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Datasheet for the decision of 31 May 2017

Case Number: T 0936/15 - 3.3.04

Application Number: 04706762.4

Publication Number: 1587537

IPC: A61K39/095, A61K39/39, C07K14/22, A61K39/02, A61K39/09

Language of the proceedings: EN

Title of invention:
Injectable vaccine against multiple meningococcal serogroups

Patent Proprietor:
GlaxoSmithKline Biologicals SA

Opponent:

Headword:
Injectable vaccine/GLAXOSMITHKLINE

Relevant legal provisions:
EPC Art. 100(c), 111(1), 123(2)

Keyword:
Main request - added subject-matter - (yes)
Auxiliary request 1 - added subject-matter - (no)
Remittal to the department of first instance - (yes)

Decisions cited:

Catchword:

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Case Number: T 0936/15 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 31 May 2017

Appellant: (Patent Proprietor)	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 1330 Rixensart (BE)
Representative:	Pontremoli, Guido GlaxoSmithKline SA Global Patents CN925.1 980 Great West Road Brentford, Middlesex TW8 9GS (GB)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 2 March 2015 revoking European patent No. 1587537 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairwoman	G. Alt
Members:	B. Claes
	M. Blasi

Summary of Facts and Submissions

I. The appeal from the patent proprietor (appellant) lies from the decision of the opposition division to revoke European patent No. 1 587 537. The patent has the title "*Injectable vaccines against multiple meningococcal serogroups*" and was granted for European patent application No. 04706762.4, which was filed as an international application and published as WO 2004/067030.

II. The opposition division decided that the claims of the main request and of auxiliary requests 1 to 4, all filed with a letter dated 25 September 2013, and of auxiliary request 5, filed during the oral proceedings before the opposition division, did not comply with the requirements of Article 123(2) EPC. In its decision, the opposition division did not express any opinion on the other grounds for opposition invoked.

III. After receipt of the notice of appeal, the sole opponent (respondent) withdrew the opposition.

IV. With the statement of grounds of appeal the appellant submitted a new main request as well as new auxiliary requests 1 to 5 and submitted arguments that the claims complied with the requirements of Article 123(2) EPC.

Independent claims 1 and 7 of the main request read (emphasis added by the board):

"1. An injectable immunogenic composition comprising capsular saccharides from serogroups A, C, W135 and Y of *Neisseria meningitidis*, wherein: (i) said capsular saccharides are conjugated to carrier protein via a linker group, to give separate conjugates for each of

the four serogroups; (ii) the conjugates have a saccharide:protein ratio (w/w) with excess protein **of between 1:1.25 and 1:5**; and (iii) the composition contains between 10 µg and 25µg of meningococcal capsular saccharide per dose, with a quantity of 2.5µg, 5µg or l0µg of each saccharide.

7. An injectable immunogenic composition comprising capsular saccharides from serogroups A, C, W135 and Y of *Neisseria meningitidis*, wherein: (i) said capsular saccharides are conjugated to carrier protein, to give separate conjugates for each of the four serogroups, wherein the carrier protein is tetanus toxoid; (ii) the conjugates have a saccharide:protein ratio (w/w) with excess protein **of between 1:1.25 and 1:5**; and (iii) the composition contains between 10 µg and 25µg of meningococcal capsular saccharide per dose."

These claims differ from the same claims of the main request considered by the opposition division by the insertion of the feature emphasised in bold. Claims 2 to 6 and 8 to 24 were dependent on claim 1 and/or claim 7 and were identical to the same claims of the main request considered by the opposition division.

Auxiliary request 1 differed from the main request by the replacement of the feature "of between 1:1.25 and 1:5", emphasised in bold, in claims 1 and 7 with the feature "of between 1:1.25 and 1:2.5".

V. In a communication pursuant to Article 17(1) RPBA, the board informed the appellant of its preliminary opinion that independent claims 1 and 7 of auxiliary request 1, unlike the same claims of the main request, complied with the requirements of Article 123(2) EPC and that the board intended to set aside the decision under

appeal and to remit the case to the opposition division for further prosecution on the basis of the claims of auxiliary request 1.

VI. The appellant informed the board that it agreed with the procedure as envisaged by the board in its communication and that in that case it did not request oral proceedings. The appellant therefore requested the board to set aside the decision under appeal and to maintain the patent in amended form on the basis of the claims of the main request or, alternatively, on the basis of one of auxiliary requests 1 to 5 filed with the statement of grounds of appeal. It further requested that the case be remitted to the opposition division for further prosecution if the board were to decide that independent claims 1 and 7 of auxiliary request 1 complied with the requirements of Article 123(2) EPC.

VII. The appellant's arguments relevant for the present decision can be summarised as follows:

Main request - claims 1 and 7 - added subject-matter (Article 123(2) EPC)

The amendment in claim 1 for the claimed composition to comprise saccharides in general, as opposed to **oligo**saccharides as referred to in claim 1 of the application as filed, was derivable from the application as filed, e.g. on page 15, line 20; page 16, line 6; page 17, line 9; page 18, line 18; page 19, line 10 and page 25, line 25. In fact, oligosaccharides and polysaccharides contained exactly the same short repeating units which made up the important epitopes.

A basis for a saccharide:protein ratio (w/w) "of between **1:1.25-1:5**" was derivable from the application as filed on page 16, lines 10 to 12. The most preferred range was 1:1.25 to 1:2.5, which gave the one limit of the range. The other limit of the range, 1:5, was the one limit of the preferred range of 1:5 to 5.1. Therefore, the range of 1:1.25 to 1:5 was clearly present as a preferred range to the skilled person.

The feature of the meningococcal saccharide dose being "between **10 µg and 25µg**" found a basis for the limit of "less than 25 µg" in claim 19 of the application as filed, which was dependent on any preceding claim. Claim 1 was therefore merely a variant of original claim 19. The limit of "at least 10µg" was found on page 19, lines 1 to 2 of the application as filed. For arriving at a saccharide dose of 10µg to 25µg it was thus not necessary to make any choices contrary to those clearly present in the application as filed.

Reasons for the Decision

1. The appeal is admissible.

2. In view of its withdrawal of the opposition, the respondent ceased to be a party to the appeal proceedings as regards substantive issues. Other issues for which the respondent would have remained a party to the proceedings did not arise in the present case. The patent proprietor's appeal against the decision to revoke its patent is not affected by the withdrawal of the opposition.

Main request - claims 1 and 7 - added subject-matter (Article 123(2) EPC)

3. Claim 1 of the application as filed read:

"1. An injectable immunogenic composition comprising capsular saccharides from at least three of serogroups A, C, W135 and Y of *Neisseria meningitidis*, wherein said capsular saccharides are conjugated to carrier protein(s) and are oligosaccharides, and wherein the composition comprises less than 50 µg meningococcal saccharide per dose."

4. In the decision under appeal the opposition division considered three amendments now present in claims 1 and 7 of the main request to constitute added subject-matter over claim 1 of the application as filed, namely

a) the composition comprising "saccharides" not being specified as being "**oligo**saccharides";

b) the amount of meningococcal saccharide per dose **being between 10µg and 25µg**; and

c) the saccharide:protein ratio (w/w) with excess protein **of between 1:1.25 and 1:5**.

In addition, the opposition division held that (d)) the selection of the carrier protein in claim 7 to be **tetanus toxoid** also amounted to added subject-matter.

5. Concerning feature a) the board notes various passages in the application as filed which refer to capsular saccharides in general without specifying that they are **oligo**saccharides. Indeed, on page 1, lines 30 to 33, at the onset of the "*Disclosure of the invention*", the

application as filed discloses that "*The invention provides an injectable immunogenic composition comprising capsular saccharides from at least two of serogroups A, C, W135 and Y of N. meningitidis, wherein said capsular saccharides are conjugated to carrier protein(s) and/or are oligosaccharides, and wherein the composition comprises ≤50 µg meningococcal saccharide per dose.*"

6. A further basis for the feature can be identified on page 15, line 20 of the application disclosing that "*Capsular saccharides in compositions of the invention will usually be conjugated to carrier protein(s)*"; on page 16, line 6 that "*A single carrier protein might carry more than one saccharide antigen [92]*"; on page 17, lines 9 and 10 that "*Compositions of the invention comprise capsular saccharides from at least two of serogroups A, C, W135 and Y of N. meningitidis*"; on page 18, line 18 that "*Within each dose, the amount of an individual saccharide antigen will generally be between 1-50 µg, ...*"; on page 19, lines 9 and 10 that "*..., but it is preferred to combine adjuvant with a saccharide antigen prior to admixing of different saccharides*" and on page 25, line 25 that "*The invention provides a composition comprising conjugated capsular saccharides from at least three serogroups A, C, W135 and Y of N. meningitidis, ...*". The use of saccharides is therefore disclosed at various places in the description as filed.

7. In view of these disclosures in the application as filed the board is satisfied that feature a) in claims 1 and 7 finds clear and unambiguous disclosure in the application as filed (Article 123(2) EPC).

8. Concerning feature b), above, *i.e.* the amount of meningococcal saccharide per dose **being between 10µg and 25µg**, the board refers to claim 19 of the application as filed which reads:

"19. The composition of any preceding claim, comprising less than 25 µg meningococcal saccharide per dose."

9. A combination of claims 1 (see point 3) and 19 of the application as filed therefore provides a basis for claims 1 and 7, in the aspect of "less than 25 µg meningococcal saccharide". A further basis for the feature, and in particular for the lower limit of "at least 10 µg", is identified in the paragraph bridging pages 18 and 19 of the application as filed, which discloses in particular that: "*Preferred compositions of the invention comprise less than 50 µg meningococcal saccharide per dose. Other preferred compositions comprise ≤25 µg meningococcal saccharide per dose. ..., ideally, compositions of the invention comprise at least 10 µg meningococcal saccharide per dose*".

10. In view of these disclosures in the application as filed the board is satisfied that feature b) in claims 1 and 7 does not constitute added subject-matter, being clearly and unambiguously disclosed in the application as filed (Article 123(2) EPC).

11. Concerning feature c) above, *i.e.* the saccharide:protein ratio (w/w) with excess protein **of between 1:1.25 and 1:5**, reference is made to page 16, lines 10 to 12 of the application as filed which reads:

"*Conjugates with a saccharide:protein ratio (w/w) of between **1:5** (i.e. excess protein) and 5:1 (i.e. excess saccharide) are preferred. Ratios between 1:2 and 5:1*

*are preferred, as are ratios between **1:1.25** and 1:2.5 are more preferred.*" (emphasis added by the board)

12. The passage refers to the "more preferred" range of the ratio being 1:1.25 to 1:2.5, thereby disclosing one limit of the range in the claims. The other limit of the range of the ratio in the claims is 1:5, which is disclosed as a limit of the "preferred range" of the ratio of 1:5 to 5:1.

13. The board is therefore satisfied that the combined range of the ratio with excess protein of 1:1.25 to 1:5 constitutes one of the clearly and unambiguously disclosed combinations of the various ranges disclosed in the cited passage on page 16. This amounts to the selection of one particular range from the various ranges disclosed, which does, as such, not amount to added subject-matter. Accordingly, the board is satisfied that claim 1 complies with the requirements of Article 123(2) EPC.

14. The board notes, however, that the situation in respect of claim 7 is different in view of the fact that this claim, besides the selection of the particular range from the considerable number of ranges disclosed in the description on page 16 (which in fact amounts to a list of disclosed ranges), specifies that the carrier protein is **tetanus toxoid**. A basis for this feature is disclosed in the application as filed on page 15, lines 25 to 32 which read: "*Preferred carrier proteins are bacterial toxins or toxoids, such as diphtheria toxoid or tetanus toxoid. The CRM_{197} diphtheria toxoid ... is particularly preferred. ... Preferred carriers are diphtheria toxoid, tetanus toxoid, H.influenzae protein D, and CRM_{197}.*"

15. Therefore, the selection in claim 7 of the particular carrier protein tetanus toxoid amounts to a further selection from a second list of considerable length of possible carrier proteins. This selection of particular embodiments, *i.e.* the range and the carrier protein, from two lists of alternative features of considerable length infringes, in the opinion of the board, the requirements of Article 123(2) EPC. Accordingly, claim 7 does involve added subject-matter.

Auxiliary request 1 - claims 1 and 7 - added subject-matter (Article 123(2) EPC)

16. As compared to claims 1 and 7 of the main request, the same claims of auxiliary request 1 now define the saccharide:protein ratio (w/w) with excess protein **of between 1:1.25 and 1:2.5**.

17. On page 16, lines 10 to 12, the application as filed comprises a direct disclosure of this range which is said to be "more preferred" (see point 11 above) rendering it therefore the most preferred range disclosed in the passage. Accordingly, claim 1 complies with the requirements of Article 123(2) EPC.

18. In addition, the board is satisfied that the particular and preferred emphasis put on the range now claimed in the passage on page 16 of the application as filed, *i.e.* making it the most preferred range, means that combining this feature with that of the carrier protein being tetanus toxoid does not infringe the requirements of Article 123(2) EPC, as the combination of features merely amounts to the choice from one list of features, *i.e.* the list of the carrier proteins. Accordingly, claim 7 too complies with the requirements of Article 123(2) EPC.

19. The decision under appeal does not express the view that any of the dependent claims of auxiliary request 1 give rise to added subject-matter.

20. In view of the above considerations, the board concludes that the claims of auxiliary request 1 do not relate to added subject-matter.

Remittal to the opposition division

21. The decision under appeal was based on only one of the grounds of opposition invoked by the opponent, namely that the subject-matter of the European patent extended beyond the content of the application as filed (Articles 100(c) and 123(2) EPC). The opposition division did not decide on the other grounds of opposition put forward by the opponent.

22. Under Article 111(1) EPC, when deciding on an appeal after examining its allowability, the board may either exercise any power within the competence of the department which took the decision appealed or remit the case for further prosecution.

23. In a case such as the present one, where the opposition division has dealt with only one of the grounds of opposition, the board, exercising its discretion under Article 111(1), second sentence, EPC, decides to remit the case to the opposition division for further prosecution, thereby giving the patent proprietor as party in this case the possibility of having its case heard by two instances. Moreover, the appellant has agreed with remittal.

24. The case is accordingly remitted to the opposition division for further prosecution on the basis of the claims of auxiliary request 1.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution on the basis of the claims of auxiliary request 1.

The Registrar: The Chairwoman:

P. Cremona G. Alt

Decision electronically authenticated