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Datasheet for the decision of 18 September 2020

Case Number: T 0188/18 - 3.3.01

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Language of the proceedings: EN

Title of invention:
METHOD OF PREPARING HIGHLY DISPERSIBLE WHOLE GRAIN FLOUR

Patent Proprietor:
The Quaker Oats Company

Opponent:
Société des Produits Nestlé S.A.

Headword:
Preparation of hydrolysed whole grain flour/QUAKER OATS

Relevant legal provisions:
EPC Art. 83

Keyword:
Sufficiency of disclosure - reproducibility (no)

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Case Number: T 0188/18 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 18 September 2020

Appellant: (Patent Proprietor)	The Quaker Oats Company 555 West Monroe Street Chicago, IL 60661 (US)
Representative:	Jenkins, Peter David Page White & Farrer Bedford House John Street London WC1N 2BF (GB)
Respondent: (Opponent)	Société des Produits Nestlé S.A. Avenue Nestlé 55 1800 Vevey (CH)
Representative:	Rupp, Christian Mitscherlich PartmbB Patent- und Rechtsanwälte Sonnenstraße 33 80331 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 7 November 2017 revoking European patent No. 2442661 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	J. Molina de Alba
Members:	G. Seufert
	L. Bühler

Summary of Facts and Submissions

I. The patent proprietor (appellant) lodged an appeal against the decision of the opposition division revoking European patent No. 2 442 661.

II. The present decision refers to the following document:

D27 Data sheet Validase® BAA 1000L, Valley Research, two pages

III. Notice of opposition was filed by the respondent (opponent) requesting revocation of the patent in suit on the grounds of lack of novelty and inventive step, insufficiency of disclosure and added subject-matter (Article 100(a), (b) and (c) EPC).

IV. The decision under appeal is based on a set of claims according to a main request and sets of claims according to the first to fifth auxiliary requests, all filed by letter dated 10 January 2017 and attached as Annex 2 to the decision under appeal.

The opposition division decided that the requirement of sufficiency of disclosure was not complied with because the invention could not be reproduced without undue burden. Essential information on the hydrolysis step a) considered crucial for obtaining the desired highly dispersible whole grain product was missing. According to the opposition division, the lack of guidance could not be compensated for by common general knowledge.

The main request on which the decision is based consists of 11 claims with claim 1 readings as follows:

"*1. A method of preparing a highly dispersible whole grain flour comprising the sequential steps of:*

a) hydrolyzing a whole grain flour using alpha-amylase, the alpha-amylase hydrolyzes the whole grain flour while maintaining the integrity of the whole grain, and heating the hydrolyzed whole grain flour in a cooking extruder and gelatinizing the whole grain flour by mechanical action to form a whole grain flour dough, whereby the mixture resides in the extruder for a time sufficient to gelatinize and cook the starch, generally at least 1 minute, wherein prior to exiting the extruder, the hydrolyzed whole grain flour dough is heated to a temperature of 121°C - 149°C (250-300°F) to deactivate the alpha-amylase;

b) pelletizing the hydrolyzed whole grain flour dough to form hydrolyzed whole grain pellets;

c) finely milling the hydrolyzed whole grain pellets to a particle size of 50-200 microns to form hydrolyzed whole grain particles; and

d) agglomerating the hydrolyzed whole grain particles to form highly dispersible hydrolyzed whole grain flour."

Independent claims 10 and 11 are directed to products obtained according to the method of claim 1.

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

Claim 1 of the second auxiliary request differs from claim 1 of the main request in that the feature "*wherein the hydrolyzed whole grain particles are agglomerated to a particle size of 400-1000 microns*" has been added to step d).

Claim 1 of the third auxiliary request is identical to claim 1 of the second auxiliary request.

Claim 1 of the fourth auxiliary request differs from claim 1 of the second auxiliary request in that the particle size in step d) has been limited to "*400-700 microns*".

Claim 1 of the fifth auxiliary request is identical to claim 1 of the fourth auxiliary request.

In the first, third and fifth auxiliary requests, the product claims have been deleted.

V. In the statement of grounds of appeal, the appellant defended the patent in suit on the basis of the sets of claims on which the decision was based, i.e. the main request and the first to fifth auxiliary requests filed by letter of 10 January 2017.

VI. In the reply to the statement of grounds of appeal, the respondent maintained, *inter alia*, its objection of lack of sufficiency of disclosure.

VII. By letter dated 19 March 2020, the respondent filed document D27 and provided further arguments regarding sufficiency of disclosure.

VIII. In a communication pursuant to Article 15(1) RPBA 2020, following the summons to oral proceedings, the board

summarised the issues to be discussed at the oral proceedings and conveyed its preliminary opinion on sufficiency of disclosure.

IX. By letters dated 18 August 2020 (appellant) and 4 September 2020 (respondent), both parties provided further arguments in support of their case.

X. The oral proceedings took place by videoconference to which both parties agreed.

XI. The arguments of the appellant, as far as they concern the decisive issues of the present decision, can be summarised as follows.

- Sufficiency of disclosure - main request

The claimed invention was sufficiently disclosed. The person skilled in the art would have been able to carry out the claimed method and obtain a product with the stated effects using the information provided in the patent in suit and common general knowledge.

The opponent, who had the burden of proof, had not provided any evidence to the contrary. Contrary to the situation in T 63/06 on which the opposition division relied, the patent in suit provided enough technical information on how to implement the claimed method, including the hydrolysis step a). The person skilled in the art would also have readily determined whether the desired product had been obtained.

The invention was directed to a hydrolysed whole grain flour that maintained its nutritional value and whole grain status throughout processing and was highly dispersible in liquid and semi-solid media (see

paragraphs [0004], [0007], [0010] and [0012]). It was prepared by the claimed method with steps a) to d). The expression "maintaining its whole grain status" or "maintaining the integrity of the whole grain" as used in step a) was defined in paragraph [0010] of the patent in suit. The subsequent paragraphs [0011], [0012] and [0015] made it clear that the hydrolysis step a) controlled the maintenance of the integrity of the whole grain flour and that the subsequent steps b) to d) provided the high dispersibility of the resultant whole grain flour.

As regards the hydrolysis step, the patent in suit contained in Table 1 and paragraphs [0010] and [0011] a clear disclosure of the nature and properties of the starting material and the hydrolysed intermediate and final material produced from the starting material. The skilled person would have known exactly what they were aiming at. Table 1 described a specific example of the whole grain starting material and the final hydrolysed material. It was apparent from Table 1 that the change in food constituents of the hydrolysed final material was negligible.

The maintenance of the starch integrity had been verified and validated. The results were provided in Figures 1 and 2. Similar to Table 1, these figures described examples of starting material and hydrolysed product and made it possible to determine whether the integrity of the whole grain in the starting material had been maintained during hydrolysis. Acceptable margins for the hydrolysed product were provided in Figure 2, which showed that the starch content of hydrolysed whole grain oat flour was within the $+2\sigma$ and -2σ boundaries.

In paragraphs [0013], [0014] and [0015], the patent in suit also provided enough information on the process parameters to enable the skilled person to convert the starting material into the desired hydrolysed material. The essential process features, such as temperature, time and pressure, particularly in the extruder, were disclosed. The hydrolysis in the extruder was the essential step which determined the composition of the hydrolysed whole grain flour. The pre-extrusion hydrolysis was not relevant. The appropriate selection of further parameters, such as the pH, salt content, amount and activity of the enzyme would have been within the common general knowledge of the person skilled in the art. These parameters could have been established by routine trial and error experimentation. The same applied regarding the extrusion parameters. Given the explicit instruction in the patent in suit, i.e. that the starch molecules and the nutritional backbone of the whole grain were maintained throughout processing, it would have been clear to the person skilled in the art that the hydrolysis had to be carried out gently to reduce the size of the starch molecules while simultaneously avoiding the formation of oligomers and reducing sugars.

As regards the alpha-amylase enzymes to be used in the hydrolysis step, the teaching in the patent in suit was neither incomplete nor insufficient. These enzymes are commonly available, and their use is widely known in the field of cereal processing and the hydrolysis of cereal products. The selection of a suitable alpha-amylase and the required process conditions would have been within the skilled person's common general knowledge when the composition of the starting material and the composition of the hydrolysed material were known. For sufficiency of disclosure, identification of

a specific alpha-amylase was not essential. Any alpha-amylase known in the field could be used. This was illustrated, for example, by document D27. D27 explained the functionality and usage of a commercially available alpha-amylase, namely to hydrolyse/break down starch and starch fractions (see first page, left-hand column, second and third paragraph, and right-hand column, third and fourth paragraphs). It also showed that carrying out tests to find appropriate process conditions for the hydrolysis would have been routine for the person skilled in the art (see D27, first page, right-hand column, fourth paragraph). Relevant process parameters were discussed, and the product of the hydrolysis were defined (see second page, left-hand column).

The skilled person trying to succeed rather than to fail could easily have selected process conditions resulting in smaller starch molecules while at the same time avoiding the breakdown of the starch molecules into smaller molecules no longer considered to be starch molecules.

Although the patent in suit contained no example expressly combining a specific starting material with a specific hydrolysed material and a specific set of process parameters necessary for the conversion of one into the other, the information in Table 1, Figures 1 and 2, and the disclosure of the narrow ranges for the process parameters in paragraphs [0013] to [0015] would have provided adequate guidance for the skilled person to perform the invention without undue burden. The skilled person could have readily determined whether the hydrolysis had begun and continued, whether gelatinisation and cooking had occurred, and whether a hydrolysed whole grain product was obtained. They could

readily have selected suitable process parameters to obtain a hydrolysed product in which the starch molecules were maintained and the formation of reducing sugar was avoided. No research programme was necessary.

- Sufficiency of disclosure - first to fifth auxiliary requests

The subject-matter of the auxiliary requests was sufficiently disclosed for essentially the same reasons as for the main request.

XII. The arguments of the respondent, as far as they concern the decisive issues of the present decision, can be summarised as follows.

- Sufficiency of disclosure - main request

The patent in suit did not disclose the invention in a manner sufficiently clear and complete for it to have been carried out by the person skilled in the art. In particular, it failed to indicate at least one way to carry out the invention.

The patent in suit did not provide any information regarding the implementation of the essential hydrolysis step. In such a case, it was sufficient for the opponent to raise serious doubts of whether the person skilled in the art could have carried out the invention as claimed in the form of comprehensible and plausible arguments (see T 63/06 and T 491/08). The burden of proof that common general knowledge would have enabled the skilled person to carry out the invention laid with the patent proprietor.

In the decision under appeal, the opposition division correctly stated that for the patent to meet the requirement of sufficiency of disclosure, it must be possible to reproduce the claimed method and obtain a whole grain flour in which the integrity of the whole grain was maintained.

As regards the desired product, the skilled person would have been left without any guidance on how the claimed effect, i.e. the maintenance of the integrity of the whole grain, should be determined. No disclosure was provided in the patent in suit on how the relevant properties of the starting material and the product could be measured or when the hydrolysis should be stopped. Table 1 was not helpful in this respect. It did not specify the enzyme or any other process parameters to be used in the hydrolysis step. It did not contain any information on how the contents of the ingredients were measured and was silent on the acceptable margins for the starch degradation. It was not even clear what was encompassed by the term "starch". In view of the typical effect of alpha-amylases, which readily hydrolyse starch into a spectrum of dextrins, oligomers and sugars, the presence of such dextrins and oligomers in the "starch" component of Table 1 could not be excluded. Furthermore, the data provided in Table 1 was questionable because the starch content increased after the hydrolysis, and the respective amounts of the ingredients added up to more than 100%. Figures 1 and 2 were not helpful either in determining the changes which occurred during hydrolysis.

The definition of "whole grain benefits" in paragraph [0012] of the patent in suit reflected regulatory requirements, which usually depended on the

geographic area. It was not appropriate to clearly define the meaning of "maintaining the integrity of the whole grain".

Furthermore, contrary to the appellant's assertion, paragraphs [0011] and [0013] to [0015] of the patent in suit failed to provide sufficiently detailed hydrolysis conditions that would have enabled the skilled person to prepare the desired product. Details regarding the temperature, pH, reaction time, enzyme activity, pressure, concentration of substrate and enzyme, were missing. Contrary to the appellant's allegation, none of these paragraphs disclosed narrow ranges for any of the process parameters. Moreover, no information was provided on the pre-extrusion hydrolysis step.

It was known that alpha-amylase randomly hydrolysed, i.e. degraded, starch into a variety of polysaccharides, dextrins, oligosaccharides and monosaccharides (see, for example, D27, first page, left-hand column, first paragraph; second page, left-hand column, last paragraph). Depending on the amount and the process conditions, the enzyme of D27 was able to rapidly and fully dextrinise starch to low degree polymerisation products (see D27, first page, right-hand column, fifth paragraph). According to the claimed invention, the integrity of the whole grain, and consequently the integrity of the starch, had to be maintained. This was exactly the opposite of what was usually achieved when starch was hydrolysed with alpha-amylase. Furthermore, numerous types of alpha-amylases existed. This resulted in a different outcome depending on various parameters. The patent in suit provided no guidance on the selection of a suitable alpha-amylase and appropriate process conditions to avoid substantial starch degradation and prevent the formation of low

molecular compounds. The skilled person trying to implement the process according to the invention and obtain the desired whole grain flour product would have been compelled to carry out an entire research programme. This amounted to undue burden.

- Sufficiency of disclosure - first to fifth auxiliary requests

The subject-matter of the auxiliary requests lacked sufficiency of disclosure for essentially the same reasons as for the main request.

XIII. The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution on the basis of the set of claims according to the main request or, alternatively, one of the sets of claims according to the first to fifth auxiliary requests, all filed by letter dated 10 January 2017 and attached as Annex 2 to the decision under appeal.

XIV. The respondent requested that the appeal be dismissed, or, alternatively, that the case be remitted to the opposition division for further prosecution if the main request or any of the first to fifth auxiliary requests was held to comply with the requirement of sufficiency of disclosure. In addition, the respondent requested the admission of document D27 filed by letter of 19 March 2020.

XV. At the end of the oral proceedings, the decision of the board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. Admission of document D27

Document D27 was filed by the respondent at a late stage in the appeal proceedings. The appellant did not object to its admission since it aided its case. The board had no reason to reject this document either. Accordingly, document D27 was admitted into the appeal proceedings (Article 13(1) RPBA 2020).

Main request

3. Sufficiency of disclosure

3.1 According to established case law of the boards of appeal, an invention is sufficiently disclosed if it can be performed by the person skilled in the art without undue burden in the whole area claimed, using common general knowledge and taking into account further information provided in the description of a patent or patent application. An invention is in principle sufficiently disclosed if at least one way is clearly indicated enabling the person skilled in the art to carry out the invention.

3.2 Claim 1 of the main request is directed to a method for the production of a highly dispersible whole grain flour comprising the steps a) to d) (see point IV above). According to step a), a whole grain flour is hydrolysed using alpha-amylase, the alpha-amylase hydrolyses the whole grain flour while maintaining the integrity of the whole grain; the hydrolysed whole grain flour is heated in a cooking extruder and

gelatinised by mechanical action to form a whole grain flour dough, whereby the mixture resides in the extruder for a time sufficient to gelatinise and cook the starch, generally at least one minute, wherein prior to exiting the extruder, the hydrolysed whole grain flour dough is heated to 121 to 149 ^{o}C to deactivate the alpha-amylase.

3.3 The board agrees with the opposition division that for compliance with the requirement of sufficiency of disclosure, it must have been possible for the skilled person to reproduce the claimed process and obtain the desired product, which is a highly dispersible whole grain flour. The board also agrees with the opposition division that step a) resulting in the formation of a hydrolysed whole grain flour dough is crucial for the maintenance of the whole grain status in the final product. The skilled person would understand that after the deactivation of the alpha-amylase at the end of step a), no further significant hydrolysis occurs in the subsequent pelletising, milling and agglomeration steps.

3.4 It is undisputed that the outcome of the hydrolysis step can be influenced by a variety of process parameters including, for example, the type of alpha-amylase and its concentration, reaction time, temperature or pressure, pH, etc. It is equally undisputed that the patent in suit contains no working example in which a specific starting material, a specific intermediate product according to step a) and a specific final product is disclosed in combination with a set of specific process parameters for the conversion of the starting material into the desired product.

3.5 The appellant essentially argued that the patent in suit clearly discloses the nature and properties of the starting material, the hydrolysed intermediate product and the final product and contains sufficiently detailed information on the process parameters for the person skilled in the art to have carried out the claimed process. Process parameters which were not explicitly disclosed could easily have been supplemented by the person skilled in the art based on their common general knowledge and their clear knowledge of the intended product.

3.6 As regards the nature and properties of the starting material and the desired product, the appellant relied on paragraphs [0004], [0007], [0010] to [0012], Table 1, and Figures 1 and 2 of the patent in suit.

3.7 Paragraph [0004] characterises the product according to the invention as "hydrolysed whole grain flour that maintains its whole grain structure and nutritional value and is highly dispersible". A similar wording can be found in paragraph [0007], which states that "an enzyme hydrolyzes the whole grain flour while maintaining the integrity of the whole grain". In paragraph [0010], the desired product is defined as "hydrolysed whole grain flour that maintains its whole grain status throughout processing and is highly dispersible in liquid and semi-solid media". This is followed by the statements that, "[T]he whole grain may be any suitable cereal grain such as oat, wheat, corn (maize), rice, barley, rye, quinoa, sorghum, millet, triticale or combination thereof". Subsequently, paragraph [0010] defines the expressions "whole grain status", "whole grain standard of identity", "standard of identity of the whole grain" or "maintaining the integrity of the whole grain", which "shall mean whole

grains consisting of the intact, ground, cracked or flaked caryopsis, whose principal anatomical components - the starchy endosperm, germ and bran - are present in the same relative proportion as they exist in the intact caryopsis".

Paragraph [0011] of the patent in suit explains that the (whole grain) flour is hydrolysed using an enzyme that "allows the whole grain flour to maintain its standard of identity as whole grain", for example, alpha-amylase. The enzyme "hydrolyzes the alpha 1-4 bonds on the amylopectin molecules that makes up the starch portion of the whole grain". Furthermore, it is stated that "[T]esting and analysis of whole grain flours, such as wheat flour and oat flour using the method set forth herein has verified and validated that the starch molecules are maintained through processing. The results of such testing are reflected in Figures 1 and 2 and table 1 below". It is also stated in paragraph [0011] that any change of the food constituents is negligible at best.

According to paragraph [0012] "the nutritional backbone of the whole grain flour is maintained throughout processing" and the hydrolysed whole grain flour "provides the same nutritional benefits as un-hydrolysed whole grain flour". No further information regarding the nutritional backbone or benefits are provided.

3.8 Considering the disclosure of the paragraphs mentioned in point 3.7 above, it is the board's view that the person skilled in the art would have been confronted with contradictory requirements. On the one hand, the relative proportions of germ, bran and starchy endosperm are to be maintained to keep the whole grain

status, which in the board's and the appellant's view requires that the starch portion is maintained. This is consistent with the statement in paragraph [0011] of the patent that the starch molecules are maintained, i.e. not changed, throughout processing. On the other hand, hydrolysis of alpha 1-4 bonds with alpha-amylase takes place. This breaks down the starch molecules and consequently changes the starch molecules and the starch properties. No information as to the nature of the change is provided in the patent specification.

3.9 According to the appellant, the skilled person would have understood from the disclosure of the patent in suit that the hydrolysis step a) according to the invention breaks down the starch molecules into smaller starch molecules but does not go so far as to convert the starch molecules into smaller molecules, such as oligomers or reducing sugars.

3.10 Although this may be a reasonable assumption to make for the person skilled in the art to reconcile the contradictory requirements of maintaining and hydrolysing, i.e. degrading, the starch molecules, it immediately raises the question as to the degree of change permitted without affecting the integrity of the starch. The board notes that the patent in suit is completely silent in this respect. No criteria are provided in the patent that would have allowed the skilled person to determine if and when the integrity of the starch, and consequently the integrity of the whole grain, was maintained. There is no information on the degree of depolymerisation or the chain length of the hydrolysed starch molecules and no information on any other property based on which the skilled person could have established that the integrity of the starch

and therefore the integrity of the whole grain had been maintained.

3.11 Table 1 on which the appellant relied is not helpful in this context. It lists the "%" - the board assumes weight percent - of various components, including starch, of a whole oat flour and a hydrolysed oat flour. However, the disclosure in Table 1 does not allow any conclusion as to the difference between the starch component in the "whole oat flour" (i.e. the unhydrolysed starting material) and the "hydrolysed oat flour". Indeed, in accepting the appellant's argument that the small changes between the whole oat flour and the hydrolysed oat flower observed in Table 1 are within the experimental error of the tests and analysis that had been carried out, the only objective conclusion that can be drawn from Table 1 is that no change in the starch has occurred and therefore no hydrolysis had taken place. This contradicts the disclosure of the patent in suit (see paragraph [0014] and claim 1). Table 1 provides no answer as to the extent of the chemical change permitted without compromising the integrity of the starch and consequently the integrity of the whole grain.

3.12 Figures 1 and 2 of the patent in suit do not disclose anything more than Table 1 as regards the hydrolysed product. Figure 1 provides the "% starch" of corn and wheat flour pre- and post-extrusion. No information on the method for the determination of these values is disclosed. Nor is it possible to determine the change in the starch which occurred during the hydrolysis. The same applies to Figure 2, which also merely provides the "% starch" of whole oat flour after extrusion or extrusion/hydrolysis. The board is not convinced by the appellant's argument that Figure 2 reflects acceptable

margins for the starch degradation. The value 2σ is a commonly used statistical value (2 standard deviation) which reflects the area in which almost all the values of a data set can be found. In the case at hand, this is the data set which led to the determination of the mean value (i.e. 53.66) of the starch content for the pre-processed whole oat flour. No conclusion as to the degree of depolymerisation or the nature of the starch molecules and therefore to any margin of starch degradation can be drawn from Figure 2.

3.13 Furthermore, as already explained in point 3.4 above, the patent in suit does not contain any information on the preparation of the products in Table 1 or Figures 1 and 2. The skilled person could not have reproduced and analysed them to obtain at least some guidance as to the degree of degradation permissible without jeopardising the integrity of the whole grain.

3.14 The board also agrees with the opposition division and the respondent that the information on the process parameters in step a) is scarce and those parameters specified are certainly not narrow as argued by the appellant. In this context, the board notes that according to the patent specification, a hydrolysis step takes place before the hydrolysed whole grain flour is transferred to the extruder in which the hydrolysis and breakdown of the whole grain flour continues (see claim 1 and paragraph [00014], first sentence). No information at all is provided regarding the process parameters of this pre-extrusion hydrolysis, e.g. the type of amylase, its concentration, the temperature and pressure of reaction mixture, etc., all of which significantly influence the outcome of the hydrolysis (see point 3.4 above). The appellant's argument that the pre-extrusion hydrolysis

was not relevant is therefore not convincing. Moreover, the alleged insignificance is not derivable from the patent in suit.

3.15 According to paragraph [0014] of the patent, the hydrolysis continues in the extrusion step. Similar to the pre-extrusion hydrolysis, most of the process parameters in the extrusion step, such as type and concentration of amylase, temperature and pressure, are not disclosed. Paragraph [0014] states that the material in the extruder is heated from an initial inlet temperature to a final exit temperature. The allegedly narrow temperature range to which the appellant referred in this context is the temperature range for the enzyme destruction and at best refers to a temperature range for the exit temperature. The same applies to the pressure, which is the pressure at the exit of the extruder.

3.16 The board accepts that some information on the duration of the hydrolysis steps is derivable in the patent in suit (see paragraph [0015]). However, this information concerning a single parameter is not sufficient in a situation where the outcome of a reaction, in the case at hand, the hydrolysis before and during the extrusion, depends to a significant extent on a number of other parameters, which are not defined or are only insufficiently defined.

3.17 At the oral proceedings, document D27 was extensively discussed and relied on by both parties. According to the appellant, D27 showed that the selection of appropriate reaction conditions is a purely routine task if the skilled person knows what they want to achieve.

3.18 D27 is a datasheet for a commercially available alpha-amylase, namely "Validase BAA 1000L". The document explains, *inter alia*, the functionality, activity and usage of the enzyme and provides information on certain parameters that can influence the performance of the enzyme (amount, pH and temperature). According to D27, Validase BAA 1000L selectively and efficiently breaks down starch and starch fragments. It reduces their size, shape and chain length; breaks down interior alpha-1,4-glycosidic bonds; and liberates dextrins and oligosaccharides (see first page, left-hand column, second and third paragraph). It can be used to liquefy starch and readily hydrolyses starch into dextrins, maltose and glucose (see first page, right-hand column, third paragraph; second page, left-hand column, last paragraph). At a dose of 0.035 to 0.070% based on starch weight and under optimal processing conditions, it adequately liquefies a 30 to 35% starch slurry in 15 to 30 minutes (see first page, right-hand column, fifth paragraph). D27 also provides information as to the effective and optimum range of certain parameters such as pH and temperature (see first page, left-hand column, fifth paragraph; second page, sections regarding the effect of pH and temperature).

In sum, D27 provides important information regarding the use of Validase - a representative for alpha-amylase in general - in the liquefaction of starch, i.e. the degradation of starch into a spectrum of dextrins, oligosaccharides and maltose, the exact opposite of what the patent wants to achieve. The routine tests to which the appellant referred (see D27, first page, right-hand column, first paragraph) are tests to find the optimum conditions for the liquefaction, for which there is sufficient guidance in D27 (e.g. amount of enzyme, effective and optimal pH

and temperature). However, no guidance is provided as to how to control the hydrolysis in such a way that the starch molecules are essentially maintained while at the same time the formation of low molecular molecules, such as dextrins and maltose, is avoided.

Moreover, the board is convinced that the routine selection of appropriate process parameters for the hydrolysis with the help of Validase or any other alpha-amylase is only possible if the desired product is clearly defined, for example, in terms of a permissible degree of breakdown or depolymerisation or any other clearly defined property that would have allowed the skilled person to conclude that the hydrolysis had not changed the starch to such a degree as to compromise its integrity and therefore the integrity of the whole grain. Precisely this information is missing in the patent in suit (see point 3.10 above).

3.19 For the aforementioned reasons, the board concludes that the patent in suit neither sufficiently defines the hydrolysed intermediate or final product nor clearly discloses at least one way of obtaining such a product. Contrary to the appellant's opinion, the lack of this information is not merely a clarity issue. Rather, it concerns the very essence of the invention, the preparation of a hydrolysed whole grain flour product in which the integrity of the whole grain is maintained.

3.20 The appellant also argued that the respondent had not discharged its burden of proof because it had not provided any experimental evidence to support its objection of lack of sufficiency of disclosure (i.e. it had not tried to carry out the invention).

3.21 The board agrees with the appellant that the burden of proof of insufficiency rests as a general rule with the opponent.

However, as explained in points 3.4 and 3.10 to 3.18 above, the patent in suit does not contain instructions (e.g. specific protocol or working example) which are sufficiently complete and detailed enough for the skilled person to rework the invention and to obtain the intended, functionally defined product. In these circumstances, it is sufficient for the opponent to raise serious doubts as to whether the skilled person can carry out the invention by showing that there are gaps in the disclosure which the skilled person cannot close using their common general knowledge. If a patent lacks a complete and detailed disclosure in relation to a functional feature, the opponent cannot be expected to compensate for the lack of information and to close existing gaps in an inventive manner.

In the case at hand, the board judges that the opponent has discharged its burden of proof. It was then up to the patent proprietor to rebut the opponent’s argument and to explain why there are no gaps and why the information provided in the patent in suit in combination with common general knowledge is sufficient for the skilled person to carry out the invention and to obtain a whole grain flour, which maintains the integrity of the whole grain. For the reasons set out in points 3.8 to 3.19 above, the appellant's arguments in favour of sufficiency of disclosure do not convince the board.

3.22 Hence, the board concludes that the subject-matter of claim 1 of the main request does not comply with the

requirement of sufficiency of disclosure. The main request is therefore not allowable for non-compliance with Article 83 EPC.

First to fifth auxiliary request

4. Sufficiency of disclosure

In claim 1 of each of the auxiliary requests, the hydrolysis step a) is identical to the hydrolysis step a) of the main request. Thus, the same observations and conclusion under Article 83 EPC apply *mutatis mutandis* to the subject-matter of claim 1 of the first to fifth auxiliary request. Therefore, these requests are not allowable either.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow J. Molina de Alba

Decision electronically authenticated