1.

III. By decision announced at oral proceedings, the opposition division revoked the patent under Article 101(2)(3)(b) EPC, because none of the pending claim requests was considered to fulfil the requirements of the EPC.

The opposition division decided that the claims according to the main request and to the first and third auxiliary requests lacked novelty, that the claims according to the second auxiliary request added subject-matter contrary to Article 123(2) EPC, and that the claims according to the fourth auxiliary request lacked inventive step.

IV. The patent proprietor (appellant) lodged an appeal against that decision. With the statement of the grounds of appeal, the appellant requested that the patent be maintained according to the main request or, alternatively, according to auxiliary requests 1 to 5, all filed with the grounds of appeal.

V. All opponents (respondents) submitted replies to the grounds of appeal, requesting that the appeal be dismissed and the patent revoked in its entirety.

VI. With letter dated 12 January 2011, the appellant replaced its requests by a new main request and new auxiliary requests 1 to 5.

Claim 1 of the **main request** reads:

"1. An enzyme-containing granule comprising a core unit and a shell unit, wherein the core unit comprises the enzyme and is enclosed in a shell unit comprising less than 5 mg of enzyme per gram shell, the ratio between the diameter of the granule and the diameter of the core unit being at least 1.1 and wherein the enzyme content in the core unit, calculated as pure enzyme protein, is in the range of from 25% to 100% by weight of the enzyme core unit, such as no less than 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, or 95% by weight."

Claim 1 of **auxiliary request 1** differs from claim 1 of the main request by addition of the feature "... wherein the size of the core unit, in terms of its relative mass compared to the overall mass of the granule, is up to about 30%."

Claim 1 of **auxiliary request 2** differs from claim 1 of the main request in that the ratio should be at least 1.5: "... the ratio between the diameter of the granule and the diameter of the core unit being at least ~~1.1~~ 1.5..."

Claim 1 of **auxiliary request 3** differs from claim 1 of the main request by addition of the feature "..., and wherein the size of the enzyme core unit, in terms of its diameter in its longest dimension, is between 100 and 500 µm."

In **auxiliary request 4**, claim 1 has been amended by combining the amendments of auxiliary requests 1 and 3.

In **auxiliary request 5**, claim 1 has been amended by combining the amendments of auxiliary requests 2 and 3.

VII. Oral proceedings before the board took place on 8 February 2017 as scheduled. At the end of the oral proceedings, the chairman announced the board's decision.

VIII. The documents cited during the opposition and appeal proceedings include the following:

D15 WO 97/39116
D26 WO 94/19444
D32 Experimental report, filed 9 November 2009

IX. The appellant's submissions may be summarised as follows:

Novelty - main request and auxiliary request 3

The objections of lack of novelty over D15 relied on different parts of this document, in a "pick and mix" approach. The different features were not disclosed in combination in D15, nor were they illustrated by D15's examples. Coating was optional (page 21, first paragraph); the range disclosed in lines 33 to 34 of page 21 was so broad that many of its values would fall

outside of the claimed range. The enzyme content of 0.5 to 20% per weight of the whole granule (page 31, lines 13 to 16) was outside the claim unless coating was present. On page 31, lines 18 to 24, reference was made to a Savinase® activity of 1 to 20 KNPU/g, which was very low as apparent from D26, page 6, last sentence of second full paragraph. D15 did not disclose operating at the very top end of the enzyme content and still less in combination with the top end of the coating content; on the contrary, as the examples showed: page 52, lines 21 to 23 (Example 3); page 53, lines 19 to 20 (Example 4); page 60, line 19 (Example 11), referring to activities which were between 1 and 4% of the activity of D26. The conventional knowledge of the prior art was to have low enzyme content in order to avoid problems with dosing. Hence the skilled person would not seriously contemplate operating in the small area of overlap. The allegedly novelty-destroying embodiments of D15 were not directly and unambiguously disclosed, and would in fact be "added subject-matter" to D15. From D15, page 9, line 21 onwards, it was apparent that the core should also include high proportions of other materials, such as e.g. starch, which lowered the relative amount of enzyme present. In relation to auxiliary request 3, the further feature was again not disclosed in D15 in combination with the other features; hence a further selection had to be made.

Inventive step - auxiliary requests 1, 2, 4 and 5

The patent disclosed the technical problem on page 4, lines 14 onwards, and taught its solution by combining a thinner, more concentrated, core with a thicker shell. This solution, which was rendered plausible by the patent's disclosure, was confirmed by D32: not only

a thicker shell but also a concentrated enzyme activity in the core led to the best residual activity. The technical problem was not to provide alternative granules but rather to provide granules with lower dusting and increased stability. D15 did not disclose that these problems could be solved by using the top ends of the ranges and combining them with this core weight percentage. In fact D15 did not teach to combine these features, and while the skilled person could have put the features together there was no indication that he would do so in order to solve the technical problem. D32 was adequate post-published data, because the solution had been made plausible in the patent, contrary to the situation underlying decision T 1329/04.

X. The respondents' arguments may be summarised as follows:

Novelty - main request and auxiliary request 3

Respondent I referred to page 7, first paragraph, of D15, which disclosed that virtually all of the enzyme was present in the core; hence it could be concluded that the shell unit comprised less than 5 mg of enzyme per gram shell, which was in line with the definition given in the patent in paragraph 14. A diameter ratio of at least 1.1 was also disclosed in D15, as evidenced by the calculations presented in writing by opponent 2. The enzyme content in the core unit was calculated from the ranges given on page 31, lines 13 to 16, and page 21, lines 33 to 34, for the enzyme content in the granule and the coating content, respectively. When using the end points of both ranges, the enzyme content in the core was 40%: this was thus an embodiment that clearly fell within claim 1. Moreover D15 did share the

patent's idea that most of the enzyme should be in the core. The appellant's arguments concerning Savinase®'s activity were not relevant for the claimed subject-matter, which only referred to enzyme in general (not even protease); clearly, different enzymes had different specific activities. The further feature of claim 1 of auxiliary request 3 was disclosed in D15, page 20, lines 9 to 14.

Respondent II added that the calculation of the enzyme content in the core disclosed in D15 did not require a two-fold selection, but rather the use of two parameters. By using the two ranges given on pages 31 and 21, the enzyme content in the core was calculated as being 0.503 to 40%. This range overlapped with the range of 25 to 100% of the claim and the skilled person would consider working in the overlap, as evident from D15, page 31, lines 8 to 11. The entire teaching of D15, and not only the examples, was relevant for the question whether the skilled person would contemplate working in the overlap (T 124/87). As regards auxiliary request 3, the further feature consisted of an arbitrary limitation within the range that was familiar to the skilled person.

Respondent III added that there was no prejudice in the prior art against using high enzyme content in the granule: on the contrary, D15 taught it (page 31). Claim 1's range was very broad and started at 25%, which was well below the 40% upper end of D15. As regards the use of starch, disclosed on page 9 of D15, claim 1 also encompassed carrier material, and in fact this was also the case for the examples of the patent (dextrin, PEG, etc.). Additionally, the reference to pure enzyme in claim 1 did not mean active enzyme but also included inactive enzyme.

Inventive step - auxiliary requests 1, 2, 4 and 5

Respondent I argued that the distinguishing feature over D15 had no technical effect, since none was disclosed in the patent nor put forward by the appellant in its submissions. As such it was a randomly selected feature which could not justify an inventive step. The problem to be solved was just an alternative. D32's experiments did not relate to the distinguishing feature, since D32 did not refer to mass of the core unit. D32's conclusions that a thicker shell led to less dust formation and more stability were already obvious from D15 (page 21). As regarded auxiliary request 2, the same arguments applied: there was likewise no technical effect associated with the feature that the ratio should be above 1.5 (as opposed to at least 1.1). The same arguments also applied, mutatis mutandis, to auxiliary requests 4 and 5.

Respondent II added that, in accordance with T 1329/04, the post-published data in D32 should not be taken into account since the patent was entirely silent on a credible effect for any feature at all, and it would not be plausible that any enzyme and any shell content would provide the advantages alleged by the appellant. Moreover, D32 used batches that differed not only in enzyme content, but also e.g. in the sodium sulphate content. The only problem that was plausibly taught in the patent was the provision of an alternative to the granules of D15. Since D15 already disclosed two or more layers of coating (e.g. claim 31), it would be obvious to increase the shell. In fact, D15 made exactly the same assertions as the patent (page 21, line 12 ff.). In relation to auxiliary request 2, following the appellant's submissions on page 6 of the

grounds of appeal (section 5.4) and the calculations submitted in writing, a ratio of at least 1.5 corresponded to a relative core unit mass of up to 30%. Hence the same reasoning as for auxiliary request 1 applied. Similar arguments also applied to auxiliary requests 4 and 5.

Respondent III argued that D32 was not relevant for the subject-matter now claimed. In fact, the combination of features that the appellant considered responsible for the effect was not novel over D15, and D32 did not allow comparison with the novelty-destroying granules of D15, wherein a higher enzyme content was disclosed. D15 also disclosed the technical problem of producing granules with low dust formation (page 3, page 6) and with improved enzyme stability (page 6). Since there was no data allowing comparison with the closest prior art and no technical effect shown related to the distinguishing feature, the problem had to be formulated as the provision of alternative formulations of stable enzyme granules comprising a granule core. The solution was obvious from D15 alone, teaching that an increase in the protective layer resulted in less dust formation and in stabilization of the enzyme. The size of the protective layer would be chosen according to the applications of the enzyme. The same arguments applied to auxiliary requests 2, 4 and 5.

XI. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or, alternatively, of one of the first to fifth auxiliary requests filed with letter of 12 January 2011.

The respondents (opponents) requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. Main request

2.1 Claim 1 - novelty over D15

2.1.1 Document D15 discloses enzyme-containing granules comprising a core unit and a shell unit ("coating layer" in D15, described e.g. on page 21, first paragraph), wherein the core unit comprises the enzyme (page 7, first paragraph). As regards the further features of claim 1, none of them is explicitly disclosed in D15. The board hence has to decide whether they can be considered implicitly disclosed in D15.

a) **shell unit comprising less than 5 mg of enzyme per gram shell**:

The above-mentioned passage of D15 on page 7, first paragraph, states that "at least 90% w/w" or even "essentially all (i.e. essentially 100% w/w) of the enzyme content of the granule is present as enzyme absorbed within the core". If 100% of the enzyme is within the core, then there will be no enzyme at all in the shell unit, meaning that the requirement of less than 5 mg of enzyme per gram shell is fulfilled. This conclusion is also in line with the patent's definition (paragraph [0014]) of "substantially enzyme free" shell unit as being equivalent to "less than 5 mg of enzyme per gram shell".

b) **ratio between the diameter of the granule and the diameter of the core unit being at least 1.1:**

Claim 1 does not restrict the particle size in terms of absolute values but instead in terms of a ratio between the diameter of the whole particle and the diameter of the core unit. D15, on the other hand, does not specify any ratios, but discloses a mean particle size of the granules of 50 to 4000 µm (page 19, line 35 to page 20, line 1) and a mean particle size of the core unit of 50 to 200 µm (page 20, lines 12 to 14); although not specified in D15, the reference to "size" in this context is in fact a reference to diameter, and this interpretation is also in line with the patent, which refers to size as being defined in terms of "diameter in its longest dimension" (paragraph [0021]). It follows that the granules of D15 necessarily have a ratio between the diameters of the granule and of the core unit of between 1.0 (when no shell unit is present) and 80 (largest granule size with smallest core unit: 4000/50=80). Since D15 envisages particles with a size of up to 4000 µm but with a core unit size of at the most 200 µm, it is implicit that a large number of the particles disclosed in D15 fulfil the ratio requirement of at least 1.1, namely at least all those with a granule size between 220 µm and 4000 µm (220/200=1.1).

c) **enzyme content in the core unit, calculated as pure enzyme protein, is in the range of from 25% to 100% by weight of the enzyme core unit:**

D15 discloses on page 31, lines 13 to 16, that the enzyme content is 0.5 to 20% per weight of the enzyme-containing granule. On page 21, lines 33 to 34, D15 discloses that the coating constitutes 0.5 to 50% per

weight of the finished granule. It is thus apparent that the enzyme content in the core unit per weight of the enzyme core unit is up to 40% (enzyme content of 20% with a coating of 50%/weight of the enzyme-containing granule, considering that essentially all enzyme is present in the core: D15, page 7, first paragraph). This range thus overlaps with the claimed range of 25 to 100%, meaning that a large number of D15's granules fall within the claimed range.

2.1.2 Hence each of the features of claim 1 of the main request is disclosed in D15, either explicitly or, as discussed above, implicitly and directly derivable from explicitly disclosed features. The combination of these features is also disclosed in D15, because these features are not part of specific examples but rather of the general disclosure of D15. They are also interrelated, since e.g. a diameter ratio between the whole granule and its core unit is only relevant for granules comprising a shell unit, and the calculations of the enzyme content in the core unit are also performed in the context of shell-unit-comprising granules, wherein essentially all enzyme is in the core unit. Finally, that the shell unit should be substantially free of enzyme is disclosed in D15 as a "particularly valuable" embodiment. D15 thus directly and unambiguously discloses enzyme-containing granules comprising a core unit and a shell unit, wherein the shell unit is substantially free of enzyme, wherein the ratio between the diameter of the granule and of the core unit is at least 1.1, and wherein the enzyme content in the core unit is in the range of up to 40% by weight of the enzyme core unit.

2.1.3 It follows that, contrary to the appellant's arguments, the novelty objection is not based on an unallowable

selection from different lists, namely the presence or absence of a coating layer combined with the ranges for granule size, core size, total enzyme content and percentual coating content. In fact, there are no lists at all in D15, but rather ranges of values for granule and core sizes and enzyme and coating contents. In order to arrive at the parameters which define the subject-matter as claimed, these ranges had to be combined because the parameters used in the claim, being in the form of ratios or percentages, are themselves a combination of parameters: granule and core sizes had to be combined to calculate the ratio between granule and core diameter, and the percentual enzyme content of the granule and coating percentage per weight had to be used in order to estimate the percentual enzyme content of the core. Hence the need to refer to distinct parts of D15 derives from the fact that the granules as claimed and the granules of D15 are defined by different parameters.

2.1.4 A further argument of the appellant was that none of D15's examples fell within the scope of claim 1; in particular they did not work within the above-mentioned area of overlap of the enzyme-content range. Hence the skilled person would not seriously contemplate working within this area of the disclosed range, and this was also in line with the usual practice in the field, which favoured the use of less concentrated enzyme (thus lower percentual enzyme content) in e.g. powder formulations. Moreover, D15 referred on page 31, lines 18 to 21, to typical enzyme activities that corresponded to enzyme contents below the one claimed, as was made apparent by D26, disclosing the enzyme activity of Savinase®.

As regards these arguments, the board notes that novelty is to be assessed vis-à-vis the whole disclosure of a prior art document, the examples being only a part thereof: it is therefore sufficient that the general part of the description of a prior art document discloses embodiments which are novelty-destroying, even if the embodiments disclosed in the examples are not. Moreover, it is noted that D15 in fact teaches that "For many applications, the enzyme content will be as high as possible or practicable" (page 31, lines 10 and 11), which is thus a clear teaching to work at the higher end of the range. The argument concerning Savinase® activity is also not relevant for present claim 1, because this claim is not restricted to Savinase® at all, nor to any protease. The fact that a passage of D15's description (on page 31, lines 18 to 21) refers, by way of example, to a specific protease activity does not impose any limitations on the remaining disclosure. Moreover, claim 1 refers to "pure enzyme" content but is not restricted to active enzyme: in fact, it is not excluded that inactive enzyme may also be present, which of course would not feature in the calculations made on basis of the enzyme activity.

2.1.5 Finally, the appellant also made reference to page 9, line 21 ff., of D15, teaching that preferred types of cores also comprised high proportions of other materials, such as e.g. starch, which necessarily led to a decrease in the relative amount of enzyme that could be loaded into the core. The board notes that the claimed subject-matter also does not exclude the presence of components other than enzyme in the core unit, and in fact, since the enzyme content range starts at 25% w/w by weight of core unit, there is plenty of room to accommodate 25% w/w or even 50% w/w

(based on total core weight) of starch, as disclosed in the mentioned passage of D15.

2.1.6 The board thus comes to the conclusion that claim 1 of the main request lacks novelty over D15. The main request is therefore not allowable for lack of compliance with Article 54(2) EPC.

3. Auxiliary request 1

3.1 Claim 1 of this request differs from claim 1 of the main request by addition of a feature (see section VI). The respondents had no novelty objections based on document D15 against this claim.

3.2 Claim 1 - inventive step

3.2.1 The patent is directed to enzyme-containing granules comprising a core unit and a shell unit, which display advantages such as low dust and odour levels, reduced contents of granulate additive and improved storage ability of the enzyme. In order to achieve these advantages, the granules of the patent have the enzymatic activity concentrated into the central core unit, which is small and is surrounded by a thicker shell unit (paragraph [0016]).

3.2.2 Document D15 also discloses enzyme-containing granules and teaches the use of coating layers in order *inter alia* to further reduce dust formation and enhance the storage stability of the enzyme (page 21, lines 8 to 25). Hence D15, which has the same aim as the patent, is considered the closest prior art.

3.2.3 The difference between D15 and claim 1 of auxiliary request 1 is that D15 does not disclose that "the size

of the core unit, in terms of its relative mass compared to the overall mass of the granule, is up to about 30%". There is no information in the patent or elsewhere on file (e.g. post-published experimental data of D32, see also below) that allows to conclude that the granules according to this claim have any advantage over the granules of D15. Hence the technical problem is formulated as the provision of alternative enzyme-containing granules, and the board is satisfied, based on the information given in the patent alone, that this problem has been solved by the subject-matter as claimed.

3.2.4 D15 discloses that the coating has advantageous effects such as reducing dust formation and enhancing enzyme stability, and it also teaches the use of two or more layers of coating (e.g. claim 31). Hence granules with an increased shell unit mass appear an obvious alternative to the granules of D15. An increase of the shell unit mass necessarily results in a percentual reduction of the core unit mass, and the specific limit of 30% core unit mass in relation to the overall granule mass is considered an arbitrary selection. Hence the claimed solution does not involve an inventive step.

3.2.5 The appellant argued, based on D32, that the technical problem was not to provide alternative granules but rather to provide granules with lower dusting and increased stability in comparison to the granules of D15. The board notes however that D32 does not allow to conclude that the granules according to the patent are improved in relation to those of D15 because none of the granule batches which are used as control in D32 corresponds to those granules of D15 which constitute the closest prior art, i.e. those granules of D15 which

only differ from the granules as claimed by the relative mass of the core unit. As can be seen in the table of page 2 of D32, batches 1 and 3 have a protein (i.e. enzyme) content in the core unit of only 4%, which is outside the overlapping range area of 25 to 40% (section 2.1.1, item (c)).

3.2.6 As regards appellant's argument that D15 did not teach to combine all the features as claimed in order to provide granules with lower dusting and increased stability, the board notes that in fact D15 does teach using a coating layer for this very purpose (see section 3.2.4). This argument is thus not persuasive in the context of the technical problem of provision of alternative granules.

3.2.7 Auxiliary request 1 is hence not allowable for lack of compliance with Article 56 EPC.

4. Auxiliary request 2

4.1 Claim 1 - inventive step

4.1.1 The board agrees with respondent II's observations that a size ratio of at least 1.5 essentially corresponds to a relative core mass of up to 30%; this was not disputed by the appellant. Hence claim 1 of auxiliary request 2 covers the same subject-matter as claim 1 of auxiliary request 1, and is thus likewise not inventive.

4.1.2 Auxiliary request 2 is hence not allowable for lack of compliance with Article 56 EPC.

5. Auxiliary request 3

5.1 Claim 1 - Novelty

5.1.1 In addition to the features discussed in connection with claim 1 of the main request (see section 2.1 above), document D15 also discloses granules comprising core units with a size falling within the range of 100 to 500 µm (e.g. page 20, line 14, disclosing a mean core particle size in the range of 50 to 200 µm). Hence claim 1 of auxiliary request 3 lacks novelty over D15.

5.1.2 The appellant's arguments that this further feature was not disclosed in D15 in combination with the other features of the claim are not convincing. One of the said other features is the ratio between the total granule diameter and the core diameter, and thus is directly related to this further feature.

5.1.3 Auxiliary request 3 is hence not allowable for lack of compliance with Article 54(2) EPC.

6. Auxiliary requests 4 and 5

6.1 Claim 1 - inventive step

6.1.1 Claim 1 of these requests comprises the amendments of auxiliary request 3, combined with the amendments of auxiliary request 1 (in auxiliary request 4) and of auxiliary request 2 (in auxiliary request 5). Hence these requests also lack inventive step for the same reasons as given above in relation to auxiliary requests 1 and 2.

6.1.2 Auxiliary requests 4 and 5 are thus not allowable for lack of compliance with Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin A. Lindner

Decision electronically authenticated