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**Datasheet for the decision
of 29 July 2020**

Case Number: T 1487/17 - 3.3.06

Application Number: 09756878.6

Publication Number: 2350250

IPC: C11D3/386, C11D17/00

Language of the proceedings: EN

Title of invention:

DELIVERY SYSTEM FOR CO-FORMULATED ENZYME AND SUBSTRATE

Patent Proprietor:

Danisco US Inc.

Opponents:

Henkel AG & Co. KGaA
NOVOZYMES A/S

Headword:

Danisco/enzyme-substrate

Relevant legal provisions:

EPC Art. 83, 123(2), 56
RPBA Art. 13
RPBA 2020 Art. 13(1), 25(3)

Keyword:

Amendments - allowable (yes)

Admissibility of appeal

Inventive step - non-obvious combination of known features -
could-would approach

Late filed request - admitted (yes)

Decisions cited:

T 0074/10

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1487/17 - 3.3.06

D E C I S I O N
of Technical Board of Appeal 3.3.06
of 29 July 2020

Appellant:
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Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
28 April 2017 maintaining European Patent No.
2350250 in amended form.**

Composition of the Board:

Chairman J.-M. Schwaller

Members: S. Arrojo

J. Hoppe

Summary of Facts and Submissions

- I. The present appeals, filed by opponent 1 ("Henkel AG & Co. KGaA") and opponent 2 ("Novozymes"), from now on also referred to as "the appellants", lie against the interlocutory decision of the opposition division to maintain European patent No. 2 350 250 on the basis of the main request as filed with letter dated 16 February 2017.
- II. With their grounds of appeal the appellants requested to set aside the above decision and to revoke the patent for lack of novelty and inventive step. Further they submitted documents D17 and D18.
- III. In its reply the patentee and respondent ("Danisco US. Inc.") requested to reject the appeals or, auxiliarily, to maintain the patent on the basis of one of auxiliary requests 1-5 filed together with this reply. Further it submitted document D19.
- IV. The board issued a communication to inform the parties of its preliminary opinion that the main request was not novel in view of document D4 (WO 01/23513 A1) and that auxiliary requests 1-5 did not appear to be inventive in view of document D10 (WO 2008/084093 A2).
- V. With letter dated 2 June 2020 the respondent submitted new auxiliary requests 4 to 9, with auxiliary requests 4 and 5 being substantively identical to those already on file, which however included minor errors in the claims dependencies.
- VI. At the oral proceedings held on 29 July 2020, the appellants requested not to admit auxiliary requests

6-9 as late filed. At the end of the debate, the respondent made auxiliary request 4 as the new main request and it withdrew all further requests.

The appellants argued that the new main request was not inventive in view of document D10 combined with either D6 (US 2008/0189871 A1) or D7 (DE 10 2007 036 392 A1), and that it did not meet the requirements of Articles 83 and 123(2) EPC.

VII. Claim 1 of the new main request reads as follows:

"A liquid delivery system for co-formulated enzyme and substrate, wherein the delivery system is a composition comprising an enzyme and a substrate for the enzyme, wherein the enzyme is encapsulated in a water-soluble polymeric matrix and the substrate is present in a substantially non-aqueous liquid phase in contact with the polymeric matrix in which the enzyme is encapsulated, wherein the polymer is not soluble in the liquid phase, wherein the substantially non-aqueous liquid phase comprises less than about 5% water; wherein:

(a) the enzyme is a perhydrolase and the substrate is an ester substrate; or

(b) the enzyme is a perhydrolase and the substrate propylene glycol diacetate;

(c) the enzyme is a laccase enzyme, and the substrate is a laccase mediator; or

(d) the enzyme is a phenol oxidizing enzyme, and the substrate is selected from the group consisting of 2,2'-azino-bis(3-ethylbenzothiazoline-6-sulfonate), syringamide, and syringonitrile; or

(e) the enzyme is a perhydrolase and the substrate is an ester substrate, and the delivery system further comprises sodium perborate."

VIII. Before the closure of the debate, the parties' requests were established to be as follows:

The appellants requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

The respondent requested that the patent be maintained in amended form based on the new main request (formerly auxiliary request 4 filed with letter dated 2 June 2020).

Reasons for the Decision

1. Admittance of the new main request

1.1 In the present case, since the summons to oral proceedings were notified before the date of entry into force of the RPBA 2020, Article 13(2) RPBA 2020 shall not apply (see transitional provisions - Article 25(3) RPBA 2020). The question of admittance is thus governed by Articles 13 RPBA 2007 and 13(1) RPBA 2020.

1.2 Since the substantial content of this request is identical to that of auxiliary request 4 filed with the reply to the grounds of appeal and corresponds to the second auxiliary request filed during first instance proceedings, the board exercises its discretion under Articles 13 RPBA 2007 and 13(1) RPBA 2020 to admit it into the appeal proceedings.

2. Article 83 EPC

2.1 The board has concluded that the invention complies with the requirements of Article 83 EPC.

- 2.2 Opponent 1 argued that the patent did not define how the features "*water-soluble*" and "*not soluble in the liquid phase*" should be interpreted. Since claim 1 encompassed polymers which were partially soluble in water and partially insoluble in the liquid phase, this would lead to partial dissolution of the particles and so to embodiments which would not solve the underlying technical problem. Furthermore, the definition of "*substrate*" also led to a problem of insufficiency of disclosure, because the invention considered laccase mediators as a substrate, which was in contradiction with the general meaning of substrates as substances on which the enzyme exerted its catalytic activity to form a product.
- 2.3 Opponent 2 argued that the claims covered embodiments in which the enzyme and the substrate were present together in the liquid phase inside a polymeric matrix. There was however no enabling disclosure as to how this embodiment could be carried out while keeping the enzyme and the substrate separated.
- 2.4 The board does not follow the appellants' argumentation for the following reasons:
- It is not reasonable to conclude that the term "*not soluble in the liquid phase*" would encompass polymers being partially soluble in the liquid phase, because this feature precisely intends to exclude polymers which would dissolve (also partially) in the liquid phase. This issue is, in any case, not considered to be relevant for the question of sufficiency of disclosure since a multitude of polymers satisfying this requirement are described in the patent in suit.

- It is not apparent for the board how the inclusion of laccase mediators as substrates would prevent the skilled person from carrying out the invention, since such products are commonly known by the skilled person.

- The board disagrees that claim 1 encompasses embodiments in which the enzyme and the substrate are present in the polymeric matrix, because the wording of the claim clearly defines that the enzyme is encapsulated in the polymeric matrix and the substrate is present in the liquid phase, so that these substances are separated from each other.

2.5 The board therefore has no reason to doubt the invention would be insufficiently disclosed.

3. Main request - Article 123(2) EPC

3.1 The board has concluded that this request complies with the requirements of Article 123(2) EPC.

3.2 The appellants argued that the amendments to claim 1 were based on an arbitrary combination of passages in the description and/or claims as originally filed. In particular, it was noted that the claim dependency did not provide a basis for the amendments, because claims 18, 19 and 21-23 as filed (which appeared to provide a basis for points a)-e) in claim 1) were not dependent on claims 2 and 3 as filed (which provided a basis for the definition of the water content of the non-aqueous liquid phase). Thus, in-line with decision T 510/10, the claims as filed could not be considered to represent an allowable support for claim 1 [the board notes that the cited decision appears to be erroneous, opponent 1 probably intended to refer here to decision T 74/10, reason 3.2]. The description as filed did also

not provide a basis for the amendments, because paragraph [06] (on which the preamble of claim 1 was allegedly based) described additional features which were omitted in claim 1 (e.g. the requirement that the enzyme does not react with the substrate for at least 10 days at 25°C). It was also noted that since claim 1 had been considered to define a non-obvious combination of features, it was contradictory to allow amendments based on a random selection of different portions of the specification as originally filed.

- 3.3 The board does not follow this argumentation because the content of the application as filed should be assessed in view of what a skilled reader would clearly and unambiguously derive from the description and claims as a whole and the reference in paragraph [06] as filed to *"In one aspect of the invention..."* is merely a formal introduction and would not prevent the skilled person from recognising that this passage, corresponding to claims 1-7 as filed, describes the basis of the invention.

While it is true that paragraph [06] is more specific than the preamble of claim 1, the skilled reader would nevertheless recognise that those features of paragraph [06] which have been omitted in the preamble of claim 1 are optional because they are defined as such in dependent claims 6 and 7 as filed.

Since, as indicated above, paragraph [06] and claims 1-7 as filed would be considered as the basis of the invention, the skilled person would clearly recognise that the features defined therein can be combined with the specific alternatives in claims 18, 19, 21, 22 and 23 as originally filed, which provide an explicit support for alternatives a) - e) in claim 1.

The board therefore considers that the subject-matter of claim 1 is supported by the combination of paragraph [06] read in the light of claims 1-7 and combined with claims 18, 19 and 21-23 as originally filed. The case is thus not analogous to that in T 74/10, because claim 1 is based on a combined reading of the claims and the description as filed.

3.4 The subject-matter of claim 1 therefore meets the requirements of Article 123(2) EPC. The dependent claims have not been contested by the opponents and the board does not see any reason to raise any issue under this Article.

4. Main request - Inventive step

4.1 The board has concluded that this request complies with the requirements of Article 56 EPC.

4.2 Closest prior art

4.2.1 Document D10 (WO 2008/084093), which the parties acknowledged as representing the closest state of the art at the oral proceedings, discloses (page 4, lines 6-23) liquid detergent compositions comprising an enzyme encapsulated in a polymeric matrix to keep it separated from substances hostile to its activity or which activate the enzyme, in order to maintain the enzyme isolated from these substances during storage and to ensure that it is only released "*upon contact with wash water*". Among the multitude of specific enzymes proposed in this document, laccase is disclosed on page 16, line 33.

The board notes that D10 does not specifically disclose any of the substances qualified as "hostile" to the

enzyme activity or the substances "which activate" the enzyme, so that it is questionable whether D10 discloses a "substrate" in the sense of the patent, namely a substance on which the enzyme performs its catalytic activity to generate a product. In any case, in the sole exemplary composition of D10 (example 2 on page 29) no substance which falls under this definition, i.e no "substrate", can be identified.

The board concurs with the appellants that D10 discloses (page 25, lines 14-17) a particular embodiment in which the liquid composition comprises less than 20% water, but D10 also refers (page 25, lines 23 to 27) to compositions comprising high amounts of water (of e.g. 30 to 90 %, or 40 to 60% or even 80 to 90 %) and in its sole exemplary composition (example 2 on page 29) the enzyme-containing detergent comprises 52,3 % of water.

4.2.2 Documents D1 (WO 2004/003123 A2), D2 (WO 97 /24177 A1), D4 (WO 01/23513 A1), D5 (EP 0356 239 A2) and D15 (WO 99/00471 A1) have also been cited in the written proceedings as possible starting points for the inventive step argumentation. The board has nonetheless concluded that these documents do not constitute a promising springboard for the following reasons:

- Documents D1 and D2 relate to delivery systems in which a protease is protected from being inactivated by an amylase. These enzymes are not only different from those defined in claim 1 at issue, but are also indicative that in D1 and D2 there is no recognition of the key idea of the invention, namely the delivery of enzymes co-formulated with substrates which enhance their efficiency at the point of use (as it is the case

with the specific enzyme/substrate pairs defined in points a)-e) of claim 1).

- Document D4 discloses (page 2, lines 29-33) providing an active (such as an enzyme), which is isolated in a polymeric matrix to prevent it from being inactivated by other substances or from inactivating other substances in a composition. This document also fails to recognise the main idea of the invention of providing a delivery system in which the enzyme is co-formulated with a substrate to enhance its properties once they come into contact with one another at the point of use.

- Document D5 is similar to D4 but further away from the invention because it proposes (columns 3-4) to encapsulate the enzyme in an aqueous phase to form particles which are dispersed in a non-aqueous phase.

- Document D15 discloses (example 1) a composition comprising protease (cellulase and amylase are also considered). While reference is made to a plurality of components including bleach catalysts, there is no disclosure or teaching of a co-formulation of an enzyme and a substrate enhancing the efficiency of the enzyme at the point of use.

4.2.3 Unlike the other cited documents, D10 explicitly refers to embodiments in which the enzyme is encapsulated to keep it separated from substances which can activate it. Thus, this particular configuration is considered as the closest to the main underlying idea of the invention, namely co-formulating an enzyme and a substrate which enhances the efficiency of the enzyme in a way which prevents contact between these substances so that they only react at the point of use.

4.2.4 The appellants argued that document D10 also disclosed:

- a non-aqueous liquid phase as defined in claim 1 because the reference to "less than 20% water" (page 25, lines 16-17) was equivalent to a range of 0-20% of water. Since claim 1 of the patent defined "*less than about 5% water*" (which corresponded to 0-5% water), the range in D10 overlapped with that of claim 1 and therefore anticipated it; and

- the combination of a laccase with a substrate, because laccase was explicitly disclosed on page 16 and the feature "compounds ... which activate the enzyme" (page 4, line 11) was equivalent to a substrate in the sense of the patent.

Consequently, the appellants concluded that claim 1 differed from document D10 only in the selection of a laccase mediator as a substrate.

4.2.5 The board disagrees with this argumentation for the following reasons:

- D10 discloses delivery systems in which it is possible to keep the enzyme away from "enzyme hostile compounds" and "compounds in the liquid which activate the enzyme" (page 4, lines 9-11). The board thus considers that the option of "compounds in the liquid which activate the enzyme", if understood as meaning "substrate" (which is questionable in view of point 4.2.1 above), needs to be selected (i.e. the alternative of keeping the enzyme away from the "enzyme hostile compounds" is - analogously to documents D1, D2, D4, D5 and D15 - different from the basic idea of the invention), and that this embodiment represents the closest prior art.

- From this starting point, considering a laccase as part of the formulation would require a second selection from the list of alternative enzymes described in D10. Thus, D10 cannot be considered to clearly and unambiguously describe a co-formulated composition of laccase with "compounds ... which activate the enzyme" as this would require two selections from lists, let alone a combination of a laccase with a laccase mediator.

- Furthermore, the feature "less than 20% water" in D10 and "*less than about 5% water*" in claim 1 are both open-ended and can thus not be considered to provide a clear and unambiguous disclosure of a liquid medium containing 0% water, so the ranges in claim 1 and D10 are not overlapping.

4.2.6 The subject-matter of claim 1 therefore differs from the closest prior art (represented by the specific configuration in D10 combining an encapsulated enzyme and a compound activating the enzyme) at least in that it requires one of the enzyme/substrate pairs defined in points a)-e), and in that the liquid phase is a non-aqueous liquid with less than 5% water.

4.3 Problem solved according to the patent

According to par. [0003], the problem solved by the invention is to provide an enzyme/substrate delivery system which is convenient, in which the enzyme is isolated from the substrate and in which the enzyme/substrate ratio can be easily maintained.

4.4 Reformulation of the problem

Assuming, for the sake of the argument, that the feature "compound activating the enzyme" in D10 anticipates the feature substrate, document D10 can be considered to solve all the above problems. However, example 4 of the patent in suit at least demonstrates that the solution proposed in claim 1 provides an alternative delivery system which maintains the stability of the enzyme/substrate co-formulation.

The board is not convinced by the respondent's argument that an improvement in stability is obtained, because there is no evidence that the non-aqueous solution of the invention provides a more stable composition than the embodiments of D10 in which the stability is enhanced by the presence of an electrolyte.

Therefore the problem solved by the invention is to be reformulated in the less ambitious way of providing an alternative delivery system which at least maintains the stability of the enzyme/substrate co-formulation.

4.5 Obviousness

4.5.1 The appellants argued that the selection of enzyme/substrate pairs as defined in points a)- e) of claim 1 was obvious in view of documents D6 (relating to cleaning compositions based on laccase/laccase mediator pairs) and D7 (relating to cleaning compositions based on perhydrolase/substrate pairs as defined in claim 1), and that the provision of a non-aqueous liquid with less than 5% of water was also hinted in the embodiment described on page 25, lines 9-17 of D10. The solution would thus be obvious in view of the combination of document D10 with either D6 or D7.

4.5.2 It is first noted that document D10 proposes a solution to the problem of maintaining the stability of the enzyme/substrate pairs based on adding an electrolyte to increase the ionic strength of the water in the composition to a point in which the polymer encapsulating the enzyme is no longer soluble in the aqueous mixture (claim 1; page 5, lines 9-14 and page 25, lines 8-12).

As pointed out by the appellants, in a particular embodiment of D10 (page 25, lines 14-17), the liquid composition is said to comprise "less than 50% water ... less than 30% water ... less than 20% water". There is however no indication as to which effect is pursued with this specific embodiment.

4.5.3 Concerning the enzyme/ substrate pairs, the board agrees with the appellants in that the selection of this feature from D6 or D7 cannot be considered as an inventive contribution.

It is however not apparent which teaching in D10 (or in D6-D7) would lead the skilled person to select a non-aqueous liquid medium with a water content lower than 5%. There is no question that the embodiment on page 25 of D10 establishes a maximum water content, therefore hinting a desire to work with a liquid medium which does not have a high water content. However, this disclosure would have to be further restricted (i.e. from a maximum of 20% water to a maximum of 5% water) and it would need to be combined with one of the specific enzyme/substrate pairs as disclosed in claim 1 of the main request in order to render claim 1 not inventive.

In view of the underlying technical problem and of the fact that some of the polymers are water-soluble, reducing the water content of the liquid medium is an alternative which could be contemplated for maintaining good stability of the enzyme/substrate pair. However, the board has come to the conclusion that the skilled person would not consider the solution in claim 1 without the benefit of hindsight, in particular for the following reasons:

- To arrive at the solution proposed in claim 1 from the closest prior art in D10, the skilled person would need to make multiple selections: a first selection of the pairs of enzyme/substrate of D6 or D7, a second selection of the embodiment on page 25 concerning the liquid medium having a maximum water content and a third selection of a further reduction of the water content to less than 5%.
- The key idea in document D10 is to maintain the stability of the composition by adding an electrolyte which reduces the solubility of the polymers in water. Consequently there is no particular incentive to reduce the water content, let alone to further reduce the minimum water content disclosed in D10 from less than 20% to less than 5%. This is well illustrated by the most preferred form of the invention in D10 (example 2) which discloses a water content of more than 50%.
- Documents D6 and D7 do also not provide any hint which would lead the skilled person to the claimed solution, because they do not even refer to the problem of stability of the enzyme/substrate pair, and some of the compositions described therein contain amounts of water significantly higher than 5% (see e.g. detergent compositions on pages 54 and 55 of D7).

- 4.5.4 The board has therefore concluded that the solution proposed in claim 1 is not rendered obvious by D10 combined with either D6 or D7.

- 4.6 The subject-matter of claim 1 is therefore considered to be inventive.

- 4.7 Claims 2-11 are dependent on claim 1 and therefore also comply with the requirements of Article 56 EPC. Claim 13 and method claims 14-16 refer back to claim 1 and/or to claims dependent on claim 1, and therefore also comply with the requirements of Article 56 EPC.

- 5. It is therefore concluded that claims 1-16 meet the requirements of the EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent in amended form based on the claims of the new main request (former auxiliary request 4 filed with letter of 2 June 2020) and a description to be adapted thereto.

The Registrar:

The Chairman:



A. Pinna

J.-M. Schwaller

Decision electronically authenticated