

Internal distribution code:

- (A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

**Datasheet for the decision
of 4 May 2017**

Case Number: T 0747/11 - 3.3.02

Application Number: 00962258.0

Publication Number: 1224272

IPC: C12N9/98, C12N9/00, C11D3/386,
A23K1/165, A23L1/03

Language of the proceedings: EN

Title of invention:
SPRAY DRIED ENZYME PRODUCT

Patent Proprietor:
Novozymes A/S

Opponent:
BASF SE

Headword:
Spray-dried enzymes/NOVOZYMES

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

Keyword:
Novelty - (no) prior disclosure - implicit features
Inventive step - (no)

Decisions cited:

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 0747/11 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 4 May 2017

Appellant: Novozymes A/S
(Patent Proprietor) Krogshøjvej 36
2880 Bagsvaerd (DK)

Representative: Potter Clarkson LLP
The Belgrave Centre
Talbot Street
Nottingham NG1 5GG (GB)

Appellant: BASF SE
(Opponent) Carl-Bosch-Str. 38
67056 Ludwigshafen (DE)

Representative: BASF IP Association
BASF SE
G-FLP-C006
67056 Ludwigshafen (DE)

Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
18 February 2011 concerning maintenance of the
European Patent No. 1224272 in amended form.

Composition of the Board:

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

Summary of Facts and Submissions

- I. European patent No. 1224272, based on European patent application No. 00962258.0, which was filed as an international patent application published as WO 2001/025411, was granted with 28 claims.
- II. Opposition was filed against the granted patent, the opponent requesting revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Articles 54(2) and 56 EPC and Article 100(a) EPC), and lack of sufficiency of disclosure (Article 100(b) EPC).
- III. During the proceedings before the opposition division, the patent proprietor requested that the opposition be rejected and the patent maintained as granted (main request) or alternatively according to one of the first to fourth auxiliary requests.
- IV. By an interlocutory decision announced at oral proceedings, the opposition division decided to maintain the patent in amended form on the basis of the fourth auxiliary request filed at the oral proceedings (Articles 101(3)(a) and 106(2) EPC).

The opposition division considered that the claim sets according to the main request (claims as granted) and the second and third auxiliary requests lacked novelty, and that the claims according to the first auxiliary request lacked inventive step.

- V. The patent proprietor lodged an appeal against that decision. With its statement of grounds of appeal, the appellant-patent proprietor requested that the patent be maintained as granted (main request) or

alternatively according to one of the first to seventh auxiliary requests filed with the grounds of appeal.

VI. The opponent also lodged an appeal against the decision of the opposition division. With its statement of grounds of appeal, the appellant-opponent requested that the decision be set aside and the patent revoked in its entirety.

VII. Both parties sent replies to each other's grounds of appeal.

VIII. During the oral proceedings before the board, which took place on 4 May 2017, the appellant-patent proprietor withdrew the pending main request, first auxiliary request and fifth auxiliary request. The pending second, third, fourth, sixth and seventh auxiliary requests filed with the grounds of appeal hence became the main request and first to fourth auxiliary requests respectively. At the end of the oral proceedings, the chairman announced the board's decision.

IX. Claim 1 of the **main request** is identical to claim 1 as granted. It reads:

"1. A process for preparing an enzyme containing particle comprising spray drying a fermentation broth starting material comprising an enzyme and a biomass, to obtain a solid particle comprising an enzyme and a biomass, and wherein the biomass comprises cell debris."

Claim 1 of **auxiliary request 1** is identical to claim 1 of the main request.

Claim 1 of **auxiliary request 2** differs from claim 1 of the main request by the following amendment:

"1. A process for preparing an enzyme containing particle comprising spray drying a sterilised fermentation broth starting material ..."

Claim 1 of **auxiliary requests 3 and 4** differs from claim 1 of the main request by further defining that the enzyme is to be selected from carboxylic ester hydrolases (EC 3.1.1.-), phytases (EC 3.1.3.-), peptidases (EC 3.4, also known as proteases), α -amylases (3.2.1.1), β -amylases (3.2.1.2), glucan 1,4- α -glucosidases (3.2.1.3), cellulases (3.2.1.4), endo-1,3(4)- β -glucanases (3.2.1.6), endo-1,4- β -xylanases (3.2.1.8), dextranases (3.2.1.11), chitinases (3.2.1.14), polygalacturonases (3.2.1.15), lysozymes (3.2.1.17), β -glucosidases (3.2.1.21), α -galactosidases (3.2.1.22), β -galactosidases (3.2.1.23), amylo-1,6-glucosidases (3.2.1.33), xylan 1,4- β -xylosidases (3.2.1.37), glucan endo-1,3- β -D-glucosidases (3.2.1.39), α -dextrin endo-1,6- α -glucosidases (3.2.1.41), sucrose α -glucosidases (3.2.1.48), glucan endo-1,3- α -glucosidases (3.2.1.59), glucan 1,4- β -glucosidases (3.2.1.74), glucan endo-1,6- β -glucosidases (3.2.1.75), arabinan endo-1,5- α -L-arabinosidases (3.2.1.99), lactases (3.2.1.108) and chitosanases (3.2.1.132).

X. The documents cited during the proceedings before the opposition division and the board of appeal include the following:

E4 WO 91/18521
E5 EP 615693
E6 WO 97/47736

E9 GB 1360969
E10 WO 91/06638
E16 EP 758018

XI. The submissions of the appellant-patent proprietor, in so far as relevant to the present decision, may be summarised as follows:

Novelty (main request and auxiliary request 1)

E6 did not directly and unambiguously disclose the combination of features as claimed, in particular it did not disclose a particle, obtained by spray-drying, comprising an enzyme and cell debris. E6 taught that the cells had to be lysed if the enzyme was retained within the cells, but it did not teach what happened to the cell lysate; the skilled person would consider that the lysate was removed before spray drying, since this was the usual practice in the prior art (E4, page 21 lines 14 ff., page 23, lines 16 ff., page 39, Example 7, lines 14 to 16; E9, page 2, lines 16 to 39; E10, page 6, second full paragraph). In fact, before the priority date fermentation efficiency was so low that the obtained enzyme concentration in the fermentation broth would not be sufficient to recover enough enzyme without further purification; moreover it would be undesirable to have the colour and/or odour of the fermentation broth in the final product, e.g. a household detergent. The opponent's argument that the prior art also taught the possibility of keeping the cells in the final product just proved that there were multiple alternatives, and hence that it was not implicit in E6 that biomass was present in the spray-dried product. E4 disclosed a completely different embodiment on page 29 and in Example 20, namely a "direct fed microbial" comprising whole cells (not cell

debris), which were required in the final product. The passage in E9 on page 3, line 23, tied in with the passage on page 2, lines 17 to 21, also disclosing salt precipitation, which made it clear that the fermentation broth should be purified before spray-drying. The skilled person would hence either use enzyme preparations with whole cells (E4) or purified enzyme (E9), but not enzyme preparations with cell debris.

Inventive step (auxiliary requests 2 to 4)

The effect of sterilising the fermentation broth was to produce cell debris. E9 was the closest prior art because it was directed to the same aim as the patent (patent, paragraph [0008]), and shared many features with the claimed subject-matter. By contrast, E6 related to a very particular, niche enzyme and not to recovery of enzymes in general. E9 related to industrial, large-scale, enzyme production, and disclosed three embodiments on page 2, lines 17 to 39, which all required a fermentation liquor without cell debris. E5 did not mention enzymes at all. The deliberate generation of cell debris by sterilisation had the surprising effect that, even keeping cell debris in the system, a product with high enzymatic activity could be produced, as shown in the examples of the patent. When starting from E6, the disclosure on pages 10 and 11 would not lead the skilled person to carry out a process with sterilisation. Auxiliary requests 3 and 4, unlike E6, focused more on industrially interesting enzymes. Starting from E9, which mentioned some of these enzymes, the technical problem would be to provide another process for producing the same product. There was no motivation to combine E9 with E6 and even if one were to do so, E9

clearly taught to remove the cell debris from the fermentation broth.

- XII. The arguments of the appellant-opponent, in so far as relevant to the present decision, may be summarised as follows:

Novelty (main request and auxiliary request 1)

E6 disclosed all the features of claim 1, the only disputed feature being the presence of cell debris in the spray-dried product. The passage on page 11, first two lines, taught to lyse cells, meaning that the cells were not intact and hence cell debris was present. On the same page, the passage starting on line 17 made it clear that the product was not completely purified when spray dried, and that it could still be further purified afterwards. It was not considered mandatory in the prior art to remove the biomass before spray-drying: E4, page 29, line 7 ff. and Example 20 on pages 53 and 54; E9, page 3, line 19 ff., line 31 ff. and line 39 ff.

Inventive step (auxiliary requests 2 to 4)

In auxiliary request 2, the feature "sterilised" had been introduced just to render claim 1 novel, but it did not add any technical effect. E6 was the closest prior art and the technical problem was to provide an alternative method. Combination with E5, which taught thermal and chemical sterilisation of fermentation broths (page 7, lines 49 to 50) in processes involving spray-drying, rendered the claimed solution obvious. E6's enzyme was also of industrial interest, in particular it was used to produce herbicides. There was no data indicating that the method as claimed resulted

in higher enzymatic activity than the method of E6. Moreover, it was of course known that the cells would be destroyed by sterilisation. Regarding auxiliary requests 3 and 4, the selection of around 30 enzymes rendered the claim novel but not inventive. Some of these enzymes were also disclosed in E9 (claims 8 to 10), E4 (page 1, lines 8 to 9) and E16 (page 3, line 34 ff.). Additionally, *Aspergillus oryzae* itself produced several enzymes, such as amylases, phytases, etc. Starting from E9, the technical problem would be to obtain the non-secreted enzymes; E6 would teach to produce lysates. The fact that E6 related to a different enzyme played no role, because it was common knowledge that the same process could be used for many different enzymes.

XIII. The appellant-patent proprietor requested that the decision under appeal be set aside and that the patent be maintained according to the main request filed as auxiliary request 2 with the statement of grounds of appeal, or, alternatively, according to any of auxiliary requests 1 to 3 filed as auxiliary requests 3, 4 and 6 with the statement of grounds of appeal, or, alternatively, that the opponent's appeal be dismissed (which corresponds to the maintenance of the patent according to auxiliary request 4 filed as auxiliary request 7 with the statement of grounds of appeal).

The appellant-opponent requested that the decision under appeal be set aside and that European patent No. 1224272 be revoked.

Reasons for the Decision

1. Both appeals are admissible.

2. Main request

2.1 Novelty of claim 1

2.1.1 Claim 1 is essentially directed to a process for preparing a solid particle comprising an enzyme and cell debris, wherein the process comprises spray-drying a fermentation broth comprising an enzyme and cell debris (for the exact claim wording see section IX).

2.1.2 Document E6 discloses methods for the recombinant production of an enzyme (5-aminolevulinic acid synthase) by the fungal host cell *Aspergillus oryzae*, which involve fermenting the host cell and recovering the enzyme either directly from the medium - if the enzyme is secreted - or from the cell lysates - if the enzyme is not secreted (page 10, line 22 to page 11, line 2). On page 11, lines 14 to 16, E6 further specifies that the enzyme is recovered from the fermentation medium by conventional procedures, including spray-drying. By definition, spray-drying produces a solid material, i.e. solid particles, and cell lysates are composed of destroyed cells, i.e. undissolved parts of cells, also called cell debris. Hence E6 explicitly discloses a process for preparing an enzyme, comprising spray-drying a fermentation broth starting material which contains an enzyme and a biomass comprising cell debris. As such, E6 is novelty destroying for the subject-matter of claim 1.

- 2.1.3 The appellant-patent proprietor essentially argued that the enzyme particles of E6 did not contain cell debris because, as shown by E4, E9 and E10, it was normal practice to filter and/or purify fermentation broths prior to spray-drying. Hence, although not explicitly disclosed in E6, the skilled person would interpret E6's teaching as necessarily requiring the removal of biomass before spray-drying.
- 2.1.4 The board is not convinced that any of the documents mentioned (E4, E9, E10) can be considered as representative of the "conventional method" of spray-drying at the time of the invention: instead, they describe different methods for recovery of enzymes from a fermentation broth, none of them being identified as the "conventional" method. Additionally, the passage in E4 referred to by the appellant-patent proprietor, namely page 23, lines 16 to 21, is not relevant for the claimed subject-matter because it is not in the context of enzyme recovery by spray drying. In fact the two passages in E4 where spray-drying is disclosed do not require any removal of cells or cell debris at all (E4, page 29, last paragraph, and page 54, lines 7 to 9). Similarly, E9 discloses a process wherein a "fermentation liquor from which all suspended particles have been removed" is used (page 2, lines 28 to 29), but it also discloses a process wherein "filter cakes containing the proteolytic enzyme together with inactive organic matter" (page 3, lines 23 to 25) are used for spray-drying (page 3, lines 39 to 42).
- 2.1.5 Hence, it cannot be concluded from the documents available that it was conventional in the art, let alone mandatory, to remove the biomass from the fermentation broth before spray-drying it. Since E6 does not disclose such a purification step or a step of

removing biomass, there is no reason to assume that such a step would be implicit in the disclosure. On the contrary, the disclosure of the relevant passages of E6 shows that, even if such a step occurred, it nevertheless did not remove all the biomass: in the same paragraph that refers to spray-drying as one of the possible "conventional procedures" for protein recovery, E6 teaches further purification of the protein after its recovery (page 11, lines 16 to 19).

2.1.6 The appellant-patent proprietor further argued that, in view of low fermentation yields and to avoid the final product having an undesirable colour and/or odour, the skilled person would consider that further purification was needed before spray-drying. The board notes, however, that further purification could take place after protein recovery instead, as envisaged by E6 (supra), if deemed necessary. The above-mentioned passage of E6 makes it clear that, even if some removal of biomass may have conceivably taken place before spray-drying, it was, however, not complete: this is also in line with the patent's disclosure, wherein all examples comprise a sieve step "to remove large solid particulates" which is performed before spray-drying.

2.1.7 The main request is thus not allowable for lack of novelty (Article 54(2) EPC).

3. Auxiliary request 1

3.1 Claim 1 of auxiliary request 1 is identical to claim 1 of the main request. Hence this request is also not allowable for lack of novelty (Article 54(2) EPC).

4. Auxiliary request 2

4.1 Inventive step of claim 1

4.1.1 The patent is directed to processes to produce dry particulate enzyme products, whereby the "products should be cheap with respect to processes and process components and chemicals but should also provide the enzyme product with desired properties such as improved enzyme storage stability, lowered dusting characteristics, improved particle mechanical strength, desired color, shape and size" (paragraph [0004]). Paragraph [0008] further states that "[t]he present invention provides simple and cost effective processes for producing dry enzyme particles having good properties".

4.1.2 The closest prior art should hence also be a document that discloses production of solid enzyme particles. As discussed above in relation to the novelty of claim 1 of the main request, document E6 discloses a method of producing a particle comprising an enzyme and cell debris by "conventional procedures" such as spray-drying (page 11, lines 14 to 16). Document E6 is hence the closest prior art.

4.1.3 The only difference over the method of E6 is that the method as claimed makes use of a sterilised fermentation broth. The patent does not disclose any technical effect associated with this particular feature, and the appellant-proprietor confirmed that the technical effect was to deliberately produce cell debris. Since the same effect of generating cell debris is implicitly disclosed in E6 as well (as concluded above under novelty, point 2.1.2), the technical problem can be formulated as the provision of an alternative method for enzyme recovery. The board is

satisfied that the technical problem is solved by the solution as claimed.

- 4.1.4 However, the board considers that the difference of the claimed method over the method of the closest prior art is simply a trivial routine modification - known e.g. from E5 (page 7, lines 49 to 50) - of the known method. Hence, no inventive step can be acknowledged.
- 4.1.5 The appellant-proprietor disagreed that E6, which was directed to a very specific enzyme rather than to methods of enzyme purification in general, could be considered the closest prior art. In its view, the closest prior art should be E9, since this document was directed to the same aim as the patent and shared many features with the claimed subject-matter.
- 4.1.6 According to the established case law of the boards of appeal, the closest prior art for assessing inventive step is normally a prior art document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural modifications. As regards the first criterion, the board notes that a *priori* any document disclosing production of solid enzyme particles could be a suitable starting point for the discussion of inventive step. Such documents include E9 but also E6, which is clearly concerned with the production of enzymes too: even if the focus of the document is on the provision of a new enzyme, E6 nevertheless discloses its production as well, as discussed above; in fact, methods of production of the enzyme are also a central aspect of E6's disclosure, as is apparent from e.g. the abstract and the sections "Field of the Invention" and "Summary of the

Invention". E6, moreover, further satisfies the second criterion of having the most relevant technical features in common with the claimed subject-matter, since it discloses all the technical features of the claimed method, with the exception of the distinguishing feature that the fermentation broth is sterilised.

4.1.7 Auxiliary request 2 is thus not allowable for lack of inventive step (Article 56 EPC).

5. Auxiliary request 3

5.1 Inventive step of claim 1

5.1.1 Claim 1 of auxiliary request 3 differs from claim 1 of the main request in that it is restricted to particular groups of enzymes which, according to the appellant-patent proprietor, are enzymes of industrial relevance.

5.1.2 For the reasons mentioned above in relation to auxiliary request 2, E6 is the closest prior art. The difference between E6 and the subject-matter as claimed is that a specific enzyme is used in E6, namely 5-aminolevulinic acid synthase, while the claim, directed to a large number of different enzymes belonging to different groups, does not encompass this particular enzyme. Apart from the production of further enzymes, there is no evidence in the patent or elsewhere on file that this difference is associated with any specific technical effect. The technical problem is thus formulated as the provision of processes for the production of further enzymes, and the board is satisfied that this problem has been solved by the claimed subject-matter.

- 5.1.3 The board concludes, however, that the solution lacks inventive step, because it would be trivial for the skilled person, motivated to produce further enzymes, to simply use the process disclosed for one particular enzyme (such as in E6) for other enzymes too.
- 5.1.4 The appellant-patent proprietor maintained that, as for auxiliary request 2, E9 and not E6 should be taken as the closest prior art, in line with the decision of the opposition division. In particular, in view of the fact that the claim was directed to industrially-relevant enzymes, the skilled person would not rely on E6, which was concerned with an enzyme of academic rather than industrial interest. The board does not find these arguments persuasive. E6 refers to "conventional" enzyme recovery methods in general and is not restricted to enzyme purification at laboratory scale. Moreover, as argued by the appellant-opponent and not contested by the appellant-patent proprietor, the specific enzyme of E6 also has industrial applications that require its large-scale production. It thus follows that again E6 has the most features in common with the claimed subject-matter, as it in fact discloses all the technical features of the claimed method, with the exception of the specific enzymes.
- 5.1.5 Auxiliary request 3 is thus not allowable for lack of inventive step (Article 56 EPC).

6. Auxiliary request 4

- 6.1 Claim 1 of auxiliary request 4 is identical to claim 1 of auxiliary request 3. Hence this request is also not allowable for lack of inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



N. Maslin

A. Lindner

Decision electronically authenticated