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Datasheet for the decision of 8 September 2010

Case Number: T 0206/08 - 3.3.06

Application Number: 97908958.8

Publication Number: 0885285

IPC: C11D 3/386

Language of the proceedings: EN

Title of invention:
Detergent compositions comprising proteases and improved amylases

Patentee:
THE PROCTER & GAMBLE COMPANY

Opponents:
Unilever N.V.
Henkel AG & Co. KGaA

Headword:
Detergent with enzymes/PROCTER

Relevant legal provisions:
-

Relevant legal provisions (EPC 1973):
EPC Art. 83

Keyword:
"Sufficiency of disclosure (main and first auxiliary request): no - large amount of experimental work needed"
"Sufficiency of disclosure (second auxiliary request): yes - reasonable number of trial and error experiments"

Decisions cited:
T 1250/01

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0206/08 **-** 3.3.06

D E C I S I O N
of the Technical Board of Appeal 3.3.06
of 8 September 2010

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 28 November 2007 revoking European patent No. 0885285 pursuant to Article 102(1) EPC 1973.

Composition of the Board:

Chairman: P.-P. Bracke
Members: P. Ammendola
J. Geschwind

Summary of Facts and Submissions

I. This appeal is from the decision of the Opposition Division to revoke European patent No. 0 885 285 concerning detergent compositions comprising proteases and α-amylases (hereinafter AAs) because none of the then pending Patent Proprietor's requests for maintenance of the patent in amended form satisfied all requirements of the EPC.

II. The grant of the European patent had been opposed on the grounds of Articles 100(a) (novelty and inventive step) and 100(b) (insufficiency of disclosure) EPC 1973.

III. During the opposition proceedings the Patent Proprietor filed, *inter alia*, three sets of seventeen claims as first to third auxiliary requests.

Claim 1 of this first auxiliary request reads:

"*1. A detergent composition comprising a protease and from 0.00018% to 0.06% pure enzyme by weight of total composition of:*

(a) α-amylase characterized by having a specific activity at least 25% higher than the specific activity of Termamyl® at a temperature range of 25°C to 55°C and at a pH value in the range of 8 to 10, measured by the Phadebas® α-amylase activity assay comprising diluting said α-amylase in 50 mM Britton-Robinson buffer, adding 1 ml of this α-amylase solution to 5 ml 50 mM Britton-Robinson buffer containing one Phadebas® tablet suspended therein and

measuring the absorbance at 620 nm after 10 or 15 minutes of incubation (testing time) in the range of 0.2 to 2.0 absorbance units; and/or;

(b) α-amylase according (a) comprising the amino sequence shown in SEQ ID No. 1 or an α-amylase being at least 80% identical with the amino acid sequence shown in SEQ ID No.1 and/or;

(c) α-amylase according (a) comprising the amino sequence shown in SEQ ID No.2 or an α-amylase being at least 80% identical with the amino acid sequence shown in SEQ ID No.2 and/or;

(d) α-amylase according (a) comprising the following amino sequence in the N-terminal: His-His-Asn-Gly-Thr-Asn-Gly-Thr-Met-Met-Gln-Tyr-Phe-Glu-Trp-Tyr-Leu-Pro-Asn-Asp (SEQ ID No.3) or an α-amylase being at least 80% identical with the amino acid sequence shown (SEQ ID No.3) in the N-terminal and/or;

(e) α-amylase according (a-d) wherein the α-amylase is obtained from an alkalophilic Bacillus species and/or

(f) α-amylase according to (e) wherein the amylase is obtained from any of the strains NCIB 12289, NCIB 12512, NCIB 12513 and DSM 935 and/or;

(h) Variant of a parent α-amylase, which parent α-amylase (i) has one of the amino acid sequences shown in SEQ ID No. 1 , ID No.2 or

ID No.4 respectively, or (ii) displays at least 80% identity with one or more of said amino acid sequences, in which variants:
(i) at least one amino acid residue of said parent α-amylase has been deleted; and/or

(ii) at least one amino acid residue of said parent α-amylase has been replaced by a different amino acid residue; and/or

(iii) at least one amino acid residue has been inserted relative to said parent α-amylase; said variant having an α-amylase activity and exhibiting at least one of the following properties relative to said parent α-amylase: increased thermostability, increased stability towards oxidation, reduced Ca ion dependency, increased stability and/or a-amylolytic activity at neutral to relatively high pH values, increased a-amylolytic activity at relatively high temperature and increase or decrease of the isoelectric point (pI) so as to better match the pI value for α-amylase variant to the pH of the medium."

The passage in feature "(a)" of this claim reading "*comprising diluting said α-amylase in 50 mM Britton-Robinson buffer, adding 1 ml of this α-amylase solution to 5 ml 50 mM Britton-Robinson buffer containing one Phadebas® tablet suspended therein and measuring the absorbance at 620 nm after 10 or 15 minutes of incubation (testing time) in the range of 0.2 to 2.0 absorbance units*" was not present in claim 1 as granted

and is hereinafter referred to as the added passage starting at "*comprising*".

Claim 1 of the second auxiliary request differed from that of the first auxiliary request only by the deletion of the whole section "*(h)*" (i.e. in that the wording "*DSM 935 and/or (h)... of the medium.*" has been replaced by "*DSM 935.*").

Claim 1 of the third auxiliary request reads:

"*1. A detergent composition comprising from 0.005% to 0.1% pure enzyme by weight of total composition of a protease and from 0.00024% to 0.048% pure enzyme by weight of total composition of:*

(a) an α-amylase characterized by having a specific activity at least 25% higher than the specific activity of Termamyl® at a temperature range of 25°C to 55°C and at a pH value in the range of 8 to 10, measured by the Phadebas® α-amylase activity assay comprising diluting said α-amylase in 50 mM Britton-Robinson buffer, adding 1 ml of this α-amylase solution to 5 ml 50 mM Britton-Robinson buffer containing one Phadebas® tablet suspended therein and measuring the absorbance at 620 nm after 10 or 15 minutes of incubation (testing time) in the range of 0.2 to 2.0 absorbance units; and

comprising the amino sequence shown in SEQ ID No. 1 or an α-amylase being at least 80%

identical with the amino acid sequence shown in SEQ ID No.1 or;

(b) the α-amylase according (a) comprising the amino sequence shown in SEQ ID No.2 or an α-amylase being at least 80% identical with the amino acid sequence shown in SEQ ID No.2 or;

(c) the α-amylase according (a) comprising the following amino sequence in the N-terminal: His-His-Asn-Gly-Thr-Asn-Gly-Thr-Met-Met-Gln-Tyr-Phe-Glu-Trp-Tyr-Leu-Pro-Asn-Asp (SEQ ID No.3) or an α-amylase being at least 80% identical with the amino acid sequence shown (SEQ ID No.3) in the N-terminal

wherein the α-amylase is obtained from an alkalophilic Bacillus species and/or

is obtained from any of the strains NCIB 12289, NCIB 12512, NCIB 12513 and DSM 935.".

IV. The decision under appeal only addressed the compliance of the then pending requests with Article 123(2) and (3) EPC and the issues of sufficiency of disclosure and clarity.

In particular, in this decision it was found that the versions of claim 1 according to the then pending first to third auxiliary requests did not meet the requirement of sufficiency of disclosure for, *inter alia*, the following reasons:

As also explicitly indicated in the patent description, AAs displaying 25% superior amylolytic activity in the "*Phadebas® α-amylase activity assay*" (hereinafter PAA assay) and, thus, suitable for producing the claimed detergent compositions, were already disclosed in

document (1) = WO 95/26397

and

document (2) = WO 96/23873.

However, these citations described only a few examples of these enzymes and gave no guidance other than the definition of the PAA assay. Hence, a person skilled in the art could only use the system of trial and error for identifying further AAs possessing the required activity.

Even when considering the additional requirements for the AAs given in claim 1 of the then pending third auxiliary request, the person skilled in the art could only rely on the system of trial and error. Indeed, document (1) itself proved the existence of many AAs obtainable from the defined sources among which to search further enzymes suitable for the invention.

V. The Patent Proprietor (hereinafter Appellant) lodged an appeal against this decision.

VI. The **main request** and the **first auxiliary request** filed with the grounds of appeal were respectively identical to the first auxiliary request and the second auxiliary

request considered by the Opposition Division (see above section III).

The second auxiliary request filed with the grounds of appeal differed from the third auxiliary request considered by the Opposition Division only in that a redundant dependent claim present in this latter has been deleted and it, thus, contained only sixteen claims renumbered where necessary.

The third auxiliary request filed with the grounds of appeal differed from the second auxiliary request filed with the grounds of appeal only by the presence at the end of claim 1 of the additional wording "*wherein the % identity is determined via the algorithm described by Lipman and Pearson in Science 227, 1985, 1435.*".

VII. Oral proceedings took place as scheduled in the presence of all Parties.

During the hearing the Opponents (hereinafter Respondents) argued for the first time that a lack of clarity derived from the indexing of the features as present in claim 1 of the second and third auxiliary requests filed with the grounds of appeal.

The Appellant replaced these auxiliary requests by two new sets of claims. These (final) second and third auxiliary requests differed from the previous ones only in the wording of claim 1.

Claim 1 of the (final) **second auxiliary request** filed at the hearing read:

"*1. A detergent composition comprising from 0.005% to 0.1% pure enzyme by weight of total composition of a protease and from 0.00024% to 0.048% pure enzyme by weight of total composition of:*

(a) an α-amylase characterized by having a specific activity at least 25% higher than the specific activity of Termamyl® at a temperature range of 25°C to 55°C and at a pH value in the range of 8 to 10, measured by the Phadebas® α-amylase activity assay comprising diluting said α-amylase in 50 mM Britton-Robinson buffer, adding 1 ml of this α-amylase solution to 5 ml 50 mM Britton-Robinson buffer containing one Phadebas® tablet suspended therein and measuring the absorbance at 620 nm after 10 or 15 minutes of incubation (testing time) in the range of 0.2 to 2.0 absorbance units; and

(b) the α-amylase according to (a) comprising the amino sequence shown in SEQ ID No. 1 or an α-amylase being at least 80% identical with the amino acid sequence shown in SEQ ID No.1 or;

(c) the α-amylase according (a) comprising the amino sequence shown in SEQ ID No.2 or an α-amylase being at least 80% identical with the amino acid sequence shown in SEQ ID No.2 or;

(d) the α-amylase according (a) comprising the following amino sequence in the N-terminal: His-His-Asn-Gly-Thr-Asn-Gly-Thr-Met-Met-Gln-Tyr-Phe-Glu-Trp-Tyr-Leu-Pro-Asn-Asp (SEQ ID

No.3) or an α-amylase being at least 80% identical with the amino acid sequence shown (SEQ ID No.3) in the N-terminal

wherein the α-amylase is obtained from an alkalophilic Bacillus species and/or

is obtained from any of the strains NCIB 12289, NCIB 12512, NCIB 12513 and DSM 935."

Claim 1 of the (final) **third auxiliary request** filed at the hearing only differed from the just-reported claim 1 of the (final) second auxiliary request also filed at the hearing, by the presence at the end of the claim of the additional wording "*wherein the % identity is determined via the algorithm described by Lipman and Pearson in Science 227, 1985, 1435.*".

VIII. The Appellant's arguments presented in writing and orally that are relevant for the present decision may be summarised as follows:

The second auxiliary request and third auxiliary request submitted at the oral proceedings before the Board were filed in response to the clarity objection against claim 1 of the previous second and third auxiliary requests, an objection that had been raised by the Respondents' for the first time at the hearing before the Board.

Even though claim 1 of the **main** and **first auxiliary request** in these appeal proceedings allowed for the presence in the claimed detergent composition of any AA possessing the superior amylolytic activity defined in

feature "*(a)*", no undue amount of experimental work was needed for identifying further embodiments of the claimed subject-matter, but only to carry out the PAA assay on the available AAs. The Respondents' allegation that in doing so the person skilled in the art would encounter more failure than success was not substantiated by any verifiable fact; hence the Respondents had not relieved themselves of the burden of proving the existence of serious reasons justifying the allegation that the claimed invention could not be carried out.

The combination of ranges for the amounts of protease and AA introduced at the beginning of claim 1 of the **second auxiliary request** would be supported in the patent application as filed by the generally applicable teaching at page 29, lines 3 to 7, and by the definition of the preferred embodiment of the invention as given e.g. in claim 2.

The wording "*obtained from*" also present in claim 1 of the second auxiliary request would be implicitly supported by the corresponding original wording "*obtainable from*". It corresponded as well to the expression "*produced by*" originally disclosed at page 5, lines 25 to 31, of the patent application as filed.

The added passage starting at "*comprising*" in feature "*(a)*" also present in claim 1 of the second auxiliary request only specified essential features of the PAA assay described at pages 9 to 10 of document (1). Since claim 1 as granted simply referred to this PAA assay without giving any further details thereof, no

additional lack of clarity could possibly have been produced by the introduction of this passage into claim 1.

As to the sufficiency of disclosure of the second auxiliary request, the Appellant considered that only a very limited number (if any) of trial and error experiments was needed for identifying further AAs with the required superior activity, because claim 1 of this request additionally mandatorily required the AA to be obtained from specified microorganisms and to possess amino acid sequences at least 80% identical to the three specified amino acid sequences (hereinafter the specified sequences). In the opinion of the Appellant, at least a very large fraction of the AAs complying with all these additional limitations would also possess the desired improved activity. Hence, the person skilled in the art would have high expectation of success when carrying out the PAA assay on any AAs so similar to the specified sequences. It would be unjustified to reject this reasonable assumption simply on the basis of unsupported allegations of the contrary made by the Respondents, or simply because the total number of theoretically possible AAs would still be very high.

The further objections that had been raised by the Respondents in view of Article 83 EPC 1973 (also) against claim 1 of the second auxiliary request were neither relevant nor proved.

Indeed, the variability of the measured values for the amylolytic activity allegedly descending from the absence in the patent in suit of certain details on the

PAA assay conditions and reagents had not been proven to produce such frequently substantial differences in the measured results as to leave very often the person skilled in the art in doubt as to whether the tested AAs did not possess the required superior activity. In any case, these ambiguities would at most render unclear the scope of protection of the claims and were, thus, possibly relevant in view of the assessment of novelty or inventive step, but certainly irrelevant for the issue of sufficiency of disclosure.

The Respondents' objection under Article 83 EPC 1973 that, due to the "open ended" definition of feature "*(a)*", claim 1 covered compositions containing still-to-be-discovered AAs with very high activity that were not rendered available to the skilled reader of the patent in suit, would just be an unsupported hypothetical allegation.

The Appellant also rebutted as unsubstantiated the objection under Article 83 EPC 1973 to the "*percent of identity*" between amino acid sequences indicated in features "*(b)*" to "*(d)*" of claim 1 of the second auxiliary request. The "*percent of identity*" of amino acid sequences was a parameter well-established in the technical field and, contrary to the unsupported statements of the unspecified experts that the Respondents had alleged to have consulted, the experts consulted by the Appellant confirmed that the person skilled in the art knew how to determine it. The fact that the article by "*Lipman and Pearson in Science 227, 1985, 1435*" (hereinafter the article in *Science*) referred to at page 3, lines 26 to 28, of the patent in suit, did not even mention "*percent of identity*", was

irrelevant because this article was only mentioned in the patent in suit simply as an example of the known algorithms to be performed for determining the actual percent value.

IX. The Respondents' arguments presented in writing and orally that are relevant for the present decision may be summarised as follows:

The second and third auxiliary requests filed by the Appellant at the oral proceedings before the Board were belated.

Claim 1 of the **main request** and that of the **first auxiliary request** were already contrary to Article 83 EPC 1973 because they embraced among the possible ingredients any AA complying with feature "*(a)*" alone. As correctly established by the Opposition Division, the AAs suitable as ingredients of the claimed detergent composition could only be found by means of trial and error experiments. Since there would undisputedly exist many sorts of AAs of different origins and, thus, of totally different structures, the skilled person could just rely on chance, without any reasonable expectation of success, when attempting to identify further alternatives for carrying out the claimed invention among all naturally occurring AAs and all possibly conceivable variations thereof.

The Respondents objected to the combination of ranges for the amounts of protease and AA given at the beginning of claim 1 of the **second auxiliary request** in view of Article 123(2) EPC.

Moreover, the wording "*obtained from*" present in claim 1 of the second auxiliary request was possibly technically encompassed but not explicitly disclosed by the original wording "*obtainable from*". Nor would the original expression "*produced by*" correspond to "*obtained from*".

The Respondents also objected that the added passage starting at "*comprising*" in feature "*(a)*" of claim 1 of the second auxiliary request would leave open the possibility of unspecified further modifications of the assay. Hence, this wording would represent an amendment contrary to Article 84 EPC 1973.

In the opinion of the Respondents, claim 1 of the second auxiliary request remained extremely broad, despite the further restrictions introduced therein for the AA. In particular the definition of feature "*(d)*" encompassed an endless number of variants. A very large number of trial and error experiments was therefore still likely to be needed in order to carry out further embodiments of the detergent compositions claimed.

Additionally, the Case Law of decision T 1250/01 (unpublished in the OJ) affirmed that if a method for measuring a parameter was insufficiently disclosed, then also the products defined by means of that parameter would be insufficiently disclosed. Hence, the detergent composition defined in claim 1 of the second auxiliary request would violate Article 83 EPC 1973 also because the PAA assay would not be described in the patent in suit (via the reference to document (1)) with sufficient precision to allow consistent and unambiguous results.

In the present case, already the fact that the test reagents for the PAA assay were only identified by their trade names rendered it impossible to establish with certainty whether or not a given AAs could be used to carry out the invention. Indeed, the composition of the reagents sold under such trade names was likely to change with time and, thus, one could determine for the same AA an activity superior or inferior to the required level, depending on the compositions of the Termamyl® and of the Phadebas® tablets available at the time at which the assay was made.

Variability of the results of the PAA assay would also derive from the missing indication in the patent in suit of the actual enzymatic activity of the solution of Termamyl® to be used as reference, since this latter would change with the freshness of preparation of the solution and with the initial activity of the batch of Termamyl® used for preparing it.

A further source of variability of results in the PAA assay derived from the missing indication as to whether the water to be used was deionised or distilled.

Finally, the actual enzymatic activities measured by means of the PAA assay depended also on the specific pH and/or temperature that the operator could arbitrarily choose within the ranges indicated in feature "*(a)*".

The Respondents considered also relevant under Article 83 EPC 1973 the fact that the definition of feature "*(a)*" of claim 1 of the second auxiliary request would be "open-ended", i.e. that the whole range of AAs defined by such feature covered high

activity enzymes that were undisclosed in the patent in suit and still to be found.

They further objected to the sufficiency of disclosure in view of features "*(b)*" to "*(d)*" of claim 1 of the second auxiliary request because the patent in suit did not disclose how to determine the "*percent of identity*" between amino acid sequences. Indeed, according to experts consulted by one of the Respondents, there was no generally accepted conventional method for determining this parameter. This was also apparent from the patent in suit, explicitly confirming the possibility of using different algorithms, whose results would be expected to be different. Moreover, the sole source of information precisely disclosed in the patent in suit, i.e. the article in *Science*, would not even mention "*percent of identity*", but just disclosed an algorithm resulting in a value that was not even a percent. Only by making certain assumptions would it be possible to use the algorithm described in the article in *Science* for arriving, depending on the assumptions made, at possibly very different values of "*percent of identity*".

X. The Appellant requested that the decision under appeal be set aside and the case be remitted back to the Opposition Division for a decision on further grounds of opposition on the basis of the main request, or alternatively, of the first auxiliary request both filed with the grounds of appeal, or the second or third auxiliary requests filed during the oral proceedings.

The Respondents requested that the appeal be dismissed.

Reasons for the decision

Procedural issues

1. The Respondents have considered belated the Appellant's second and third auxiliary requests filed at the oral proceedings before the Board.

However, as correctly observed by the Appellant and undisputed by the Respondents, these requests only differ from the corresponding previous requests already on file for the reintroduction of the original indexing of some of the claim features, i.e. the same indexing already present e.g. in claim 1 of the present main request (compare above sections VI above VII of the Facts and Submissions). Hence, this amendment is manifestly in response to the Respondents' objection, raised for the first time at the hearing, that the indexing of the claim features as present in the **previous** second and third auxiliary requests rendered these latter unclear.

Therefore, the Board decided to admit these requests into the proceedings.

Appellant's main request

2. The Board finds that the main request complies with Article 123(2) EPC and with Article 84 EPC 1973. However, no details need to be given in these respects, as this request fails for lack of sufficient disclosure for the reasons given here below.

3. Sufficiency of disclosure (Article 83 EPC 1973): claim 1

3.1 This claim (see above section VI of the Facts and Submissions) defines detergent compositions containing protease and a defined amount of AA. In particular, the claimed compositions may comprise **any** AA that displays a superior amylolytic activity in the PAA assay as defined in feature "*(a)*" (due to the option "*and/or*" at the end of this feature).

3.2 According to the established jurisprudence of the Boards of Appeal the requirement for sufficient disclosure should be objected to by rendering credible that there exist serious doubts, substantiated by verifiable facts, that the disclosure provided is insufficient for carrying out the invention.

It is also established jurisprudence of the Boards of Appeal that, even though a reasonable number of trial and error experiments is permissible, there must be available adequate instructions in the specification or on the basis of common general knowledge which would lead the skilled person necessarily and directly towards success through the evaluation of initial failures or through an acceptable statistical expectation rate in the case of random experiments (see Case Law of the BoA of the EPO, 6th edition 2010, point II.A.4.2).

3.3 In the present case, the definition of the AAs suitable for preparing the claimed detergent compositions **only** in terms of the superior activity to be verified as described in feature "*(a)*" extends the area in which

the skilled person should possibly search further suitable AAs to all naturally occurring or engineered amylolytic enzymes. On the other hand, the patent in suit just discloses (also via the reference to documents (1) and (2)) only a few examples of the AAs complying with feature "*(a)*", all manifestly similar in their structure, in particular at the N-terminal.

Under these circumstances, the fact brought forward by the Respondents, and undisputed by the Appellant, that there exist many other sorts of AAs whose structures can be completely different from those of the AAs exemplified in the patent in suit, renders evident that the person skilled in the art enters a totally unexplored field when searching for further embodiments of the claimed subject-matter among the AAs substantially different from the few exemplified in the patent in suit. Accordingly, he cannot have **any particular expectation of success** when randomly attempting the PAA assay among these AAs. Alternatively, the skilled person is obliged to start a **complete research program** in the hope of finding any criteria (e.g. as to which other segments of amino acid sequence, in addition to those present in the sequences already specified in claim 1, are more frequently associated with the required superior enzymatic activity) for selectively limiting the group of AAs in which to search.

Hence, the Board concludes that the skilled person is very likely to face a large amount of experimental work, before being able to realize embodiments of the claimed detergent composition based on AAs substantially different from the few exemplified.

3.4 Therefore, the Board finds that the subject-matter of claim 1 is not sufficiently disclosed and, thus, that the Appellant's main request is not allowable in view of Article 83 EPC 1973.

Appellant's first auxiliary request

4. Since the detergent composition defined in claim 1 of this request, similarly to that of claim 1 of the main request, may comprise **any** AA that possesses an improved activity according to feature "*(a)*", this request is also not allowable in view of Article 83 EPC 1973 for substantially the same reasons given above at point 3.3.

Appellant's second auxiliary request

5. Added subject-matter (Article 123(2) EPC)

5.1 In the Respondent's opinion the wording "*obtained from*", present twice in the final part of claim 1 of the second auxiliary request (for specifying the microorganisms from which the AAs must be obtained, see above section VII of the Facts and Submissions), is not supported in the patent application as originally filed, because the meaning of this wording is possibly technically encompassed but not directly and unambiguously disclosed by the passages in the original description that define the AAs of the invention as "*obtainable from*" the relevant microorganisms. Nor would the expression "*produced by*" present in the passage of the originally filed description at page 5, lines 25 to 31, correspond to "*obtained from*".

The Board notes that the Respondents have provided no supporting evidence for the allegation that the expressions "*produced by*" and "*obtained from*" would be generally acknowledged to possess clearly distinct meanings.

It appears instead to the Board that the expression "*produced by*" is used in the referred passage at page 5 (reading "*In the context of the present invention, the term "obtainable from" is intended not only to indicate an amylase produced by a Bacillus strain but also an amylase encoded by a DNA sequence isolated from such a Bacillus strain and produced in an host organism transformed with said DNA sequence*.") to express substantially the same meaning normally given to "*obtained from*", i.e. just to indicate that the enzyme has been synthesized by the specified microorganism(s).

Hence the Board concludes that the wording "*obtained from*" introduced in claim 1 does not violate Article 123(2) EPC already because it corresponds to the expression "*produced by*" of the above-cited passage of the original patent application.

5.2 The Respondents have also considered the combination of amount ranges for the protease and the AA given in claim 1 of this request as lacking support in the patent application as filed.

The Board notes, however, that, as convincingly argued by the Appellant and undisputed by the Respondents, the teaching as to the most preferred range for the amount of protease in the composition of the invention disclosed at page 29, lines 3 to 7, of the application

as published is manifestly meant to be generally applicable. Hence, it was also within the disclosure directly and unambiguously provided by the application as originally filed to consider this teaching in combination with the definition of the invention as given e.g. in claim 2 as originally filed.

Hence, the Board concludes that the combination for the ranges for the protease and the AA given in claim 1 of this request does not violate Article 123(2) EPC either.

6. Clarity (Article 84 EPC 1973)

The Respondents have objected for lack of clarity to the added passage starting at "*comprising*" under feature "*(a)*" (see above section VII of the Facts and Submissions).

In their opinion, the fact that this added passage starts with "*comprising*" and defines only some of the test features described at pages 9 to 10 of document (1) would imply that the PAA assay defined in the claim was no longer necessarily exactly the same defined in paragraph [0012] of the patent in suit as that: "*described at pages 9-10*" of document (1). The added passage would rather leave open the possibility of unspecified further modifications of the assay of document (1), thereby rendering obscure which kind of PAA assay was intended.

The Board finds this objection unconvincing, since claim 1 as granted already referred to the PAA assay **without giving any further details on such test** (indeed

feature "*(a)*" of claim 1 as granted read: "*(a) α-amylase characterized by having a specific activity at least 25% higher than the specific activity of Termamyl® at a temperature range of 25°C to 55°C and at a pH value in the range of 8 to 10, measured by the Phadebas® α-amylase activity assay and/or;*"). Hence, no additional lack of clarity can possibly originate from the fact that claim 1 of the present request now specifies some aspects of the PAA assay undisputedly taken from pages 9 to 10 of document (1).

7. Sufficiency of disclosure (Article 83 EPC 1973)

7.1 The Respondents have only raised objections of insufficiency of disclosure of the second auxiliary request in view of the definition of the AA given in claim 1 (see above section VII of the Facts and Submissions). This definition differs from that given in claim 1 of the main request because the former no longer embraces any AAs displaying superior activity in the PAA assay, but requires that the AAs must also be obtained from certain *Bacillus* species and must possess an amino acid sequence at least 80% identical to any of the specified sequences "*SEQ ID No.1*", "*SEQ ID No.2*" or "*SEQ ID No.3*".

7.2 In the opinion of the Respondents, these additional restrictions introduced in the definition of the AA are not sufficient to appreciably reduce the number of unsuccessful trial and error experiments needed for identifying further AAs **possessing the required superior activity in the PAA assay**, in particular because the definition of feature "*(d)*" would still embrace an endless number of variants.

7.2.1 The Board notes preliminarily that the Respondents have submitted no evidence of the repeated failures that, in their opinion, the skilled person would encounter in the necessary trial and error experiments.

Additionally, the Respondents in their argument do not seem to attribute any relevance to the requirement that the AAs must also be obtained from the microorganisms specified in claim 1. The Board is instead of the opinion that this requirement results necessarily in the exclusion of a relevant fraction of the "endless" number of the possible amino acid sequences according to feature "*(d)*".

In any case, the simple observation that the number of theoretically possible variations of the AAs among which to search might turn out to be very high does not *per se* render credible that the skilled person would face failure more often than success when checking the activity in the PAA assay among the possible alternatives for the AA.

On the contrary, the Board finds that the additional requirements for the AAs in present claim 1 impose severe limitations as to where to search for further alternatives for this essential ingredient of the claimed detergent compositions and, thus, render **at least plausible** the Appellant's argument that, if not all, at least a very large fraction of the AAs complying with these additional requirements also possess the desired superior activity.

Moreover, these additional requirements are also found to implicitly provide guidance for the skilled person as to how to react in case a tested AA did not display the required superior activity in the PAA assay. In case of a failure the skilled person would reasonably attempt to increase his chances of success in the subsequent trial and error experiments by focusing on the AAs whose amino acid sequences are **more similar** to the specified sequences - in particular in the N-terminal - than the enzyme(s) already proved to be unsatisfactory. Thus, it is apparent that, in respect of the definition of the AA given in claim 1 of the second auxiliary request, the person skilled in the art does not enter a totally unexplored field (as he did in the case of the classes of AAs having structures completely unrelated to those exemplified in the patent in suit and that are embraced in claim 1 of the main request).

Hence, the Board considers that the percent of sequence identity in respect of the N-terminal sequence and the limitation as to the microorganism producing the enzyme not only render plausible, in the absence of any evidence to the contrary, a reasonable expectation of success in random experiments directed at finding AAs with the required superior activity, but also represent a guidance for the skilled person in case of an initial failure.

7.2.2 The Board concludes, in the absence of any evidence to the contrary, that the skilled person is likely to need just a reasonable number of trial and error experiments in order to identify further AAs displaying the required superior activity and, thus, in order to

realize further embodiments of the claimed detergent composition.

7.3 In the opinion of the Respondents, the definition of the AAs in terms of the improved enzymatic activity to be measured by the PAA assay would also entail insufficiency of disclosure because of the absence in the patent in suit (and in document (1) cited therein) of a detailed description of this assay.

In particular, the Respondents have considered relevant in this respect the fact that the relative level of amylolytic activity measured by the PAA assay on a given AA could **substantially vary** depending:

i) on the point in time in which the assay is carried out, because the actual composition of the assay reagents available on the market under the trade names Termamyl® and Phadebas® tablet is not necessarily constant, but could rather change with time;

ii) on the starting level of activity of the Termamyl® solution used in the assay, because this level would depend on the initial activity of the enzyme batch used for preparing the solution as well as on the freshness of preparation of the solution;

iii) on the fact that the water for the test can be distilled or deionised;

and

iv) on the arbitrary choices made by the operator as to the temperature and/or pH at which to carry out the assay, because the actual enzymatic activities would appreciably vary within the ranges allowed for these parameters in feature "*(a)*".

In support of the relevance of these arguments in view of the issue of sufficiency of disclosure, the Respondents have referred to the Case Law of T 1250/01.

7.3.1 The Board notes, however, that the sole consequence of the above-listed possible sources of uncertainty i) to iv) (if found immediately credible or proved) would be the impossibility for the person skilled in the art to establish unambiguously, in a certain (possibly even a very low) number of cases, if an **already available** AA falls or not within the scope of claim 1, because the level of activity that he is **able to measure** on that enzyme depends on the reagents and the conditions used for the assay.

Hence, these sources of ambiguity imply **neither** that the skilled person would not know how to perform any reasonable reduction into practice of the (allegedly not precisely described) PAA assay **nor** that an undue amount of experimental work would be required in order to carry out any such reasonable reduction into practice of the assay. Thus, the (alleged) variability of the measured activity levels does not substantiate any difficulty in preparing the detergent compositions claimed.

7.3.2 For the same reasons it is also found that the Case Law referred to by the Respondents is not relevant for the

present case. Indeed, as discussed above, the skilled reader of the patent in suit is **able to carry out the PAA assay** (also by making, when needed, arbitrary choices among the reasonable alternatives for the test conditions possibly not precisely defined in the patent in suit) and to measure the enzymatic activity of any available AAs, inclusive of those falling in the grey area allegedly produced by the above-listed sources of result variability i) to iv). Instead, in the case considered in T 1250/01 (see points 1.2 to 1.5 of the reasons) the consequence of an error in the description was that **no method** for measuring an essential parameter was disclosed and, thus, the skilled person was **not able to make any measurement** of the relevant essential parameter.

7.3.3 Hence, the Board concurs with the Appellant that the Respondents' objections "i)" to "iv)" identified above appear not relevant for the issue of sufficiency of disclosure and, thus, no further decision as to their credibility and/or as to the extent of uncertainty descending therefrom has turned out to be necessary.

7.4 The Respondents have also considered insufficiency of disclosure to derive from the fact that the definition of the AA is "**open-ended**" because it does not indicate any upper limit for the difference in activity between the AA to be used in the invention and the standard Termamyl®. Hence, claim 1 of the second auxiliary request would embrace even detergent compositions based on AAs whose activities are many times higher than that of Termamyl®. However, these "high-activity" AAs were not already available at the time of the invention and not rendered available to the skilled reader of the

patent in suit. Hence, the claim embraced subject-matter still to be invented.

The Board notes preliminarily that the Respondents' reasoning appears to imply the unjustified expectation that at least some of the possible AAs that differ substantially from the exemplified enzymes (and, thus, are allegedly undisclosed in the patent in suit) should **necessarily** display high activities, whereas e.g. all AAs only marginally different in their sequence from the exemplified ones (and thus possibly rendered available by the allegedly limited disclosure of the patent in suit) should **necessarily** display about the same level of activity as the examples.

However, even in the hypothetical case that this unjustified expectation turned out to be right, it would still not imply *per se* the occurrence of any difficulties in realizing embodiments of the claimed subject-matter.

Hence, this hypothetical objection cannot possibly substantiate insufficiency of disclosure.

7.5 The remaining objection under Article 83 EPC 1973 submitted by the Respondents is that the expression "*at least 80% identical*" in features "*(b)*" to "*(d)*" of the definition of the AAs was not supported by sufficient disclosure in the patent in suit as to how to assess the "***percent of identity***" between two amino acid sequences. Indeed, according to experts consulted by the Respondents, there existed no generally accepted method for measuring this parameter and the sole source of information in this respect mentioned in the patent

in suit, i.e. the article in Science, would not even mention "*percent of identity*". Only by making certain arbitrary assumptions would it be possible to arrive at the desired parameter, starting from that kind of algorithm. Moreover, different algorithms were available to the skilled person (as explicitly confirmed at page 3, lines 26 to 28, of the patent in suit). Hence, possibly very different values of "*percent of identity*" could be determined for any given pair of enzymes.

7.5.1 The Board notes preliminarily that the statements made by the (unidentified) experts allegedly consulted by the Respondents as to the fact that the skilled reader of the patent in suit did not already know how to measure the "*percent of identity*" are not supported by any evidence and have been disputed by the Appellant by means of the symmetrical unsupported allegation that the (unidentified) experts consulted by this latter have instead confirmed that knowing how to assess this conventional parameter was common general knowledge.

The Board notes however the fact mentioned by the Appellant (and undisputed by the Respondents) that the evaluation of the extent of similarity (sometimes also referred to as identity or homology) between different proteins, enzymes, etc. is often expressed in terms of percent values.

The Board finds that this fact renders plausible the existence of common general knowledge in the technical field of enzyme characterization sufficient to enable the skilled reader of the patent in suit to determine

"*percent of identity*" between pairs of amino acid sequences.

The Board finds instead irrelevant in this respect the fact stressed by the Respondents that the article in *Science* does not mention this parameter. Indeed, the passage at page 3, lines 26 to 28, of the patent in suit only discloses that the comparison between two amino acid sequences is "*performed via algorithms*" such as the one described in the article in *Science*. Hence, this citation was certainly **not** indicated in the patent in suit as a (complete) description of the method for measuring the "*percent of identity*".

Also irrelevant is the Respondents' argument that the skilled person could arrive at substantially different values of "*percent of identity*" on the very same pair of AAs (because the actually determined values depended on which of the known algorithms was used, as well as on the kind of arbitrary assumptions allegedly necessary in order to derive the relevant parameter using any such algorithm). Indeed, the existence of several alternatives for determining the "*percent of identity*" allegedly producing different results implies neither difficulties in carrying out the invention (even in the grey area generated by such variability) nor the absence of common general knowledge on the method(s) for determining the "*percent of identity*" between amino acid sequences.

7.5.2 Hence, the Respondents have provided no convincing argument for disputing the apparent plausibility of the Appellant's statement that the person skilled in the art knows what to do in order to determine if an

available AA is or is not "*at least 80% identical*" to one of the amino acid sequences specified in claim 1.

7.6 Thus, the Board concludes that the subject-matter of claim 1 of the second auxiliary request is sufficiently disclosed and, hence, that this request also complies with the requirements of Article 83 EPC 1973.

8. Remittal

In the present case the decision under appeal has only addressed the compliance of the then pending requests with Article 123(2) and (3) EPC and the issues of sufficiency of disclosure and clarity.

Taking into account the request for remittal made by the Appellant and that none of the Respondents has objected thereto, the Board finds that it is appropriate in the present case to remit the case to the Opposition Division for further prosecution.

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 for further prosecution on the basis of the second auxiliary request.

The Registrar: The Chairman:

D. Magliano P.-P. Bracke