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**Datasheet for the decision
of 15 March 2016**

Case Number: T 1609/11 - 3.3.02

Application Number: 04739011.7

Publication Number: 1649287

IPC: G01N33/551, G01N33/50,
G01N33/68, A61K39/00

Language of the proceedings: EN

Title of invention:
EVALUATION OF ADJUVANTED VACCINES

Patent Proprietor:
ALK-Abelló A/S

Opponents:
Novartis Vaccines and Diagnostics, Inc.
STALLERGENES SA

Headword:
Evaluation of adjuvanted vaccines/ ALK-ABELLO

Relevant legal provisions:
EPC Art. 113(1), 123(2)
RPBA Art. 15(3)

Keyword:

Decisions cited:

G 0004/92

Catchword:



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D E C I S I O N
of Technical Board of Appeal 3.3.02
of 15 March 2016

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
6 May 2011 concerning maintenance of the
European Patent No. 1649287 in amended form.**

Composition of the Board:

Chairman U. Oswald
Members: T. Sommerfeld
 D. Prietzel-Funk

Summary of Facts and Submissions

- I. Two oppositions were filed against European patent No. 1649287, based on European patent application No. 04739011.7, which was filed as an international patent application published as WO 2005/022157. Both opponents requested revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Articles 54(2) and 56 EPC and Article 100(a) EPC) and lack of sufficiency of disclosure (Article 100(b) EPC). Additionally, opponent 2 requested revocation of the patent on the grounds of Article 100(c) EPC and challenged the validity of the priority of the patent.
- II. By its interlocutory decision announced at oral proceedings, the opposition division decided that the patent be maintained in amended form on the basis of the second auxiliary request filed during the oral proceedings (Articles 101(3) (a) and 106(2) EPC).
- The opposition division considered that the claims according to the main request (claims as granted) met the requirements of Article 123(2) EPC but not those of Article 54 EPC, while the first auxiliary request was found to contravene the requirements of Article 56 EPC.
- III. Both the patent proprietor and opponent 2 lodged an appeal against that decision. The statements of the grounds of appeal were duly submitted and were followed by the respective replies from each of the appellants.
- IV. Summons for oral proceedings before the board were issued with an accompanying communication pursuant to Article 15(1) RPBA.

V. By letter dated 15 January 2016, the patent proprietor withdrew its appeal and replaced all of its requests by one sole request, namely that the opponent's appeal be dismissed. The patent proprietor (hereinafter respondent) also withdrew its request for oral proceedings and stated that it would not attend oral proceedings.

VI. Oral proceedings before the board took place on 15 March 2016 as scheduled. As announced by the letter dated 15 January 2016, the respondent was not represented at the oral proceedings. Opponent 1, who did not make any submissions during the entire appeal proceedings, was also not represented at the oral proceedings. At the end of the oral proceedings, the chairman announced the decision of the board.

VII. The appellant's submissions, in so far as relevant to the present decision, may be summarised as follows:

Claims 1, 3 and 5 contravened Article 123(2) EPC. The application as filed did not directly and unambiguously disclose that the antigen-specific antibody bound to an antibody solid phase could be an IgE. While immunoassays could use up to 3 antibodies, the antibody which was detected was never the antigen-specific antibody bound to an antibody solid phase. The specific combination of "IgE in combination with an antibody selected from the group consisting of IgA, IgG, IgM and combinations thereof" (claim 3) was also not directly and unambiguously disclosed in the application as filed. By its dependence on claim 1, claim 5 was directed to an immunoassay wherein both the capture antibody and the detection antibody were IgE, and only IgE; however, such an immunoassay was not disclosed in

the application as filed: in original claim 5 either the capture or the detection antibody would be an IgE.

VIII. The respondent's arguments, in so far as relevant to the present decision, may be summarised as follows:

Since claims 3 and 5 as originally filed referred to the antibody of claim 1 (and not to "an" antibody of claim 1), it was thus clear that the antigen-specific antibody bound to a solid phase of claim 1 was intended; this was further supported by paragraph [0051] of the patent.

IX. The appellant requested that the decision under appeal be set aside and that the European patent be revoked.

The respondent requested in writing that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.
2. The oral proceedings before the board took place in the absence of the patent proprietor and opponent 1 who had both been duly summoned but decided not to attend. The present decision is based on the facts and evidence put forward during the written proceedings, on which all parties have had an opportunity to comment. Therefore, the conditions set forth in Enlarged Board of Appeal opinion G 4/92, OJ EPO 1994, 149, are met.

3. Article 123(2) EPC

3.1 The sole request is identical to the request submitted as auxiliary request 2 during oral proceedings before the opposition division, which was considered to be allowable in the impugned decision. With the statement of grounds of appeal, the appellant raised objections under Article 123(2) EPC against claims 1, 3 and 5.

3.2 Claims 1 to 5 are derived from originally filed claims 1 to 5, respectively. The text of claims 1 to 5 is displayed below, indicating the amendments made to the original claims (insertions underlined and deletions struck through):

"1. An in vitro method of evaluating the immunological activity of a vaccine preparation in the form of a mixture of a molecular protein antigen, which is an allergen, and a carrier in the form of aluminium hydroxide, wherein the mixture comprises a liquid phase and a solid phase, to which at least a part of the antigen is attached, the method comprising the steps of

i) subjecting the vaccine to one or more measurements selected from the group consisting of:

- 1) the immunological activity of the mixture,
- 2) the immunological activity of antigen in the liquid phase,
- 3) the immunological activity of antigen in the solid phase,
- 4) the immunological activity of antigen in the liquid phase upon a treatment of the mixture to displace the antigen from the solid phase, and

5) the immunological activity of antigen in the solid phase upon a treatment of the mixture to displace the antigen from the solid phase,

wherein the immunological activity measurement is selected from the group consisting of a) antibody binding capacity using an immunoassay employing an antigen-specific IgE antibody bound to an antibody solid phase, b) ability to activate effector cells and c) potential for inducing anaphylaxis; and

ii) using the measurement results to evaluate the immunological activity of the vaccine.

2. A method according to claim 1, wherein the immunological activity is measured as the antibody binding capacity.

3. A method according to claim 2, wherein the antibody used or detected is IgE in combination with an antibody selected from the group consisting of IgA, ~~IgE~~, IgG, IgM and combinations thereof.

4. A method according to claim 3~~2~~, wherein the antibodies used or detected are both IgE and IgG.

5. A method according to claim 3~~2~~, wherein the antibody used or detected is only IgE."

3.3 As is apparent from the above, original claim 1 specifically referred - in alternative a) for the measurement of immunological activity - to the use of an immunoassay for the measurement of the antibody binding capacity. Although a number of different immunoassay formats exist, all of them, by definition, involve the use and/or detection of at least one

antibody, which should be antigen-specific. Page 18, lines 18 to 30, of the application as filed provides details on the types of immunoassays that can be used for measuring antibody binding capacity:

"Suitable types of assays include 1) assays wherein the antigen to be assayed is passively attached to a solid phase, and 2) assays wherein the antigen to be assayed is captured by a first antigen-specific antibody coupled to a solid phase. For both type 1) and 2) assays, the antigen [*or the antibody in a type 2) assay: note added by the board*] attached to the solid phase may a) be reacted with a second antigen-specific antibody, or b) with a modified antigen.

When using option a), i) the second antigen-specific antibody may be labelled (direct assay) or ii) it may be reacted with a labelled anti-antibody specific to the second antigen-specific antibody (indirect assay). When using option b), the modified antigen may be labelled or be adapted to be coupled to a label, e. g. by a linker system. One example of such a linker system is the biotin-avidin/streptavidin system."

It is thus apparent from this passage of the description that when using the assay described under 2) - which is the assay format corresponding to the embodiment claimed in original claim 1 - a second antigen-specific antibody may be used (alternative "a)" above), which may be labelled itself (alternative "i)" above) or which may be reacted with a labelled anti-antibody specific to the second antigen-specific antibody (alternative "ii)" above).

Hence, it can be concluded that while claim 1 refers to an (antigen-specific) antibody only, this does not mean that it is solely directed to immunoassays employing

only this antibody. In fact, up to 3 antibodies can be used (assay type corresponding to 1(a)(ii) above) and dependent claim 3 makes clear that the use of multiple antibodies is foreseen, since it stipulates that combinations of antibodies of different isotypes (classes) may be used; dependent claim 4 further describes one such embodiment where antibodies of two different isotypes are used.

Therefore, the board cannot follow the respondent's arguments that claims 3 to 5 refer back to the antibody of claim 1. In fact, claims 3 and 5 refer to the method of claim 1, and further characterise "the antibody used or detected"; claim 4, referring back to the method of claim 2, even refers to the "antibodies used or detected" (emphasis added by the board). In view of the fact that claim 1 encompasses methods using more than one antibody, it cannot be concluded that the features of claims 3 and 5 solely define the "antigen-specific antibody bound to an antibody solid phase" of claim 1.

3.4 Whether or not the requirements of Article 123(2) EPC are fulfilled for the amended claims has thus to be assessed in the light of the above conclusions.

3.5 Claim 1:

3.5.1 The following passages of the originally filed application constitute a basis for the amendments of claim 1: page 8, line 19 (molecular protein antigen); original claim 49 (allergen); original claims 47 and 48 (carrier in the form of aluminium hydroxide).

3.5.2 In respect of the feature "antigen-specific IgE antibody", the board disagrees that original claim 5 by itself provides a suitable basis, because it is not

apparent from claim 5 that the "antibody to be used or detected" is the antigen-specific antibody of claim 1. As discussed above, original claim 1 referred only to an antigen-specific antibody but did not exclude that further antibodies might be present, and in fact, original claims 3 and 4 rendered clear that the presence of more antibodies was indeed foreseen. Contrary to the respondent's arguments, original claim 5 did not refer to the antibody of claim 1 but rather to the method of claim 1, wherein the antibody used or detected (not necessarily an antigen-specific antibody) is IgE.

Nevertheless the board concludes that there is a basis for this amendment in the description as filed, namely on page 20, lines 1 and 2, referring to an "antigen-specific IgE coupled to an antibody solid phase", and in Example 1 (page 30, lines 12 and 13), disclosing a "solid phase absorbed IgE" which binds the antigen. It is further noted that in Example 1 the antigen is an allergen which is adsorbed to an aluminium hydroxide gel adjuvant, and thus this example indeed relates to the same embodiment as the present claim 1. The board thus accepts that the requirements of Article 123(2) EPC are fulfilled for claim 1.

3.6 Claim 3:

3.6.1 While original claim 3 (identical to granted claim 3) was directed to the method of claim 2, wherein the antibody used or detected was to be selected from the group consisting of IgA, IgE, IgG, IgM and combinations thereof, present claim 3 is now directed to the method of claim 2, wherein the antibody used or detected is IgE **in combination** with an antibody selected from the group consisting of IgA, IgG, IgM and combinations

thereof. This specific combination, although encompassed in the generic term "combinations thereof" in original claim 3, was not directly and unambiguously disclosed in the application as filed. Throughout the application reference is made to the antibody used being IgE, without any indication of possible combinations with other immunoglobulin classes (see e.g., Examples). Only the passage on page 20, lines 21 to 29, and original claim 3 disclose the possibility of combining different immunoglobulin classes but these passages do not individualize such combinations which necessarily comprise IgE, let alone IgE bound to an antibody solid phase. It is moreover noted that in fact, this amendment even results in the deletion of one particular subgroup, namely the subgroup wherein an IgE antibody is combined with another IgE antibody, i.e. that subgroup which is now claimed in present claim 5: such subgroups - individualised in the present claims 3 and 5 - were not however disclosed in the application as filed.

3.7 Claim 5:

3.7.1 While originally filed claim 5 was directed to the antibody used or detected as being IgE, present claim 5 is directed to the antibody used or detected as being only IgE (emphasis added). When read in combination with original claim 1, original claim 5 only required that the antibody "used or detected" in the immunoassay (again, not necessarily the antigen-binding antibody) be IgE, but did not exclude that other antibodies, of other immunoglobulin classes, could be used additionally. The use of only IgE antibody was encompassed in original claim 5 but was not specifically disclosed (neither explicitly or implicitly). The opposition division considered that

the amendment did not offend Article 123(2) EPC, without indicating however, where the basis for this amendment was to be found in the application as filed. Instead, it stated that it was "the logical consequence of said limitation" (decision, section 7.2). The board cannot follow this reasoning. First of all, it is not even apparent which limitation the opposition division refers to, because there is no reference to any limitation in the whole of section 7 of the decision. Assuming that "said limitation" refers to the limitation in claim 1 to an IgE antigen-specific antibody, it is still not apparent why the introduction of the word "only" should be the logical consequence of said limitation. Rather it would appear that if original claim 5 was the basis for the amendment to claim 1 - as apparently concluded by the opposition division (decision, section 7.2) - the logical consequence of said limitation would be to delete claim 5 altogether, as it became redundant. The introduction of the word "only" overcomes this redundancy by introducing a new disclosure which was not directly and unambiguously derivable from the application as filed.

3.8 Present claims 3 and 5 are thus considered to contravene the requirements of Article 123(2) EPC. Hence, the sole set of claims on file is found to be not allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar:

The Chairman:



N. Maslin

U. Oswald

Decision electronically authenticated