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Datasheet for the decision of 3 May 2011

Case Number:	т 1497/08 - 3.3.09
Application Number:	02700176.7
Publication Number:	1363506
IPC:	A23L 1/16
Language of the proceedings:	EN

Title of invention: Production of starchy food products

Patentee:

Novozymes A/S

Opponent:

DANISCO A/S DSM IP Assets B.V.

Headword:

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Relevant legal provisions:

EPC Art. 84, 123(2) RPBA Art. 13(3)

Relevant legal provisions (EPC 1973):

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Keyword:

"Clarity (no, main and first to sixth auxiliary requests)" "Amendments - added subject-matter (yes, sixth auxiliary request)" "Admissibility (no, seventh auxiliary request)"

Decisions cited:

T 0094/82, T 1156/01, T 0412/02, T 0908/04, T 0222/05, T 0555/05, T 0910/06 EPA Form 3030 06.03 C5867.D

Catchword:

Clarity of a parameter in a claim if the method to measure this parameter is given in the description only (see points 2.2-2.6 of the reasons)



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Beschwerdekammern

Boards of Appeal

Chambres de recours

Case Number: T 1497/08 - 3.3.09

DECISION of the Technical Board of Appeal 3.3.09 of 3 May 2011

Decision under appeal:	Interlocutory decision of the Opposition Division of the European Patent Office posted 27 May 2008 concerning maintenance of the European patent No. 1363506 in amended form.
Representative:	Donners, Ruth Emelia Wilhelmina DSM IP Assets B.V. DSM Intellectual Property, Office Delft (600-0240) PO-Box 1 NL-2600 MA Delft (NL)
Party as of rights: (Opponent II)	DSM IP Assets B.V. Het Overloon 1 NL-6411 TE Heerlen (NL)
Representative:	Stevens, Ian Edward Potter Clarkson LLP Park View House 58 The Ropewalk Nottingham NG1 5DD (GB)
Respondent: (Patent Proprietor)	Novozymes A/S Krogshøjvej 36 DK-2880 Bagsvaerd (DK)
Representative:	Williams, Aylsa D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Appellant: (Opponent I)	DANISCO A/S Langebrogade 1 PO Box 17 DK-1001 Copenhagen K (DK)

Composition of the Board:

Chairman:	W.	Sieber	
Members:	Μ.	Ο.	Müller
	R.	Menapace	

Summary of Facts and Submissions

- I. This decision is on an appeal by the opponent against the interlocutory decision of the opposition division that European patent No. 1 363 506 as amended met the requirements of the EPC.
- II. Opponent I (Danisco A/S) and opponent II (DSM IP Assets B.V.) had requested revocation of the patent in its entirety on the grounds that the claimed subject-matter was neither novel nor inventive (Article 100(a) EPC) and that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC).

The documents cited during the opposition proceedings included:

D13: WO 98/26057 A1 and

- D28: Declaration of L. B. Jensen and I. P. Povlsen, dated 18 February 2008.
- III. The opposition division's decision, which was announced orally on 26 March 2008 and issued in writing on 27 May 2008, was based on claims 1-3 filed as the main request during the oral proceedings before the opposition division, independent claim 1 reading as follows:

"1. A process for producing a fried flour-based product, comprising the steps of:

(a) preparing a dough comprising flour, water and an added lipolytic enzyme which has phospholipase activity in the range of 0.5-45 kLEU per kg flour,

- (b) holding the dough during or after mixing, and
- (c) frying the dough to obtain the fried
 product."

The opposition division reasoned inter alia as follows:

Claim 1 of the main request met the requirements of Article 84 EPC. The fact that claim 1 did not specify the assay used for determining the enzyme activity did not render this claim unclear as the information given in paragraphs [0042] and [0043] of the opposed patent provided sufficient detail to carry out the enzyme activity test and D28 submitted by opponent I showed that the opponent was in fact able to perform it. Moreover, T 1156/01 allowed for assays to be mentioned in the description only, if the incorporation thereof into the claim would be detrimental to the conciseness of the claim. Given the amount of detail necessary to describe the assay in the present case, it did not need to be incorporated into claim 1.

The objection that the NEFA C kit might not be available during the entire life span of the patent and further could be subject to modification was of a general nature and applicable to any test kit which may no longer be produced or modified. Such general considerations did not cast doubt on sufficiency of disclosure. Moreover, opponent I had performed the test assay described in the patent including the step of determining free fatty acid amounts using the NEFA C kit, as evidenced by D28. IV. On 23 July 2008, the appellant (opponent I) filed a notice of appeal and requested that the above decision be set aside and the patent be revoked in its entirety. The prescribed fee was paid on the same day. A statement setting out the grounds of appeal was filed on 24 September 2008 together with

- D31: Declaration of Inge Lise Povlsen, dated 7 September 2008;
- D32: ENCYCLOPAEDIA of FOOD SCIENCE FOOD TECHNOLOGY and NUTRITION, R. Macrae et al. (ed.), volume 7, Academic Press, Second Printing 2002, pages 4585-4588; and

D33: US 3,605,605 A.

- V. By letter of 12 February 2009, the respondent (proprietor) requested maintenance of the patent on the basis of the main request allowed by the opposition division and additionally submitted five sets of claims as the first to fifth auxiliary requests.
- VI. In preparation for oral proceedings scheduled for 3 May 2011, the appellant submitted additional arguments by letter of 16 February 2011, which was accompanied by the following additional documents:

D34: US 7,396,807 B2;

D35: US 6,365,204 B1; and

- D36: K. Clausen, "Enzymatic oil-degumming by a novel microbial phospholipase", Eur. J. Lipid Sci. Technol. 103, 2001, pages 333-340.
- VII. With letter of 31 March 2011, the respondent filed

D37: WO 2009/098229 A2;

D38: WO 2009/061380 A2; and

D39: WO 2008/112459 A2 together with

a sixth auxiliary request, of which claim 1 reads as follows:

"1. A process for producing a fried flour-based product, comprising the steps of:

- (a) preparing a dough comprising flour, water and an added lipolytic enzyme which has phospholipase activity in the range of 0.5-45 kLEU per kg flour,
- (b) holding the dough during or after mixing, and
- (c) frying the dough to obtain the fried product,

wherein kLEU equals 1000 LEU and 1 LEU equals the amount of enzyme capable of releasing 1 µmol of free fatty acid from lecithin per minute, as measured by adding 50 µl enzyme solution in 50 mM HEPES at pH 7 to 50 µl 4% L-alpha-phosphatidylcholine, 4% Triton X-100 and 5 mM CaCl₂ in 50 mM HEPES at pH 7, followed by incubation for 10 minutes at 30°C and stopping the reaction at 95°C for 5 minutes followed by centrifugation for 5 minutes at 7000 rpm."

- VIII. By letter of 22 March 2011, opponent II (party as of right) declared that it would not attend the oral proceedings.
- IX. On 3 May 2011, oral proceedings were held before the board. The respondent maintained the main and first to sixth auxiliary requests and filed a seventh auxiliary request, of which claim 1 reads as follows:

"1. A process for producing a fried flour-based product, comprising the steps of:

- (a) preparing a dough comprising flour, water and an added lipolytic enzyme which has phospholipase activity in the range of 0.5-45 kLEU per kg flour,
- (b) holding the dough during or after mixing, and
- (c) frying the dough to obtain the fried product,

wherein phospholipase activity (LEU) is measured as the release of free fatty acids from lecithin, wherein 50 µl 4% L-alpha-phosphatidylcholine, 4% Triton X-100, 5 mM CaCl₂ in 50 mM HEPES, pH 7 to which is added 50 µl enzyme solution diluted to an appropriate concentration in 50 mM HEPES, pH 7, wherein the samples are incubated for 10 min at 30°C and the reaction stopped at 95°C for 5 min prior to centrifugation (5 min at 7000 rpm), wherein free fatty acids are determined using the NEFA C kit from Wako Chemicals GmbH, and wherein 1 LEU equals the amount of enzyme capable of releasing 1 µmol of free fatty acid/min at these conditions. 1 kLEU = 1000 LEU."

The appellant requested that the sixth and seventh auxiliary requests should not be admitted into the proceedings. Х.

The appellant's arguments can be summarised as follows:

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The subject-matter of the main request lacked clarity. According to T 1156/01, if an invention was characterised by a parameter, the method for determining the same had to appear in the claim itself. This condition was not met for the phospholipase activity introduced into claim 1 of the main request. The claim therefore was unclear. In particular, the skilled person reading claim 1 did not know what method to apply to determine phospholipase activity. As followed from paragraph [0034] of the opposed patent as well as from D13 and D34-D36, various measurement methods existed which differed inter alia in their pH and temperature. However, different conditions led to entirely different results. Hence, different phospholipase activities would be obtained for one and the same enzyme depending on which measurement method was chosen. The fact that D37-D39 did not disclose any method for determining the phospholipase activity was not relevant in this context as these documents did not focus on and did not claim any phospholipase activity.

The sixth auxiliary request should not be admitted into the proceedings as this request had been filed less than two months prior to oral proceedings, resulted from an amendment taken from the description and contained even more clarity problems than the main request. Moreover, the sixth auxiliary request did not meet the requirements of Article 123(2) EPC as the originally-disclosed NEFA C kit had been omitted in the claim. In fact it was clear from the wording of the description as filed that this test was mandatory.

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Omitting this test from claim 1 implied that the skilled person could use any test and, depending on the test chosen, different results would be obtained. Furthermore, the omission of the requirement of an appropriate enzyme concentration in claim 1 violated the requirements of Article 123(2) EPC as, contrary to the application as filed, the claim now covered any concentration. Finally, the term "measured by" in claim 1 of the sixth auxiliary request rendered the claim unclear. In fact the wording following the term "measured by" described a chemical reaction rather than a method of measurement.

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The seventh auxiliary request should not be admitted into the proceedings either. It was filed extremely late and it was the first time that the appellant was confronted with the NEFA C kit as part of a claim. By way of including the NEFA C kit in claim 1, new issues arose. More particularly, this feature appeared to render claim 1 unclear as it had been confirmed by an employee of Wako Chemicals that the kit was no longer available. The skilled person thus did not know which method to use in order to determine the amount of free fatty acids and depending on the method chosen, different results were obtained. There was not enough time during the oral proceedings to substantiate this issue. In particular, more time would be needed to obtain a declaration from Wako Chemicals GmbH that the test was no longer available. Moreover, it would have to be studied whether the datasheet of the test that was referred to by the respondent during the oral proceedings provided sufficient information to carry to the test. As set out by the rules of procedure of the

boards of appeal, in such a situation the auxiliary request should not be admitted into the proceedings.

XI. The respondent's arguments can be summarised as follows:

The fact that claim 1 of the main request did not specify the method for determining phospholipase activity did not imply that this claim violated the requirements of Article 84 EPC. In fact, the method for determining phospholipase activity was given in paragraphs [0042] and [0043] of the opposed patent. The skilled person reading the opposed patent would therefore know what method to apply. In this context, decision T 94/82 confirmed that parameters could be used in claims when they could be determined by indications given in the description. Irrespective of this, the appellant had not proven that different measurement methods led to different results. In fact, the LEU value of 1450 LEU/mg obtained with the method reported in D35 was virtually identical to the value of 1540 LEU measured in the opposed patent with a different method. Hence, even if the skilled person did not know which method to apply, this would not render the phospholipase activity required by claim 1 unclear. Finally, the fact that the appellant itself had not specified the method for determining phospholipase activity when referring to this activity in its own patent applications D37-D39 proved that the skilled person, on the basis of common general knowledge, would know which measurement method to apply.

The sixth auxiliary request should be admitted into the proceedings as this request constituted a direct reaction to the appellant's newly introduced documents

D34-D36. The omission of the NEFA C kit in claim 1 of this request did not violate the requirements of Article 123(2) EPC as the skilled person would clearly understand that the use of this kit was not mandatory in the application as filed. Moreover, the omission of the requirement of an appropriate enzyme concentration did not violate the requirements of Article 123(2) EPC either. In particular, this requirement implied that the enzyme concentration had to be adjusted with regard to the sensitivity of the test kit used to determine the amount of free fatty acids and this was a standard procedure that was inherently part of claim 1.

The seventh auxiliary request should be admitted into the proceedings. It constituted a serious attempt to overcome the objections raised at the oral proceedings and did not diverge from the subject-matter previously claimed. The NEFA C kit had been available in 2008, as evidenced by D28, and there was no evidence that the NEFA C kit was no longer available after that date. Moreover, the datasheet of this kit could be retrieved from the Internet and provided sufficient information to carry out the test. The skilled person would thus know how to determine free fatty acid amounts with the NEFA C kit. The seventh auxiliary request was thus clearly allowable.

XII. The appellant (opponent I) requested that the decision under appeal be set aside and that the European patent No. 1 363 506 be revoked.

> The respondent (proprietor) requested that the appeal be dismissed (main request), alternatively that the decision under appeal be set aside and that the patent

be maintained on the basis of the first to fifth auxiliary requests, filed with letter of 12 February 2009, the sixth auxiliary request, filed with letter of 31 March 2011, or the seventh auxiliary request, filed during the oral proceedings before the board.

The party as of right (opponent II) took no active part in the appeal proceedings and did not file any requests.

Reasons for the Decision

1. The appeal is admissible.

Main request

- 2. Amendments Clarity
- 2.1 During the opposition proceedings, the parameter "phospholipase activity in the range of 0.5-45 kLEU per kg flour" was inserted into claim 1 of the main request. The claim does not specify how this phospholipase activity has to be measured. According to page 5, lines 7-10 of the description of the opposed patent, the phospholipase activity "may be determined by the plate assay in WO 02103805 (PCT/DK 01/00472) or by an assay WO 2000/32758, e.g. the PHLU, LEU, monolayer or plate assay 1 or 2". A specific method for determining phospholipase activity is given in paragraphs [0042] and [0043] of the opposed patent.

It has to be examined whether, under these circumstances, the insertion of the phospholipase

activity into claim 1 meets the requirements of Article 84 EPC, in particular in view of the fact that no information is contained in the claim as to how to determine this activity.

2.2 According to Article 84 EPC, the claims define the matter for which protection is sought. This implies that the claims must be clear in themselves when being read by the competent technical expert exercising normal skills, without the need to resort to information derived from the description of the patent.

> As is set out in numerous decisions (eg T 1156/01 of 21 June 2005 (points 2.2 and 2.3), T 412/02 of 16 June 2004 (points 5.6-5.9), T 908/04 of 15 February 2006 (points 3.1-3.8) and T 555/05 of 24 May 2007 (points 3.2.7-3.2.10) (none of these decisions published in OJ EPO), this implies that the method for measuring the parameter (or at least a reference thereto) must appear completely in the claim itself, if the invention is characterised by a parameter.

- 2.3 As set out above, in the present case, no such method (or reference thereto) is contained in claim 1 of the main request.
- 2.4 In this situation, the requirements of Article 84 EPC would still be met if it could be shown that
 - (i) knowing which method to employ belongs to the skilled person's common general knowledge, or

- (ii) all the methodologies known in the relevant technical field for determining this parameter yield the same result within the appropriate limit of measurement accuracy (see eg decision T 1156/01 of 21 June 2005; point 2.3).
- 2.4.1 As regards point (i), no evidence has been provided by the respondent that it is indeed part of the skilled person's common general knowledge to know which method to employ to measure phospholipase activity. In fact, the opposed patent itself acknowledges on page 5, lines 7-10 that different methods may be used to determine phospholipase activity. This is confirmed by D13, D35, D36 as well as by paragraphs [0042] and [0043] of the opposed patent, where various measurement methods are described that differ *inter alia* in terms of pH and temperature. More particularly, pH and temperature vary as follows:
 - pH 5 and 37°C ("PLU" method described on page 68, lines 10-16 of D13),
 - pH 7 and 30°C ("PHLU" method described on page 63, line 30 through page 31, line 12 of D13 and LEU method in paragraphs [0042] and [0043] of the opposed patent),
 - pH 7 and 37°C (point 2.3 on page 335 of D36) and
 - pH 8 and 40°C (column 3, lines 6-12 of D35).

The skilled person reading claim 1 would not know which of these methods to apply, and in particular which pH and temperature to use when determining the phospholipase activity required by this claim. The respondent argued in this context that the appellant itself did not specify the method for determining phospholipase activity when referring to this activity in its own patent applications D37-D39. In the respondent's view this proved that the skilled person, on the basis of common general knowledge, would know which measurement method to apply.

However, three single patent applications cannot in general constitute proof of what the skilled person's common general knowledge is. Moreover, D37-D39 focus on amylases rather than phospholipases, and no reference to phospholipase activity is made in any of the claims of these documents. It is thus not surprising that no measurement method for determining the phospholipase activity is given in these documents. In view of this, it remains unclear to the board how the omission of the method for determining phospholipase activity in D37-D39 can constitute proof that the skilled person, on the basis of common general knowledge, would know which method to apply and in particular which pH and temperature to use when determining phospholipase activity. The respondent's argument therefore must fail.

2.4.2 As regards point (ii), namely the question whether all measurement methods yield the same value for the phospholipase activity, it follows from table 4 of D13 that the phospholipase activity strongly depends on the pH employed during the measurement. More particularly, by varying the pH from 5 to 8, which is the range of pH values used in D13, D35, D36 and the opposed patent (see point 2.4.1 above), phospholipase activity determined for one and the same enzyme changes by 375%. Equally, by varying temperature from 30°C to 40°C, which is the range of temperatures used in D13, D35, D36 and the opposed patent (see point 2.4.1 above), phospholipase activity determined for one and the same enzyme changes by 18% (table 4 of D13).

The same can be observed when pH and temperature are changed simultaneously. More particularly, for one and the same enzyme, phospholipase activity is

- 1454/mg-1458 LEU/mg (opposed patent, calculated from the first two columns of the table on page 6) when measured at pH 7 and 30°C,
- 1540 LEU/mg when measured at a pH of 8 and a temperature of 40°C (column 3, lines 6-12 of D35), or
- 225 LEU/mg when measured at pH 7 and 37°C (table 7 of D13, "PHLU" is equivalent to LEU, see page 64, lines 10-12 of D13 and page 6, lines 10-11 of the opposed patent).
- 2.5 In summary, the skilled person reading claim 1 would not know which method to apply for the determination of the phospholipase activity and when trying different measurement methods, he would obtain different activities for one and the same enzyme. The activity range required by claim 1 is therefore unclear, which implies that claim 1 of the main request does not meet the requirements of Article 84 EPC.
- 2.6 The respondent argued that claim 1 met the requirements of Article 84 EPC as a measurement method was given in paragraphs [0042] and [0043] of the opposed patent. The

respondent referred in this context to decision T 94/82 (OJ EPO 1984, 75).

However, this decision nowhere contains a general statement that it is sufficient for a measurement method to be contained in the description when a claim refers to a parameter. In fact, the decision refers to the specific case in which the parameter is "usual in the art" and "can conveniently and reliably be obtained in following the instructions given in the description and in accordance with the German standard DIN 53840 mentioned therein" (point 2.3 of the reasons). This clearly differs from the present case, in which the only specific method mentioned in the description does not constitute a generally recognised German or other national standard and it is even explicitly acknowledged in the description that various methods can be applied (page 5, lines 7-10).

Accordingly, the decision referred to by the respondent and the reference in paragraphs [0042] and [0043] of the opposed patent to a specific measurement method cannot invalidate the above finding that claim 1 lacks clarity.

First to fifth auxiliary requests

3. Claim 1 of each of the first to fifth auxiliary requests contains the requirement of the phospholipase activity being in the range of 0.5-45 kLEU per kg flour, without specifying the method by which this activity has to be determined. Hence, the same objection as referred to above with regard to the main request equally applies to the first to fifth auxiliary requests. These requests must thus fall as well.

Sixth auxiliary request

4. Admissibility

The appellant requested that the sixth auxiliary request should not be admitted into the proceedings.

This request was filed on 31 March 2011. It differs from the main request only in that a method to determine phospholipase activity has been included in claim 1. This inclusion can be regarded as a direct reaction to documents D34-D36, newly submitted by the appellant with letter of 16 February 2011 to reinforce its argument that the measurement method was missing in claim 1. For this reason, and in view of the fact that the appellant had more than four weeks to consider the request, this request was admitted into the proceedings.

5. Amendments - Article 123(2) EPC

5.1 The text inserted into claim 1 reads as follows:

"wherein kLEU equals 1000 LEU and 1 LEU equals the amount of enzyme capable of releasing 1 μ mol of free fatty acid from lecithin per minute, as measured by adding 50 μ l enzyme solution in 50 mM HEPES at pH 7 to 50 μ l 4% L-alpha-phosphatidylcholine, 4% Triton X-100 and 5 mM CaCl₂ in 50 mM HEPES at pH 7, followed by incubation for 10 minutes at 30°C and stopping the reaction at 95°C for 5 minutes followed by centrifugation for 5 minutes at 7000 rpm."

5.2 This amendment is derived from page 8, line 30 through page 9, line 4 of the application as filed (WO publication), which reads as follows:

> "Phospholipase activity (LEU) is measured as the release of free fatty acids from lecithin. 50 µl 4% Lalpha-phosphatidylcholine (plant lecithin from Avanti), 4% Triton X-100, 5 mM CaCl₂ in 50 mM HEPES, pH 7 is added 50 µl <u>enzyme solution diluted to an appropriate</u> <u>concentration</u> in 50 mM HEPES, pH 7. The samples are incubated for 10 min at 30 °C and the reaction stopped at 95 °C for 5 min prior to centrifugation (5 min at 7000 rpm). <u>Free fatty acids are determined using the</u> <u>NEFA C kit from Wako Chemicals GmbH</u>. 1 LEU equals the amount of enzyme capable of releasing

1 μmol of free fatty acid/min at these conditions. 1 kLEU = 1000 LEU" (emphasis added by the board).

- 5.3 A comparison of these two passages reveals that the measurement method in claim 1 of the sixth auxiliary request differs from the originally-filed text *inter alia* in that the requirement of the free fatty acids being determined using the NEFA C kit from Wako Chemicals GmbH has been omitted. It has to be examined whether this omission is in line with Article 123(2) EPC.
- 5.3.1 According to the respondent, the skilled person reading the application as filed would know that the amount of free fatty acids does not necessarily have to be determined by the NEFA C kit but could be determined by

a different method. The use of the NEFA C kit would thus not be considered by the skilled person as mandatory in the application as filed. Therefore, in the respondent's view, the omission of the NEFA C kit in claim 1 of the sixth auxiliary request did not violate the requirements of Article 123(2) EPC.

- 5.3.2 For an amendment to meet the requirements of Article 123(2) EPC, the amendment must be directly and unambiguously derivable from the application as filed. The burden of proof that this is the case rests on the proprietor (see eg decisions T 222/05 of 12 December 2008 (last paragraph of point 3; not published in OJ EPO) and T 910/06 of 10 December 2008 (point 2.9.1; not published in OJ EPO)).
- 5.3.3 In the present case, the respondent's argument is not supported by the wording of the application as filed. More particularly, the original wording "free fatty acids are determined using the NEFA C kit from Wako Chemicals GmbH" does not contain any indication that this kit could be regarded as an example only and that another method or test kit could be used instead in order to determine free fatty acid amounts.

Moreover, the respondent (proprietor) has not shown that the NEFA C kit leads to the same fatty acid amount as obtained by other methods and that therefore the skilled person would consider the NEFA C test kit to be equivalent to and thus replaceable by other methods. In this situation, where the respondent has not discharged its burden of proof, it can only be assumed to the respondent's disadvantage that the opposite is the case, ie that different methods lead to different results and that therefore the skilled person would not replace the NEFA C test kit by any other method.

For the above reasons, the use of the NEFA C kit is clearly not optional in the application as filed. The omission of the NEFA C kit in claim 1 of the sixth auxiliary request therefore violates the requirements of Article 123(2) EPC.

5.4 Under these circumstances, the additional omission in claim 1 of the requirement "diluted to an appropriate concentration" need not be discussed further.

6. Amendments - Clarity

The amended portion of claim 1 contains the wording "1 µmol of free fatty acid from lecithin per minute, as measured by". In normal English, one would assume that the term "as measured by" will be followed by a method for measuring the amount of free fatty acids. However, in fact what is described following this term is not a measurement method but the reaction conditions for the cleavage of lecithin. The meaning of "as measured by" in claim 1 is thus unclear. Claim 1 of the sixth auxiliary request therefore does not meet the requirements of Article 84 EPC either.

Seventh auxiliary request

7. Admissibility

During the oral proceedings before the board, the respondent submitted a seventh auxiliary request. Claim 1 of this request differs from claim 1 of the previous request *inter alia* by the requirement that "the free fatty acids are determined using the NEFA C kit from Wako Chemicals GmbH" (see point IX above).

7.1 The appellant requested that this late-filed request should not be admitted into the proceedings. It argued that the NEFA C kit was equivalent to a trademark the meaning of which could change over time. In the present case, an employee of Wako Chemicals had confirmed on the phone that this kit was no longer available. It was thus not clear in the appellant's opinion how the amount of free fatty acids was to be determined. In view of the fact that different methods led to different results, the introduction of this kit into claim 1 rendered the claim unclear. Finally, the appellant explained that in order to substantiate the non-availability of the kit, it would need more time to obtain eg a declaration from Wako Chemicals GmbH.

> Concerning the respondent's argument that a datasheet for the NEFA C kit was available on the Internet and provided sufficient information to determine free fatty acid amounts, the appellant argued that this datasheet was not on file. Even if it was, more time would be needed to study the content of this sheet, in particular with regard to its date of publication.

7.2 In the board's judgement, if the NEFA C kit should indeed no longer be available and/or the datasheet should not provide sufficient information, the skilled person would not know which method to apply in order to determine the amount of free fatty acids. In this situation, claim 1 would be unclear with regard to the amount of free fatty acids and hence the phospholipase activity, unless all methods led to the same result.

In view of this, the clarity of claim 1 of the seventh auxiliary request hinges on the availability of the NEFA C kit or the information content of the datasheet related to this kit and the question of whether different methods for determining the amount of free fatty acids lead to different results.

- 7.3 The appellant was confronted with a claim relating to the NEFA C kit at an extremely late stage, namely towards the end of the oral proceedings. As set out above (point 7.2), the introduction of this feature into claim 1 raised new issues that could not be resolved in the oral proceedings. As foreseen by Article 13(3) RPBA, in this situation, the amendment is not admissible. Said amendment and with it the seventh auxiliary request were therefore not admitted into the proceedings (Article 13(3) RPBA).
- 7.4 The respondent argued that D28 showed that the NEFA C kit had been available in 2008. However, this argument is irrelevant to the above-discussed question as to whether the kit is still available now.

The respondent further argued that the seventh auxiliary request constituted a serious attempt to overcome the objections raised by the appellant during the oral proceedings and that the request should therefore be admitted into the proceedings. However, this does not alter the fact that the request raised new issues that were not resolvable during the oral proceedings. The respondent finally argued that the subject-matter of the seventh auxiliary request did not diverge from the subject-matter previously claimed and that therefore the seventh auxiliary request should be admitted. However, this is not correct as the NEFA C kit had not been contained in the claims of any of the previous requests before the board and hence, the subject-matter of the seventh auxiliary request in fact does diverge from the subject-matter previously claimed.

7.5 The respondent's arguments were therefore not convincing and hence could not change the above finding that the seventh auxiliary request could not be admitted into the proceedings.

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:

G. Röhn