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**Datasheet for the decision
of 5 August 2019**

Case Number: T 0196/15 - 3.3.04

Application Number: 10176773.9

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A61K39/295, A61K39/116

Language of the proceedings: EN

Title of invention:

Multiple vaccines including serogroup C meningococcus

Applicant:

GSK Vaccines GmbH

Headword:

Multiple vaccines/NOVARTIS VACCINES

Relevant legal provisions:

EPC Art. 123(2)

Keyword:

Amendments - added subject-matter (yes)

Decisions cited:

T 0197/08, T 0903/09

Catchword:



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Case Number: T 0196/15 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 5 August 2019

Appellant:
(Applicant)

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Decision under appeal:

**Decision of the Examining Division of the
European Patent Office posted on 29 July 2014
refusing European patent application No.
10176773.9 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair G. Alt
Members: A. Chakravarty
P. de Heij

Summary of Facts and Submissions

- I. An appeal was filed by the applicant (appellant) against the decision of the examining division to refuse European patent application No. EP 10 176 773.9, entitled "*Multiple vaccines including serogroup C meningococcus*".
- II. The examining division considered a main and six auxiliary requests. It held that the main request and auxiliary requests 2 to 5 did not meet the requirements of Article 123(2) EPC and that the subject-matter of claim 1 of auxiliary requests 1 and 6 did not meet the requirements of Article 56 EPC.
- III. With the statement of grounds of appeal, the appellant submitted a main request and eight auxiliary requests. Auxiliary requests 1 to 5 are identical to those considered by the examining division, while the main request is amended in comparison to the main request considered by the examining division. Auxiliary requests 6 to 8 are filed for the first time in the appeal proceedings.
- IV. Claim 1 of the main request and auxiliary request 1 is identical and reads:

"1. A kit, comprising a first immunogenic component, a second immunogenic component and a third immunogenic component for administration at different sites at substantially the same time, wherein: (a) the first immunogenic component comprises an aqueous formulation of more than one conjugated capsular saccharide from *Streptococcus pneumoniae* as the only antigens; (b) the second immunogenic component comprises as the only antigen a conjugated capsular saccharide from *Neisseria*

meningitidis serogroup C (MenC), wherein the MenC saccharide conjugate is in lyophilised or liquid form; and (c) the third immunogenic component comprises as the only antigens a diphtheria toxoid, a tetanus toxoid, a *B.pertussis* antigen, a hepatitis B virus surface antigen and an inactivated poliovirus antigen".

Claim 1 of each of auxiliary requests 2 to 4 also contains the expression "as the only antigen[s]" in parts (a) to (c).

Claim 1 of auxiliary request 5 reads:

"1. A kit, comprising a first immunogenic component, a second immunogenic component and a third immunogenic component for use in the reduction or prevention of pneumococcal meningitis, meningococcal meningitis, viral hepatitis B, diphtheria, tetanus, pertussis and poliomyelitis, wherein each component is for administration at different sites at substantially the same time, wherein: (a) the first immunogenic component consists of (i) an aqueous formulation of more than one conjugated capsular saccharide from *Streptococcus pneumoniae* as antigenic component and (ii) an adjuvant, an excipient, and/or a buffer as non-antigenic component; (b) the second immunogenic component consists of (i) a conjugated capsular saccharide from *Neisseria meningitidis* serogroup C (MenC) as antigenic component and (ii) an adjuvant, an excipient, and/or a buffer as non-antigenic component, wherein the MenC saccharide conjugate is in lyophilised or liquid form; and (c) the third immunogenic component consists of (i) a diphtheria toxoid, a tetanus toxoid, a *B.pertussis* antigen, a hepatitis B virus surface antigen and an inactivated poliovirus antigen as antigenic component

and (ii) an adjuvant, an excipient, and/or a buffer as non-antigenic component.

Claim 1 of each of auxiliary requests 6 to 8 also defines each of the three immunogenic components as consisting of (i) an antigenic component and (ii) a non-antigenic component.

- V. The appellant's arguments relevant to the decision summarised as follows.

Amendments - Article 123(2) EPC

Main request and auxiliary requests 1 to 4 - claim 1

The examining division held that subject-matter of the claims of the then pending main request and of auxiliary requests 2, 4 and 5 included subject-matter extending beyond the content of the application as filed (the application) because the expression "comprising ... as the only antigen" had no basis in said application. This was incorrect because the application disclosed compositions "*consisting*" of the particular antigens. The skilled person would have realised that this was synonymous with compositions comprising that antigen as the only antigen because it was not reasonable to interpret the application such that it related to compositions consisting of pure antigen, for example excluding water, because no such vaccines existed and there were no indications in the application that the claimed kit components departed significantly in their general make-up from those known to the skilled person in the technical field of the invention.

For example, the application, at page 5, lines 34 and 35, disclosed a second immunogenic component that *"comprises a conjugated capsular saccharide from N.meningitidis serogroup C"*.

The term *"comprising"* was defined on page 29 of the application as follows: *"The term "comprising" encompasses "including" as well as "consisting" e.g. a composition "comprising" X may consist exclusively of X or may include something additional e.g. X + Y"*.

In light of this definition, the passage also disclosed an immunogenic component that consists exclusively of a conjugated capsular saccharide from *N.meningitidis* serogroup C. If interpreted literally, this would introduce a contradiction as in the sentence immediately following the passage it was stated that the MenC conjugate in the component may be in a aqueous formulation or a lyophilised formulation. The only technically sensible interpretation was therefore that the disclosure at page 5 should be interpreted as meaning 'comprising as the only antigen' in light of the definition at page 29 of 'consists of an antigen', because the skilled person would have realised that an immunogenic composition would include components such as water, buffers etc. Even when in lyophilised form, a MenC conjugate component would never exclusively consist of MenC conjugate. The skilled person knew that practically a lyophilised component would include whatever substances were present in the solution containing the saccharide conjugate prior to lyophilisation, such as buffers, salts or sugar alcohols. Indeed the immunogenic component of a kit could not consist exclusively of a conjugated capsular saccharide because such conjugates would not be stable

and hence would not survive lyophilisation in meaningful amounts to retain their immunogenicity.

The examples of the application supported this position. The individual immunogenic components used each comprised a MenC conjugate, pneumococcal saccharide conjugates and DTP-HBsAG-IPV respectively as the only antigens, but included additional components such as buffers, adjuvants and other excipients.

The above position was also supported in the case law of the Boards of Appeal. In decision T 903/92 the board held that the substitution of "consisting essentially of" for "comprising" was allowable under Article 123(2) EPC. In decision T 197/08 the board came to a similar decision.

Thus, the claimed subject-matter did not infringe Article 123(2) EPC.

Auxiliary requests 5 to 8 - claim 1

Relative to claim 1 of the main request, claim 1 of auxiliary request 5 had been amended to specify that each component contains the specified antigens and an adjuvant, an excipient or a buffer. Basis for this amendment was at page 22, lines 23 to 25, of the application.

Auxiliary request 6 was further amended by specifying that the third component contains an acellular *B. pertussis* component. Basis for this amendment was found at page 16, line 7 of the application.

Auxiliary request 7 was amended to specify that the second immunogenic composition does not comprise an

aluminium phosphate adjuvant, but is supplied with an aluminium hydroxide adjuvant. Basis for this amendment was at page 6, lines 12-14 of the application.

Auxiliary request 8 further specified that the first immunogenic component consists of an aqueous formulation of 7, 9, 10, or 11 conjugated capsular saccharides from *S.pneumoniae*. Basis for this amendment was found in the application at page 15, lines 18 to 20.

- VI. The board issued a summons to oral proceedings together with a communication pursuant to Article 15(1) RPBA in which it informed the appellant that it was inclined to consider that claim 1 of the all claim requests does not comply with the requirements of Article 123(2) EPC.
- VII. The appellant informed the board in writing that they would not attend the oral proceedings and that the request for oral proceedings was withdrawn. They requested that a decision be reached on the basis of the written submissions. The board subsequently cancelled the proceedings.
- VIII. The board understands the appellant's requests to be that a patent be granted on the basis of the main request or alternatively on the basis of one auxiliary requests 1 to 8.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is therefore admissible.

Amendments - Article 123(2) EPC

Main and auxiliary request 1 - claim 1

2. The examining division held that claim 1 of the main request did not meet the requirements of Article 123(2) EPC because the expression "as the only antigen" used in claim 1 did not have a basis in the application as filed (the application).
3. The board notes that it was not disputed by the appellant that the application does not contain a *verbatim* disclosure of the phrase '*as the only antigen*' in the context of any of the three immunogenic components defined in the claim. It must therefore be assessed whether or not the application contains an implicit but nevertheless direct and unambiguous disclosure of this subject-matter (see Case Law of the Boards of Appeal of the European Patent Office, 8th edition, II.E.1.2.2).
4. The appellant relied on the passage on page 5, final paragraph when read in combination with the passage on page 29 of the application.
5. The passage on page 5 reads: "*...the invention provides a kit, comprising a first immunogenic component and a second immunogenic component, wherein: (a) the first immunogenic component comprises an aqueous formulation of a conjugated capsular saccharide from S.pneumoniae; and (b) the second immunogenic component comprises a conjugated capsular saccharide from N.meningitidis serogroup C. The MCC in the second component may be an aqueous formulation or a lyophilised formulation*".

6. It is apparent from the above that this passage does not disclose kits comprising three immunogenic components. For this disclosure the subsequent paragraph (page 6, paragraph 1) must be taken into account. This reads: "*The first and/or second component may also include one or more of: a diphtheria toxoid; a tetanus toxoid; B. pertussis antigen(s); a HBsAg; and an inactivated poliovirus antigen. Preferably all five of these additional antigens are included in either the first component or the second component. As an alternative, the five antigens may be provided as a third immunogenic component in the kit. The kit may include a conjugated Hib antigen in the first or second (or third) component.*" (emphasis added by the board).
7. Thus the application provides a basis for a kit comprising the three immunogenic components, each as defined in the above-cited passage. The passage in question discloses that the first and second immunogenic components "comprise" their respective antigens, where the first component is in an aqueous formulation and the second is either in an aqueous formulation or in lyophilised form. This disclosure is on its own not a direct and unambiguous disclosure that any of the three immunogenic components comprised their respective antigens "as the only antigen".
8. The appellant further refers to the disclosure on page 29 of the application which defines the term "comprising" as follows: "*The term "comprising" encompasses "including" as well as "consisting" e.g. a composition "comprising" X may consist exclusively of X or may include something additional e.g. X + Y*". Thus, this passage teaches the reader that the term "comprising" means both "consisting exclusively of X" or "including X plus other substances".

9. Applying this to the passage on page 5 relating to the immunogenic compositions, the skilled person is led to understand that each composition can either include or consist exclusively of its particular antigen, meaning that the composition may contain the antigen and other substances, which latter can be antigenic or not, or that the composition contains (essentially) only the antigen, without further antigenic or non-antigenic substances.

10. However, the board can find no direct and unambiguous disclosure in the application of a composition where each of the three immunogenic compositions contains the defined antigen(s) as the only antigen(s) and other non-antigenic substances (the third column as indicated in the decision of the examining division). Arriving at this subject-matter would require an undisclosed selection to be made for each antigen from either "consists exclusively of" or "includes", and if "include" was selected, a further selection as to the nature of the additionally present substance(s), i.e. antigenic or non-antigenic. For this reason alone, the claimed subject-matter does not meet the requirements of Article 123(2) EPC.

11. The appellant's argument that the skilled person would understand that, in the present case, "consisting exclusively of"/"consists exclusively of" cannot mean 'consisting of **only** the antigen', i.e. the antigen in the absence of essentially any additional ingredients, is not persuasive. The board is of the view that the skilled person, encountering the term "comprising" on page 29, would not, on the basis of their common general knowledge, exclude those meanings of the above term where the composition contains essentially only the recited ingredient. This is contrary to the direct

literal meaning of the disclosure of the application on page 29 and no evidence beyond mere allegation that such an antigenic composition would, in the eyes of the skilled person, not be feasible, has been presented.

12. It follows from this that the amendments made do not meet the requirements of Article 123(2) EPC.

Auxiliary requests 2 to 4 - claim 1

13. Claim 1 of each of these requests contains the same language as the main request in the context of each of the three immunogenic components, i.e. each is defined as being the only antigens or antigen. These claims therefore do not meet the requirements of Article 123(2) EPC for the same reasons as claim 1 of the main request.

Auxiliary requests 5 to 7 - claim 1

14. In these claims the immunogenic components are defined as consisting of (i) the particular immunogenic component and (ii) a non-antigenic component. In other words, the three components are defined as containing the recited immunogens as the only antigen. Thus, the subject-matter is the same as that of claim 1 of the main request in this respect and does not meet the requirements of Article 123(2) EPC for the reasons given above.
15. The board can see no contradiction in the above finding with that in decisions T 197/08 and T 903/09. These decisions relate to whether or not a general disclosure that an agent is useful for certain purpose also discloses that the agent can be the sole active ingredient. This question is not relevant to the

present case, which turns on whether or not a particular selection is disclosed in the application as filed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



S. Lichtenvort

G. Alt

Decision electronically authenticated