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Datasheet for the decision of 23 October 2008

Case Number: T 0362/06 - 3.3.09

Application Number: 93923347.4

Publication Number: 0669809

IPC: A23L 1/00

Language of the proceedings: EN

Title of invention:
Process for the heterotrophic production of microbial products with high concentrations of omega-3 highly unsaturated fatty acids

Patentee:
MARTEK BIOSCIENCES CORPORATION

Opponent:
Nutrinova Nutrition Specialties & Food Ingredients GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 56, 83

Relevant legal provisions (EPC 1973):
-

Keyword:
"Sufficiency - yes"
"Inventive step - yes"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0362/06 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 23 October 2008

Appellant: (Opponent)	Nutrinova Nutrition Specialties & Food Ingredients GmbH Industriepark Höchst-Building D706 D-65926 Frankfurt am Main (DE)
Representative:	Ahrens, Gabriele Jasperallee 1A D-38102 Braunschweig (DE)
Respondent: (Patent Proprietor)	MARTEK BIOSCIENCES CORPORATION 6480 Dobbin Road Columbia MD 21045 (US)
Representative:	Mallalieu, Catherine Louise D Young & Co 120 Holborn London EC1N 2DY (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted 13 January 2006 concerning maintenance of European patent No. 0669809 in amended form.**

Composition of the Board:

Chairman: P. Kitzmantel
Members: J. Jardón Álvarez
K. Garnett

Summary of Facts and Submissions

I. The grant of European patent No. 0 669 809 in respect of European patent application No. 93923347.4 in the name of OMEGATECH, INC. (now MARTEK BIOSCIENCES CORPORATION), which had been filed on 12 October 1993 as International application PCT/US93/09679 (WO - 94/08467), was announced on 4 June 2003 (Bulletin 2003/23) on the basis of 20 claims. Independent Claims 1, 14, 15, 16 and 20 read as follows:

"1. A process for growing *Thraustochytrium, Schizochytrium*, and/or mixtures thereof, comprising growing said *Thraustochytrium, Schizochytrium*, and/or mixtures thereof, in a culture medium containing a non-chloride sodium salt and having less than 500 milligrams of chloride per liter of said culture medium.

14. A microfloral biomass grown by the process of any one of claims 1 to 13, comprising *Thraustochytrium, Schizochytrium*, and/or mixtures thereof, wherein said *Thraustochytrium, Schizochytrium*, and/or mixtures thereof have a cell aggregate size less than 150µ (150 microns).

15. A method of producing shrimp comprising feeding microflora grown by the process of any one of claims 1 to 13 selected from *Thraustochytrium, Schizochytrium*, and/or mixtures thereof to larval shrimp, said microflora having a cell aggregate size less than 150µ (150 microns).

16. A food product comprising:
(a) a microflora grown by the process of any one of claims 1 to 13 selected from *Thraustochytrium, Schizochytrium*, and /or mixtures thereof; and
(b) a nutrient selected from flaxseed, rapeseed, soybean, avocado meal, and mixtures thereof.

20. A method of aquaculture comprising feeding microflora grown by a process according to any one of claims 1 to 13 selected from *Thraustochytrium, Schizochytrium*, and/or mixtures thereof to organisms selected from larval shrimp, brine shrimp, rotifers and mollusks, said microflora having a cell aggregate size less than 150µ (150 microns)".

Claims 2 to 13 and 17 to 19 were dependent claims.

II. Notice of Opposition requesting the revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Article 100(a) EPC) and insufficiency of disclosure (Article 100(b) EPC), was filed by Nutrinova Nutrition Specialities & Food Ingredients GmbH on 3 March 2004.

During the opposition proceedings *inter alia* the following documents were cited:

D1: WO - A - 91/07498

D2: G. Bahnweg, Veröff. Inst. Meeresforsch. Bremerh. (1979), 17, pages 245 - 268

D7: An undated declaration of the inventor William R. Barclay, filed on 14 September 2005, and

D8: Table including a comparison of the size of several species of *Thraustochytrium* and *Schizochytrium* in different replication phases by reference to corresponding literature (L1-L12).

III. By its interlocutory decision announced orally on 15 November 2005 and issued in writing on 13 January 2006, the Opposition Division held that the grounds for opposition raised by the Opponent did not prejudice the maintenance of the patent in amended form.

The Opposition Division in its decision held that the requirements of Article 83 EPC were fulfilled because the experimental evidence in the patent in suit and in D7 demonstrated that the claimed invention could be worked. Moreover no proof to the contrary had been presented by the Opponent.

Concerning inventive step, the Opposition Division, starting from D1 as closest prior art document, saw the technical problem to be solved by the patent in suit as being to provide a process for growing *Thraustochytrium, Schizochytrium*, and/or mixtures thereof in a culture medium with reduced corrosive properties, while still achieving satisfactory growth and omega-3 highly unsaturated fatty acid production. The solution to this technical problem through the combined presence of a non-chloride sodium salt and less than 120 mg of chloride per litre of said culture medium was in the Opposition Division's opinion not obvious having regard to D1 alone or in combination with the other cited prior art.

IV. On 10 March 2006 the Opponent (Appellant) lodged an appeal against the decision of the Opposition Division and paid the appeal fee on the same day.

In the Statement of Grounds of Appeal filed on 10 May 2006, the Appellant requested the revocation of the patent in its entirety on the grounds of lack of sufficiency of disclosure, lack of novelty and lack of inventive step.

The Appellant also filed a copy of page 2669 of Römpps Chemielexikon, 9. Auflage 1991 concerning "Meerwasser" (seawater) and the following document:

D9: P.F. Stanbury and A. Whitaker, "Principles of Fermentation Technology", Pergamon Press Ltd, 1984, pages 121 - 123, 236, 237, 242 and 243.

V. With letter dated 25 September 2006 the Patent Proprietor (Respondent) requested that the appeal be dismissed and the patent be maintained with the claims in accordance with the decision of the Opposition Division. Auxiliarily it requested that the patent be maintained on the basis of any of the auxiliary requests 2 to 6 as referred to in the decision of the Opposition Division.

VI. On 3 April 2008 the Board dispatched a summons to attend oral proceedings on 23 October 2008. In a communication dated 11 April 2008 the Board drew the attention of the parties to the points to be discussed during the oral proceedings.

VII. By letter dated 17 September 2008, the Respondent filed further arguments in support of its main request and requested that the appeal be dismissed and the patent be maintained as maintained by the Opposition Division. The Respondent further filed sets of claims for ten auxiliary requests.

VIII. By letter dated 22 September 2008 the Appellant also filed further arguments in support of its requests and the following document:

D10: D.H. Jennings "SOME ASPECTS OF THE PHYSIOLOGY AND BIOCHEMISTRY OF MARINE FUNGI", *Biol. rev.*, 1983, (58), pages 423 - 459.

IX. During the oral proceedings before the Board of Appeal the Respondent filed a set of claims for a new request ("auxiliary request 2") based on its previous first auxiliary request but with the deletion of Claims 12 to 16 and withdrew the pending main and first auxiliary requests.

Claim 1 of this request reads as follows:

"1. A process for growing *Thraustochytrium, Schizochytrium*, and/or mixtures thereof, comprising growing said *Thraustochytrium, Schizochytrium*, and/or mixtures thereof, in a culture medium containing sodium sulfate and having less than 120 milligrams of chloride per liter of said culture medium".

Claims 2 to 11 are dependent claims.

X. The arguments presented by the Appellant in its written submissions and at the oral proceedings insofar as they are relevant for the present decision may be summarized as follows:

– The Appellant maintained that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by the skilled person. It noted that the evidence provided by the Patentee in this respect included only two strains for which growth at relatively low chloride content had been demonstrated.

Insofar as the claims related to the use of *Schizochytrium,* examples 15 and 16 in the specification showed that sufficient growth of the microorganism was achieved only if certain amounts of chloride and sodium sulphate were used in the culture medium. However the claims did not specify the amount of chloride or sodium sulphate to be used and therefore included embodiments with minimal amounts of such components for which growth of the microorganisms in any substantial amount had not been shown by the Patentee.

Concerning *Thraustochytrium,* the patent specification did not include any worked example and the results in D7 merely showed that the microorganisms were able to "survive" under the conditions used. Moreover no information was given in the patent in suit as to how to optimize the results in order to achieve a method useful in commercial production.

– Concerning inventive step, the Appellant, starting from D1 as closest prior art, saw the problem underlying the patent in suit as being to provide a commercial method for growing *Thraustochytrium,* and *Schizochytrium* with reduced corrosion. The solution to this problem, namely the use of a culture medium containing sodium sulphate and less than 120 mg of chloride per litre did not involve an inventive step essentially because the skilled person knew from example 8 of D1 that *Schizochytrium* sp. S31 grew at very low salinities and that D9 gave the skilled person a hint that chloride salts could be replaced by hydroxide or sulphates in order to reduce corrosion of the equipment. Moreover it was known from D10 that sodium was required for growth of the microorganisms.

The Appellant argued further that the subject-matter of the claimed process did not involve an inventive step because the patent in suit did not solve the claimed problem across the whole range claimed. The Appellant supported this objection essentially with the same arguments used for its objection of lack of sufficiency of disclosure (see above).

XI. The arguments presented by the Respondent may be summarized as follows:

– The Respondent pointed out that the experimental data in the patent and in D7 confirmed that the technical effect was achieved using a range of concentrations of sodium sulphate and chloride and for several strains of microorganisms. It pointed out that *Thraustochytrium* and *Schizochytrium* were

microorganisms showing different patterns of growth and that for *Thraustochytrium* the experiments in D7 were carried out under the same conditions used for *Schizochytrium* - i.e. optimised for this microorganism but not for *Thraustochytrium* - in order to allow a fair comparison of the results. In any case, growth was achieved and the skilled person was able, with the information in the patent in suit, to optimize the results also for these microorganisms. It also pointed out that it was the Appellant/Opponent which had the burden of proof at this stage and that it had failed to file experimental evidence showing that the claimed invention could not be carried out by the skilled person.

– Concerning inventive step, the Respondent agreed with the Appellant that D1 represented the closest prior art document. It saw the problem to be solved as being to provide a process for growing *Thraustochytrium* and *Schizochytrium,* and/or mixtures thereof, in a culture medium with less corrosivity and without the need for controlling the pH of the medium.

The solution to this problem, namely the finding that, in the presence of sodium sulphate, chloride levels could be substantially reduced over those taught in D1 while increasing the omega-3 and total fatty acid production represented a substantial contribution not suggested by the cited prior art documents.

XII. The Appellant requested that the decision under appeal be set aside and that the European patent No. 0 669 809 be revoked.

The Respondent requested that the patent be maintained on the basis of Claims 1 to 11 of the request filed as the second auxiliary request during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. *Procedural matters*

2.1 The Respondent filed during the oral proceedings a new request based on the then pending auxiliary request 1 but with deletion of the claims directed to a method of producing shrimps (Claim 12) and the claims directed to a food product (Claims 13 to 16).

2.2 The Board decided to admit this request into the proceedings because, by deleting several claims of a pending request, the Appellant, who did not object its admission, was not confronted with any substantial change in the subject-matter of the proceedings.

3. *Sufficiency of disclosure (Article 83 EPC)*

3.1 The Board agrees with the finding in the appealed decision that the patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

3.2 The Respondent has neither disputed that at least one example enabling the skilled person to carry out the invention is clearly indicated in the patent specification nor shown that a reworking was not possible in this respect.

3.3 The Respondent argued however that the requirements of Article 83 EPC were not fulfilled because the skilled person was not given sufficient information as to how the invention could be performed across the whole range claimed. In particular the Respondent noted:

(i) that all the worked examples in the specification directed to the claimed process were carried out using only one specific strain of *Schizochytrium*, namely *Schizochytrium* ATCC No. 20888, and specific amounts of chloride ion and sodium sulphate. In its opinion the skilled person was not given any information about how to put the invention into practice when working under different conditions, for instance at a very low amount of sodium sulphate or in the absence of chloride, embodiments also falling within the ambit of the claims; and

(ii) that when using *Thraustochytrium*, the biomass yield obtained in the examples of D7 was so low that it merely would show that the microorganism could survive under the culture conditions, but the process could not be seen as adequate for commercial use.

3.4 The Board cannot accept these arguments of the Appellant for the following reasons:

3.4.1 The claimed process for growing *Thraustochytrium, Schizochytrium*, and/or mixtures thereof, is essentially characterized by the use of a culture medium containing sodium sulphate and having less than 120 milligrams of chloride per litre of culture medium. In examples 15 and 16 of the patent, *Schizochytrium* ATCC 20888 was cultured in a medium having different concentrations of sodium sulphate and chloride. These examples show that high biomass yields from glucose of greater than 50% can be obtained by selection of appropriate amounts of sodium sulphate and chloride content (see Table 10, entries 5 and 6). Additionally paragraphs [0014] and [0015] of the specification indicate the preferred ranges of chloride and sodium sulphate concentrations to be used to obtain the best growth of the microorganisms.

Consequently the Appellant's criticism that the patent did not contain specific examples using very low amounts of sodium sulphate and/or chloride is not well-founded. The gist of the present invention is precisely the use of very low chloride concentrations in the presence of sodium sulphate in the culture medium, sodium sulphate being a sodium source known to the skilled person to be an essential nutrient for these microorganisms from D10 (page 443). It is therefore evident to the skilled person that, in order to achieve the desired growth, the amount of sodium sulphate is the most relevant feature of the process and that too small an amount will result in poor growth. It would then *prima facie* be clear to the skilled person that in the case of failure due to the use of very low amounts of sodium sulphate, its amount should be increased. This finding is confirmed by paragraphs [0014] and

[0015] of the patent which indicate the preferred concentrations of sodium sulphate.

3.4.2 Concerning *Thraustochytrium,* although not exemplified in the patent, the Respondent has performed further experimental evidence showing that these microorganisms also grow and yield the desired fatty acids (see D7, Tables 3 and 6). The Respondent explained during the oral proceedings that each microorganism has a different way of growing and that, in order to allow a fair comparison, the experiments reported in D7 had been made under the same conditions as used for *Schizochytrium*, i.e. not adapted to *Thraustochytrium*, which grows much slower. It was insisted however that the skilled person would know how to optimize the results for this type of microorganism.

This assertion of the Respondent was not disputed by the Appellant during the oral proceedings and the Board sees no reason to disagree. In fact, the factors influencing the growth of the microorganism, for instance the organic carbon and nitrogen source, the phosphate additions, the various growing conditions, etc., are well within the general common knowledge of the skilled person who is thus aware of the measures to apply in order to transform initial failure into success without the exercise of inventive effort.

3.4.3 Finally, the fact that according to Example 8 of D1 some microorganisms of the type used in the patent in suit do not grow at low chloride levels has no significance at all. None of the embodiments of Example 8 of D1 corresponds to a process falling within the scope of the present invention because: (i) the amount

of chloride is still well above the amount now specified and (ii) in none of these examples is sodium sulphate present in the culture medium. They provide therefore no information about the embodiments covered by the present claims.

3.5 The Board, therefore, concludes that, under the circumstances, sufficient information and guidance is at the skilled reader's disposal enabling him to successfully carry out the claimed process within the whole range claimed. Hence the requirements of Article 83 EPC are met.

4. *Inventive step (Article 56 EPC)*

4.1 Claim 1 of the patent is directed to a process for growing *Thraustochytrium, Schizochytrium*, and/or mixtures thereof using a culture medium containing:

– sodium sulphate, and

– having less than 120 milligrams of chloride per litre of said culture medium.

4.2 Closest prior art

4.2.1 The Board considers, in agreement with the parties to the proceedings, that document D1 represents the closest prior art document.

4.2.2 D1 relates, like the patent in suit, to a method of producing omega-3 highly unsaturated fatty acids that comprises culturing *Thraustochytrium, Schizochytrium*, and mixtures thereof in a medium comprising a source of

organic carbon and a source of assimilable nitrogen (see Claims 20 - 21).

The examples in D1 show the growth of the microorganisms in a culture medium containing sodium chloride. Example 8 of D1, which represents the embodiment closest to the claimed invention, studies the salinity tolerance and fatty acid production of strains of *Thraustochytrium* and *Schizochytrium*. The strains are incubated in a range of differing salinity media prepared by diluting a medium containing the following salts: Na, 25 g/l; $MgSO_4.7H_2O$, 5 g/l; KCl, 1 g/l; $CaCl_2$, 200 mg/l. In dilutions 9 and 10, the chloride content of the medium is ca. 480 mg/l and 240 mg/l, respectively. Moreover the last sentence of example 8 of D1 indicates that strains growing at low salinities are advantageous when considering commercial production "both because of the corrosive effects of saline waters on metal reactors, and because of problems associated with the disposal of saline waters" (see page 56, lines 8 - 12).

4.2.3 The subject-matter of Claim 1 of the patent in suit differs from the disclosure of example 8 of D1 by the use of a still lower amount of chloride ion (less than 120 mg/l) and by the use of a different sodium salt, namely sodium sulphate.

4.3 Problem to be solved

4.3.1 Having regard to this prior art, the objective technical problem to be solved by the patent can be seen as the provision of a method for growing *Thraustochytrium, Schizochytrium* and/or mixtures

thereof wherein corrosivity is significantly reduced while still obtaining an effective growth of the microorganisms and production of omega-3 highly unsaturated fatty acids.

4.4 Solution to the problem

4.4.1 This problem is solved by the claimed process by further significantly reducing the amount of chloride in the culture medium and supplying the sodium content in the form of sodium sulphate.

4.4.2 As already discussed above in relation to sufficiency of disclosure the patent in suit includes several examples (see examples 13, 15 and 16) of the claimed method. These examples show that omega-3 highly unsaturated fatty acid and total fatty acid production when using sodium sulphate are comparable to or better than when using sodium chloride as a sodium salt.

Moreover example 15 includes a comparison with the above discussed embodiment of example 8 of D1 having a chloride concentration of ca. 240 mg/l. According to this example high yields of biomass, similar to those obtained in D1, are obtained when lowering the chloride concentration in the presence of sodium sulphate. According to Table 10 the biomass yield for a chloride concentration of 59.1 mg/L and 119.1 mg/L is similar to the value obtained when using a chloride concentration of 238.1 mg/L at a sodium concentration of 4.0 g/L (Table 10 right entries) and slightly reduced when using a sodium concentration of 2.37 g/L (Table 10 entries in the middle).

The further evidence filed by the Respondent during the opposition proceedings, D7, includes further examples with other microorganism strains.

4.4.3 The Appellant questioned that this evidence was sufficient to demonstrate that the problem was credibly solved across the whole area claimed using an approach similar to that used for questioning sufficiency of disclosure (see point 3.3 above).

4.4.4 In the Board's judgement the objections of the Appellant are also unfounded when relating to inventive step. The evidence on file shows that the problem has been credibly solved by the measures taken and that similar growth to that achieved in D1 can be obtained under the claimed conditions. It is also clear for the skilled person that, within the claimed ambit, some embodiments would result in a higher biomass yield than others as the result would also depend on the further elements/parameters of the process (other components of the culture medium, pH, temperature, strain used, etc.). Insofar as the essential features of the claimed process are concerned the specification discloses their nature and how they are to be modified in order to achieve satisfactory results. It would be at odds with a realistic assessment of inventive step to require that every embodiment of the patent achieves optimum results (yields) in order to establish that the problem has been credibly solved across the entire claimed area; rather the skilled person is aware that within the whole claimed area the results will vary and will necessarily include less satisfactory ones.

It is only in the situation that it is either *prima facie* unrealistic or established by appropriate evidence that a set problem cannot be solved across the entire claimed range that an inventive step argument on this basis can succeed; however, this is not the case here, especially as no evidence is on file in support of the allegation of the Appellant in this respect (on whom the burden of proof rests).

In the present case, the skilled person knows from the results in Table 10 of the patent in suit that optimum fermentation of *Schizochytrium* is achieved when working above 59.1 mg/L chloride and will make use of the information in the examples, in the other parts of the specification and within his own expertise in order to optimize the results when using different strains.

4.4.5 For these reasons the Board cannot accept the Appellant's argument that the evidence on file is not sufficient to demonstrate that the present problem has been credibly solved across the entire range claimed.

4.5 Obviousness

4.5.1 It remains to be decided whether, in view of the available prior art documents, it would have been obvious for the skilled person to solve this technical problem by the means claimed, namely by using a culture medium containing sodium sulphate and having less than 120 mg/L of chloride in said medium.

4.5.2 Insofar as the reduction of corrosion is concerned, the Board notes that the reduction of the chloride levels in order to avoid its corrosive action is well known to

the skilled person. Moreover D1 at the end of example 8 already gives a hint to the use of low salinity to avoid the corrosive affects of saline water on metal reactors.

Consequently, the Board considers that the decrease of corrosivity by using a lower amount of chloride is merely the logical consequence of the measure taken and cannot contribute to the presence of an inventive step.

4.5.3 Taking this into account, the remaining question is thus whether it would have been obvious to the skilled person that satisfactory growth of the microorganisms could be obtained at very low chloride contents in the presence of sodium sulphate.

4.5.4 There is no hint to this solution in D1, which uses in all its examples chloride concentrations well above the higher limit embraced by Claim 1. Moreover, sodium sulphate is not mentioned at all in D1 as a possible ingredient of the culture medium.

4.5.5 There is also no hint to this solution in the further documents cited during the proceedings. None of them mentions the possible replacement of sodium chloride by sodium sulphate in the culture medium. On the contrary, the presence of sodium chloride appears to be essential for growing of *Thraustochytrales* (see D2, page 255 "Virtually no growth was observed when NaCl was omitted from the medium") and there is no suggestion as to its possible replacement for sodium sulphate.

4.5.6 The Appellant argued further that it would have been obvious to arrive at the claimed process because D1 did not exclude working at still lower salinities and the skilled person knew from D9 that hydroxides and/or sulphates might be used to minimize corrosion (D9, page 237, right column, first full paragraph, lines 9 - 12) and from D10 that the presence of sodium is necessary for growing of the microorganisms (D10, pages 443 - 444 under "(a) requirement of sodium for growth").

4.5.7 The Board cannot find any hint in these documents to the claimed method. D9 merely confirms the knowledge of the skilled person that chloride should be avoided to minimize corrosion and D10 teaches that sodium is required for growth. However, sodium sulphate is not mentioned in these documents and consequently they cannot suggest its possible use for growing microorganisms when working at low chloride levels.

In the Board's judgement the approach of the Appellant in relation to inventive step does not take proper account of the established jurisprudence of the Boards of Appeal according to which, when assessing inventive step, the decisive question is not whether the skilled person could arrive at the invention (in the present case the use of sodium sulphate in the culture medium), but whether he would have done so with a reasonable expectation of obtaining a satisfactory growth of the microorganisms. Thus, the skilled person would get no incentive from D9 or from D10 to incorporate sodium sulphate into a culture medium having reduced content of chloride in order to find a solution to the existing technical problem.

4.5.8 Additionally, the use of sodium sulphate results in increased production of omega-3 and total fatty acids. Effectively, example 13 of the patent in suit clearly demonstrates that, when sodium sulphate is used as sodium source, the total fatty acid production is in some cases more than trebled and the omega-3 production is always substantially increased, thus substantiating a considerable benefit not offset by the somewhat reduced biomass yield; this is evidence for the fact that the choice of sodium sulphate as a source for sodium is not arbitrary.

4.5.9 It follows that the finding that the growing of *Thraustochytrium, Schizochytrium*, and/or mixtures thereof is achieved by using the combination of features of Claim 1 is not a teaching the skilled person being confronted with the task of finding a solution to the existing technical problem would find in the available prior art or within his general common knowledge.

4.6 The subject-matter of Claim 1 therefore involves an inventive step within the meaning of Article 56 EPC. Claims 2 to 11, which are dependent claims, also satisfy the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition Division with the order to maintain the patent on the basis of:

(a) Claims 1 to 11 of the request filed during the oral proceedings;

(b) figures 1 to 8 as granted;

and after any necessary consequential adaptation of the description.

The Registrar The Chairman

D. Sauter P. Kitzmantel