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**Datasheet for the decision  
of 2 December 2020**

**Case Number:** T 0104/16 - 3.3.04

**Application Number:** 05733998.8

**Publication Number:** 1737486

**IPC:** A61K39/095

**Language of the proceedings:** EN

**Title of invention:**

Immunising against meningococcal serogroup Y using proteins

**Patent Proprietor:**

GlaxoSmithKline Biologicals SA

**Opponent:**

Pfizer Inc.  
(opposition withdrawn)

**Headword:**

Meningococcal serogroup Y/GLAXOSMITHKLINE

**Relevant legal provisions:**

EPC Art. 56

**Keyword:**

Inventive step - (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**

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Case Number: T 0104/16 - 3.3.04

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.04**  
**of 2 December 2020**

**Appellant:** GlaxoSmithKline Biologicals SA  
(Patent Proprietor) Rue de l'Institut 89  
1330 Rixensart (BE)

**Representative:** Marshall, Cameron John  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted on 28 October 2015  
revoking European patent No. 1737486 pursuant to  
Article 101(3) (b) EPC.

**Composition of the Board:**

**Chairwoman** G. Alt  
**Members:** D. Luis Alves  
R. Romandini

## **Summary of Facts and Submissions**

- I. The appeal by the patent proprietor (appellant) concerns the decision of the opposition division to revoke European patent No. 1 737 486, entitled "*Immunising against meningococcal serogroup Y using proteins*".
- II. The patent had been opposed as a whole under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC), and under Article 100(b) and (c) EPC.
- III. The decision under appeal dealt with sets of claims of a main request (claims as granted) and eight auxiliary requests. The opposition division held that the patent as granted was sufficiently disclosed (Article 83 EPC) and did not relate to subject-matter extending beyond the content of the application as filed (Article 123(2) EPC). The claimed subject-matter was also novel (Article 54 EPC). However, the opposition division was of the opinion that the subject-matter of claim 1 of the main request and of auxiliary requests 1 to 5 did not involve an inventive step (Article 56 EPC).
- IV. With the statement of grounds of appeal, the appellant maintained all the claim requests considered in the decision under appeal and filed a further set of claims as auxiliary request 9.
- V. The opponent (respondent) filed a reply to the statement of grounds of appeal.

- VI. By letter dated 1 December 2016 the appellant withdrew all the claim requests on file. At the same time, they filed a new main and a new auxiliary request.
- VII. By letter dated 28 April 2017 the respondent withdrew the opposition.
- VIII. With a communication according to Rule 100(2) EPC, the board informed the appellant that, in its preliminary view, the arguments submitted by the former respondent with respect to the assessment of inventive step, and the opposition division's arguments in this respect in the decision under appeal, addressed subject-matter which did not require the presence of all five proteins (i) to (v) in combination. These arguments, therefore, did not apply to the subject-matter set out in claim 1 of the auxiliary request filed on 1 December 2016. The claims of this auxiliary request also overcame the respondent's clarity objection resulting from the wording "*wherein the polypeptides include*", which was raised with regard to claim 1 of auxiliary request 5 as filed with the statement of grounds of appeal. This wording was still present in claim 1 of the main request of 1 December 2016.
- IX. In reply, the appellant made the auxiliary request their sole request.
- X. Claims 1 and 12 of the main (sole) request read:
- "1. A composition comprising immunogenic *Neisseria meningitidis* serogroup B polypeptides for use in a method of immunising a subject against infection by serogroup Y of *Neisseria meningitidis*, wherein the composition includes all five of:

(i) a NadA protein, which (a) has 80% or more identity to SEQ ID NO: 2 or (b) comprises a fragment of at least 20 consecutive amino acids from SEQ ID NO: 1, wherein the fragment comprises an epitope; and

(ii) a '741' protein, which (a) has 80% or more identity to SEQ ID NO: 3 or (b) comprises a fragment of at least 20 consecutive amino acids from SEQ ID NO: 3, wherein the fragment comprises an epitope; and

(iii) a '287' protein, which (a) has 80% or more identity to SEQ ID NO: 6 or (b) comprises a fragment of at least 20 consecutive amino acids from SEQ ID NO: 6, wherein the fragment comprises an epitope; and

(iv) a '936' protein, which (a) has 80% or more identity to SEQ ID NO: 4 or (b) comprises a fragment of at least 20 consecutive amino acids from SEQ ID NO: 4, wherein the fragment comprises an epitope; and

(v) a '953' protein, which (a) has 80% or more identity to SEQ ID NO: 5 or (b) comprises a fragment of at least 20 consecutive amino acids from SEQ ID NO: 5, wherein the fragment comprises an epitope.

12. The use of immunogenic *Neisseria meningitidis* serogroup B polypeptides in the manufacture of a medicament for immunising a subject against infection by serogroup Y of *Neisseria meningitidis*, wherein the medicament includes all five of:

(i) a NadA protein, which (a) has 80% or more identity to SEQ ID NO: 2 or (b) comprises a fragment of at least 20 consecutive amino acids from SEQ ID NO: 1, wherein the fragment comprises an epitope; and

(ii) a '741' protein, which (a) has 80% or more identity to SEQ ID NO: 3 or (b) comprises a fragment of at least 20 consecutive amino acids from SEQ ID NO: 3, wherein the fragment comprises an epitope; and

(iii) a '287' protein, which (a) has 80% or more identity to SEQ ID NO: 6 or (b) comprises a fragment of at least 20 consecutive amino acids from SEQ ID NO: 6, wherein the fragment comprises an epitope; and

(iv) a '936' protein, which (a) has 80% or more identity to SEQ ID NO: 4 or (b) comprises a fragment of at least 20 consecutive amino acids from SEQ ID NO: 4, wherein the fragment comprises an epitope; and

(v) a '953' protein, which (a) has 80% or more identity to SEQ ID NO: 5 or (b) comprises a fragment of at least 20 consecutive amino acids from SEQ ID NO: 5, wherein the fragment comprises an epitope."

XI. The following documents are referred to in the present decision:

D1: Masignani, V. *et al*, J. Exp. Med. 197(6), March 2003, pages 789-799.

D2: Fletcher, L.D. *et al*, Infect. Immun. 72(4), April 2004, pages 2088-2100.

D3: Vermont, C.L. and van den Dobbelaar, G.P.J.M., Expert Rev. Vaccines 2(5), 2003, pages 673-681.

D8: Pizza, M. *et al*, Science 287, 2000, pages 1816-1820.

XII. The appellant's arguments submitted in writing, in so far as relevant to this decision, may be summarised as follows:

*Admission of the main request into the appeal proceedings - Article 13 RPBA 2007*

This request was filed as a reaction to the respondent's clarity objection, which had not been raised prior to the appeal proceedings.

*Inventive step - Article 56 EPC*

The decision under appeal did not contain any reasoning with respect to auxiliary request 5 before the opposition division, which required a combination of all five proteins 'NadA', '741', '287', '936' and '953'. This composition was used in the examples in the patent. No documents had been cited which would have led the skilled person in an obvious way to this combination of proteins.

XIII. The appellant requested in writing that the decision under appeal be set aside and that the patent be maintained on the basis of the claims of the main request filed by letter dated 24 July 2019.

### **Reasons for the Decision**

1. The appeal is admissible as it complies with the requirements specified in Articles 106 to 108 EPC and the further provisions referred to in Rule 101(1) EPC.



2. Since they withdrew their opposition, the respondent ceased to be a party to the appeal proceedings as regards substantive issues. No other issues for which the respondent would have remained a party to the proceedings arose in this case.
  
3. As the impugned decision resulted in the revocation of the patent, the withdrawal of the opposition had no procedural consequences for the appeal proceedings. The board must still examine the opposition division's decision in order to ascertain if it is to be set aside and whether the patent, account being taken of the amendments made by the appellant in the form of the main request, and the invention to which it relates, meet the requirements of the EPC.

*Main request*

4. Claim 1 concerns a composition for use in immunising a subject against infection by serogroup Y *Neisseria meningitidis*, the composition including five polypeptides as defined in the claim (for the claim wording see point X. above).

This claim differs from claim 1 of auxiliary request 5 before the opposition division in that the wording "*wherein the composition includes all five of*" replaces the wording "*wherein the polypeptides include*". Claim 12 is amended accordingly.

*Admission into the appeal proceedings - Article 13 RPBA 2007*

5. In the case in hand, the parties were sent a communication under Rule 100(2) EPC before

1 January 2020. Therefore, Article 13(2) RPBA 2020 does not apply, and Article 13 RPBA 2007 continues to apply instead (Article 25(3) RPBA 2020).

6. The main request was filed after the statement of grounds of appeal, so, in view of Article 13(1) RPBA 2007, it is at the board's discretion whether to admit it into the appeal proceedings.

According to this provision, the board's discretion is to be exercised in view of *inter alia* the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy. Furthermore, the criteria developed by the boards of appeal in the context of Article 13(1) RPBA 2007 include the suitability of the amendment to resolve the issues raised by the other party or the board in appeal proceedings without giving rise to new objections.

7. As concerns the state of the proceedings, the appellant argued that the filing was a reaction to objections in the reply to the appeal, in which questions were indeed raised about the interpretation of claim 1 of auxiliary request 5 as filed with the statement of grounds of appeal. The board notes that the decision under appeal did not discuss this possible understanding of the claim at issue. As a consequence, it appears that the issue could not have been addressed by the appellant earlier in the proceedings.
8. As discussed below (see point 13.), the request addresses this issue by making it clear that the composition includes all five polypeptides (i) to (v). This wording of the claim resolves the interpretation issue without *prima facie* creating new problems.

9. Thus, the board admits the request into the appeal proceedings.

*Inventive step - Article 56 EPC*

10. With respect to auxiliary request 5 before it, the opposition division held that the subject-matter of claim 1 did not involve an inventive step. The appellant contested this finding. As noted above, however, claim 1 of the request before the board differs from that auxiliary request in that it makes it clear that the composition includes all five polypeptides (i) to (v).
11. In the following, the board will assess how far the opposition division's reasoning with regard to previous auxiliary request 5 applies to the claims before the board, and how convincingly that reasoning is addressed by the appellant's arguments.
12. In claim 1 of the main request considered by the opposition division, the composition only had to include one, two or three polypeptides from the three defined in the claim. The claim thus defined embodiments where the composition included a single polypeptide. The opposition division held that this embodiment of the claimed subject-matter lacked an inventive step. The opposition division came to this conclusion because it considered that a composition having the '741' protein for immunising against infection by MenY was obvious having regard to document D1 in view of any of documents D2, D3 and D8.

With respect to auxiliary request 5, the opposition division reasoned that the conclusions as to the main request applied because claim 1 "*[...] of AR1-5 due to their respective wording are all referring to composition [sic] for use in a method of immunising a subject against infection by serogroup Y of Neisseria meningitidis, wherein the composition can comprise a '741' protein [...]*".

13. However, claim 1 before the board no longer includes the possibility of a composition having only one of the five proteins, instead requiring the presence of all five of them.
14. As pointed out by the appellant, since this claim requires the presence of five proteins, the reasoning in the decision under appeal does not apply.
15. The same goes for the former respondent's submissions on lack of inventive step since these were also made with regard to a claim worded such that the composition did not necessarily include each of the five polypeptides listed. On the contrary, it could include multiple '741' peptides but not any of the other polypeptides listed.
16. The board notes that the experimental results in the patent refer to bactericidal activity of a five-polypeptide combination on serogroup Y strains. The experiments did not use single-polypeptide compositions. In fact, some of the former respondent's arguments in the context of sufficiency of disclosure and inventive step (with respect to the main request previously on file) relied precisely on this point, i.e. that the claim encompassed compositions comprising

a single polypeptide whereas the experiments were carried out with a five-polypeptide combination.

17. There are no submissions on file that lead the board to conclude that the effect in terms of the bactericidal activity of the composition is due solely to the polypeptide '741'. Furthermore, the board has not been presented with arguments that would render the other components of the composition obvious.
18. Thus, there are no arguments on file which question the presence of an inventive step for the subject-matter as defined in the claims of the main request before the board.
19. Moreover, the board has come to the conclusion that none of the further arguments of the former respondent stand in the way of the allowability of the present request. The board does not see any reason to raise objections of its own motion.

## 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 the claims according to the main request and a description to be adapted thereto.

The Registrar:

The Chair:



I. Aperribay

G. Alt

Decision electronically authenticated