

**Internal distribution code:**

- (A) [ - ] Publication in OJ  
(B) [ - ] To Chairmen and Members  
(C) [ - ] To Chairmen  
(D) [ X ] No distribution

**Datasheet for the decision  
of 6 November 2013**

**Case Number:** T 0260/11 - 3.3.01

**Application Number:** 00989042.7

**Publication Number:** 1233969

**IPC:** C07H13/06, A61K39/39

**Language of the proceedings:** EN

**Title of invention:**

MONO- AND DISACCHARIDE DERIVATIVES

**Patent Proprietor:**

Protherics Medicines Development Limited

**Opponent:**

OK pat AG

**Headword:**

Disaccharide adjuvants/PROTHERICS

**Relevant legal provisions:**

EPC Art. 123, 84, 111

**Keyword:**

Admission of main request (yes)  
Amendments - broadening of claim (no) - added subject-matter  
(no)  
Claims - clarity (yes)  
Remittal (yes)



**Beschwerdekammern  
Boards of Appeal  
Chambres de recours**

European Patent Office  
D-80298 MUNICH  
GERMANY  
Tel. +49 (0) 89 2399-0  
Fax +49 (0) 89 2399-4465

Case Number: T 0260/11 - 3.3.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.01**  
**of 6 November 2013**

**Appellant:** Protherics Medicines Development Limited  
(Patent Proprietor) 5 Fleet Place  
London EC4M 7RD (GB)

**Representative:** Rutt, Jason Edward  
Rouse Patents  
Patents Agency  
11th Floor, Exchange Tower  
1 Harbour Exchange Square  
London E14 9GE (GB)

**Respondent:** OK pat AG  
(Opponent 1) Chamerstrasse 50  
CH-6300 Zug (CH)

**Representative:** Beetz, Tom  
De Vries & Metman  
Overschiestraat 180  
1062 XK Amsterdam (NL)

**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 6 December 2010  
revoking European patent No. 1233969 pursuant to  
Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairman:** A. Lindner  
**Members:** L. Seymour  
C.-P. Brandt

## Summary of Facts and Submissions

I. European patent No. 1 233 969, filed as application number 00 989 042.7, based on the international application published as WO 01/40240, was granted on the basis twenty-two claims, two of which were independent. Independent claims 1 and 22 as granted read as follows:

"1. An adjuvant formulation comprising a physiological salt solution, or an oil-in-water emulsion, or a water immiscible solid phase and optionally an aqueous phase, and comprising as an adjuvant one or more mono- or disaccharide derivatives having at least one but not more than N-1 fatty acid esters groups, wherein N is the number of hydroxyl groups of the mono- or disaccharide from which the derivative is derived.

...

22. A vaccine comprising an adjuvant formulation according to any one of claims 1-21, said vaccine further comprising an antigenic component."

II. An opposition was filed and revocation of the patent in suit was sought pursuant to Articles 100(c), 100(b) and 100(a) EPC (lack of novelty and inventive step).

III. The appeal lies from the decision of the opposition division revoking the patent under Article 101(3)(b) EPC, for contravention of Article 123(2) EPC. This decision was based on a main request and auxiliary request 1, filed with letter of 11 October 2010, and auxiliary request 2 filed during oral proceedings before the opposition division.

IV. The appellant (patentee) lodged an appeal against this decision. With the statement of grounds of appeal, the

appellant filed a main request and three auxiliary requests.

- V. In its reply dated 17 August 2011, the respondent (opponent) maintained that none of the requests on file satisfied Article 123(2) EPC.
- VI. With letter dated 26 September 2011, the appellant filed a further auxiliary request 4.
- VII. With letter of 4 October 2013, the appellant filed a main request and seven auxiliary requests to replace those previously on file. The main request and auxiliary requests 1 and 2 were newly formulated requests, and the lower-ranking request corresponded to those previously on file (cf. above points IV and VI).
- VIII. With letter of 1 November 2013, the appellant filed a replacement set of requests, which were identical to those filed with letter of 4 October 2013 (see preceding point VII), apart from a minor correction in claims 1 of the main request and auxiliary request 1.
- IX. Oral proceedings were held before the board on 6 November 2013. During the course of oral proceedings, the appellant filed an amended main request to replace all requests previously on file.

The claims of this main and sole request, which correspond to claims 1, 4 and 6 of auxiliary request 2 first filed with letter of 4 October 2013 and refiled with letter of 1 November 2013 (cf. above points VII and VIII), reads as follows:

"1. Adjuvant formulation

comprising a derivatised disaccharide (I)

having at least one but not more than N-1 fatty acid ester groups,

wherein each of the fatty acid ester groups is represented by a general formula of  $OC(=O)-(CH_2)_x-CH_3$ , wherein x is between 6 and 14,

and at least one but no more than N-1 anionic groups,

wherein N is the number of hydroxyl groups of the disaccharide from which the derivatised disaccharide is derived,

wherein the total sum of anionic groups and fatty acid esters is in the range of 6-9;

a water immiscible liquid phase,

an aqueous phase and

an emulsifier or stabilizer,

wherein the water immiscible liquid phase is squalane, squalene, a mineral oil, a plant oil, hexadecane, a fluorocarbon or a silicon oil; and the formulation is an oil in water emulsion.

2. Adjuvant formulation according to claim 1 wherein said disaccharide derivative is derived from maltose, lactose, lactulose, cellobiose, gentiobiose, sucrose, turanose, melibiose.

3. A vaccine comprising an adjuvant formulation according to claims 1-2, said vaccine further comprising an antigenic component."

X. The appellant's arguments, insofar as they are relevant to the present decision, may be summarised as follows:

The appellant argued that the main and sole request should be admitted into the proceedings. This request was based on a request that had first been filed one month prior to oral proceedings. The amendments introduced represented a clear attempt to overcome the objections raised under Article 123(2) EPC, and could readily be dealt with within the time available.

The scope of claim 1 of this request was not broader than that of granted claim 1. There was therefore no violation of Article 123(3) EPC.

As regards the basis in the application as originally filed for subject-matter of the claims of the main request (Article 123(2) EPC), the appellant referred to claims 1, 2, 6, 14, 17 and 19, in combination with page 22, line 28 of the application as originally filed. The incorporation of the feature "oil-in-water emulsion" from the description was allowable since this was clearly identifiable as a suitable carrier, based on the nature of the components present in the formulation defined in claim 1. Moreover, the vast majority of examples disclosed oil-in-water emulsions. The feature defining the maximum combined number of fatty acid ester groups and anionic groups appearing in claim 2 as originally filed was redundant, and had therefore been omitted. Claims 2 and 3 of the main request were based on claims 10 and 25 as originally filed.

The main request also fulfilled the requirements of Article 84 EPC. The total sum of anionic groups and fatty acid esters would depend on the number of free hydroxyl groups available in the disaccharide to be derived, but, in accordance with claim 1, must lie in within the range of 6-9. Thus, for disaccharide molecules having eight hydroxyl groups, the possible total would be 6, 7 or 8.

XI. The respondent's arguments, insofar as they are relevant to the present decision, can be summarised as follows:

The respondent submitted that the main and sole request should not be admitted into the proceedings, in view of the fact that it had been filed at a very advanced stage of the proceedings. The only issue addressed in the decision under appeal was the objections under Article 123(2) EPC. Therefore, any attempt to overcome these deficiencies should have been filed with the statement of grounds of appeal.

The respondent further argued that the main request did not meet the requirements of Article 123(3) EPC. In particular, the option "squalene", which had been present in claim 19 as originally filed, had been deleted in corresponding claim 16 as granted. Its reintroduction in present claim 1 created new subject-matter, which was different from that covered by the claims as granted.

The requirements of Article 123(2) EPC were also not fulfilled. Claim 6 as originally filed contained three options for the number of anionic groups envisaged, and three options for the total sum of anionic groups and

fatty acid esters. Therefore, a selection from these two lists was required in order to arrive at the claimed combination of "at least one" and "in the range of 6-9", respectively. Furthermore, three suitable types of adjuvant were listed on page 19, lines 17 to 26 of the description as originally filed, namely, "oil-in-water emulsions", "water-in-oil emulsions" and "water-in-oil-in-water emulsions", and two on page 22, lines 27 to 28, namely, "physiological salt solutions" and "oil-in-water emulsions". Therefore, at least one further selection had been carried out with respect to this feature. There was no basis in the application as originally filed for the claimed combination of features. The respondent emphasised that the formation of an oil-in-water emulsion was not an inherent property of the compositions defined in claim 1. For example, the amount and nature of emulsifier could be adjusted so as to obtain different emulsion types, such as, oil-in-water or water-in-oil emulsions. With reference to Example 26, the respondent further argued that oil-in-water emulsions did not emerge from the examples as originally filed as the only carrier envisaged. Moreover, the examples could not be generalised since they were very specific and the amount variation therein was limited.

The amended claims did not comply with the requirements of Article 84 EPC. A contradiction was to be seen in the fact that the range of 6-9 for the total sum of anionic groups and fatty acid esters could only be achieved for disaccharides bearing a sufficient number of hydroxyl groups.

- XII. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the case be remitted to the first instance for further prosecution



on the basis of the main request, filed during the oral proceedings on 6 November 2013.

The respondent (opponent) requested that the appeal be dismissed.

XIII. 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 main request into appeal proceedings*

The three claims of the main request were present in a request first filed with letter of 4 October 2013 as auxiliary request 2 (see above point IX), that is, one month prior to oral proceedings. The amendments undertaken with respect to requests previously on file were of a clear and simple nature and could therefore be readily dealt within the time available.

The additional amendments introduced at oral proceedings before the board merely consisted in the deletion of dependent claims, in direct response to formal objections raised during the oral proceedings.

Under these circumstances, the board, exercising its discretion under Article 13 of the Rules of Procedure of the Boards of Appeal, decided to to admit the main request into the proceedings.

3. *Article 123(3) EPC*

Article 123(3) EPC stipulates that a European patent may not be amended in such a way as to extend the protection conferred. In order to decide whether or not the amendments are allowable under Article 123(3) EPC, it is therefore necessary to compare the protection conferred by the claims as granted with that of the claims of the main request.

In the present case, the "adjuvant formulation" according to claim 1 of the main request has been limited with respect to that according to claim 1 as granted, namely, regarding the type of formulation ("oil in water emulsion"), the mandatory presence and definition of the disaccharide, and the presence of the further components "an emulsifier or stabilizer" and specific oils (see above points I and IX). In view of these additional features in the broadest claim of the main request, it is evident that the protection conferred by the set of claims after amendment is more restricted than that conferred by the granted set of claims.

Claim 16 as granted, referred to by the respondent, is a dependent claim listing additional optional features. Contrary to the assertion of the respondent, this claim cannot be regarded as limiting the scope of the broadest claim 1 to which it refers, and is not considered to be relevant for assessing the protection conferred by the granted claims as a whole. Claim 1 as granted refers generally to "an oil-in-water emulsion". Therefore, the definition of specific oils, including "squalene", in claim 1 of the main request does not result in a broadening of this claim.

Consequently, the requirements of Article 123(3) EPC are met by the claims according the main request.

4. *Article 123(2) EPC*

4.1 The passages of the application as originally filed referred to by the appellant provide an accurate basis for the subject-matter of the main request (cf. above point X).

4.1.1 In particular, claim 17 as originally filed lists all the basic components of the composition claimed in claim 1, that is, a mono- or disaccharide derivative (I), a water-immiscible liquid phase (II), an emulsifier or stabilizer (III), and an aqueous phase (IV). The basis for the specific components (II) appearing in claim 1 is to be found in dependent claim 19 as originally filed.

4.1.2 With respect to the saccharide component (I), claim 17 as originally filed refers back to claims 1 to 15. The basis of the derivatised disaccharide as now defined in claim 1 is to be found in claim 6 as originally filed in as far as it refers back to claims 1 and 2. The definition of the fatty acid ester group is to be found in claim 14 as originally filed.

It is to be noted in this context that the feature "wherein the combined number of fatty acid esters and anionic groups does not exceed N", which appears in claim 2 as originally filed has been omitted in present claim 1. However, the appellant's argument that this is redundant is considered to be persuasive. Thus, according to claim 1, "N is the number of hydroxyl groups of the disaccharide from which the derivatised disaccharide is derived". The derivatisations at said

hydroxyl groups are defined as "at least one but not more than N-1 fatty acid ester groups" and "at least one but no more than N-1 anionic groups". By definition, the combined number of these two groups cannot be greater than the number of hydroxyl groups available for derivatisation, and the omitted feature can therefore be considered to be redundant.

4.1.3 Claim 1 further contains the feature that "the formulation is an oil in water emulsion". On page 22, line 28 and also on page 19, line 20 of the application as originally filed, oil-in-water emulsions are disclosed amongst the possible types of carriers. The skilled person would directly and unambiguously identify the components listed in present claim 1 as being suitable for the formation of such emulsions. Moreover, the skilled person would recognise from a review of the examples that oil-in-water emulsions are employed in the overwhelming majority thereof, and are thus to be viewed as being particularly preferred. Consequently, the addition of this feature in claim 1 is not considered to present the skilled person with new information which was not unambiguously derivable from the application as originally filed.

4.1.4 Finally, claims 2 and 3 find their basis in claims 10 and 25 as originally filed.

4.2 The respondent's arguments are not considered to be convincing for the following reasons:

4.2.1 The respondent argued that a selection from lists had been undertaken with respect to the options appearing in claim 6 as originally filed, which reads as follows (emphasis added):

"6. A derivatised disaccharide according to any of the claims 1-4, having at least one anionic group, **preferably one or four anionic groups**, and at least one fatty acid ester, wherein the total sum of anionic groups and fatty acid esters is in the range of 6-9, **preferably 7 or 8.**"

It can be seen from the terms emphasised above in bold that the options referred to by the respondent are not presented on an equal footing with the most general definition, but only as preferred embodiments. The board cannot recognise that any selection has been performed in omitting these preferred embodiments and incorporating the most general definitions into claim 1 of the main request.

4.2.2 With respect to the feature "oil in water emulsion", the board agrees with the respondent that this is not an inherent property of the compositions defined in claim 1. However, as explained above in point 4.1.3, they are clearly identifiable as being suitable for this purpose. This was not disputed by the respondent.

The respondent additionally argued that the examples were too specific to allow for a generalisation of the feature "oil in water emulsion" in a broader context. The board cannot agree with this analysis, since the application as originally filed contains numerous examples in which oil-in-water emulsions are obtained for a wide variety of compositions. For example, in Examples 3 to 7, a variety of disaccharide derivatives are prepared; in Example 17, other components of the compositions are varied; in example 25, the proportions of components are varied. In all cases, the formulations are emulsified as described in Example 1,

which discloses a preparation of oil-in-water emulsions (see page 28, line 13 to page 29, line 2).

Therefore, it is maintained that the skilled person, taking the complete application as originally filed into consideration, and in particular the worked examples, would clearly identify oil-in-water emulsions as a preferred carrier in the more general context of the present compositions. This conclusion cannot be altered by the fact that a different type of composition is disclosed in Example 26.

4.3 Consequently, the requirements of Article 123(2) EPC are fulfilled.

5. *Clarity (Article 84 EPC)*

Claim 1 of the main request specifies that "the total sum of anionic groups and fatty acid esters is in the range of 6-9".

The board can see no basis for the respondent's reading of this claim that the whole of this range should be achievable for each disaccharide in question. Indeed, it is merely specified that the total sum must be within the specified range. Thus, for example, the disaccharides listed in dependent claim 2 each bear eight hydroxyl groups, and derivatives thereof with a total number of anionic groups and fatty acid esters of 6, 7 or 8 fall within the definition of the disaccharide (I) according to claim 1.

Consequently, the amended claims according to the main request fulfil the requirement of clarity.

6. *Remittal*

The board has come to the conclusion that the subject-matter of the main request fulfils the requirements of Articles 123(3), 123(2) and 84 EPC. However, the opposition division has not yet taken a decision on the further grounds of opposition raised pursuant to Articles 100(b) and 100(a) EPC (see above point II).

The board therefore finds it appropriate to exercise its discretion under Article 111(1) EPC to remit the case to the first instance for further prosecution, as requested by the appellant (see above point XII).

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution on the basis of the main and sole request (claims 1 to 3) as filed during oral proceedings on 6 November 2013.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated