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Datasheet for the decision of 03 April 2008

Case Number: T 1447/06 - 3.3.04

Application Number: 95903889.4

Publication Number: 0732937

IPC: A61K 39/39

Language of the proceedings: EN

Title of invention:
Non-toxic mucosal adjuvant

Patentee:
Novartis Vaccines and Diagnostics S.r.l.

Opponents:
Wyeth
Sanofi Pasteur Limited

Headword:
Non-toxic mucosal adjuvant/NOVARTIS VACCINES

Relevant legal provisions:
EPC Art. 54 (1)-(4), 56, 83, 84, 123 (2) (3)

Relevant legal provisions (EPC 1973):
EPC Art. 54 (4), (5)

Keyword:
"Main Request: Novelty (yes)"
"Inventive step (yes)"
"Added subject-matter (no)"
"Broadening of protection (no)"
"Clarity (yes)"
"Sufficiency of disclosure (yes)"

Decisions cited:
-
Catchword:
-

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Case Number: T 1447/06- 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 03 April 2008

Appellant I: (Patent Proprietor)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 21 December 2005 concerning maintenance of European patent No. 0732937 in amended form.**

Composition of the Board:

Chair: U. Kinkeldey
Members: R. Gramaglia
D. S. Rogers

Summary of Facts and Submissions

I. European Patent No. 0 732 937 (application No. 95 903 889.4) with the title "Non-toxic mucosal adjuvant" was granted with 14 claims.

II. Notices of opposition were filed by opponents O1 to O3 requesting the revocation of the European patent on the grounds of Article 100 (a), (b) and (c) EPC. The opposition division maintained the patent on the basis of the claims 1-6 of the sixth auxiliary request then on file.

III. With a letter dated 23 September 2004, opponent O1 withdrew its opposition.

IV. The patentee (appellant I), opponent O2 (appellant II) and opponent O3 (appellant III) filed appeals against the decision of the opposition division.

V. With a letter dated 20 February 2008, appellant II announced that he would not attend oral proceedings. With a letter dated 20 March 2008, appellant III withdrew the appeal.

VI. Oral proceeding were held on 3 April 2008, during which appellant I (patentee) submitted a new Main Request (claims 1 to 12) and a revised description. Independent claims 1, 4, 8, 10 and 11 of the new Main Request read as follows:

1. A pharmaceutical composition comprising a non-toxic mucosal adjuvant in admixture with a second antigen, characterised in that (a) said non-toxic mucosal

adjuvant is a detoxified bacterial ADP-ribosylating toxin having a mutant A subunit, wherein said bacterial ADP-ribosylating toxin is *E.coli* heat labile toxin (LT), and (b) said second antigen is a viral or bacterial antigen derived from a pathogenic organism."

"4. Use of a detoxified bacterial ADP-ribosylating toxin having a mutant A subunit as a mucosal adjuvant in the preparation of a composition for mucosal administration, wherein said bacterial ADP-ribosylating toxin is cholera toxin (CT) or *E.coli* heat labile toxin (LT)."

"8. The use of a mucosal adjuvant for the manufacture of a vaccine, wherein said mucosal adjuvant is a detoxified bacterial ADP-ribosylating toxin having a mutant A subunit, and wherein said bacterial ADP-ribosylating toxin is cholera toxin (CT) or *E.coli* heat labile toxin (LT)."

"10. A pharmaceutical composition comprising a non-toxic mucosal adjuvant and a second antigen for simultaneous administration when combined in a single vehicle, carrier or particle, characterised in that (a) said non-toxic mucosal adjuvant is a detoxified bacterial ADP-ribosylating toxin having a mutant A subunit, wherein said bacterial ADP-ribosylating toxin is *E.coli* heat labile toxin (LT), and (b) said second antigen is a viral antigen or a bacterial antigen derived from a pathogenic organism."

"11. A method for the manufacture of an adjuvanted vaccine, comprising the steps of:

(a) performing site-directed mutagenesis in the A subunit of a bacterial ADP-ribosylating toxin in order to detoxify the toxin; and
(b) bringing the detoxified toxin into association with a second antigen, such that it functions as a mucosal adjuvant,
characterised in that (a) said bacterial ADP-ribosylating toxin is *E.coli* heat labile toxin (LT), and (b) said second antigen is a viral antigen or a bacterial antigen derived from a pathogenic organism."

Claim 2 and 3 were addressed to specific embodiments of the pharmaceutical composition according to claim 1. Claims 5 to 7 related to specific embodiments of the use according to claim 4. Claim 9 related to a specific embodiment of the use according to claim 8. Claim 12 covered specific embodiments of the pharmaceutical composition according to claims 1, 2, 3 or 10.

VII. The following document are cited in the present decision:

D2 Holmgren J. et al., Vaccine, Vol. 11, pages 1179-1184 (1993);

D3 Lycke N. et al., Eur. J. Immunol., Vol. 22, pages 2277-2281 (1992);

D20 Pizza M. et al., Molecular Microbiology, Vol. 14, No. 1, pages 51-60 (1994);

D29 W0-A-92/19265;

D30 Walker R.I. et al., Vaccine Res., Vol. 2, pages 1-10 (1993);

D31 Verweij W.R. et al., Vaccine, Vol. 16, pages 2069-2076 (1998);

D32 Hartman A.B. et al., Infect. Immun. Vol. 67, pages 5841-5847 (1999);

D33 Hagiwar Y. et al., Vaccine, Vol. 19, pages 2071-2079 (2001);

D34 Tsuji T. et al., Immunology, Vol. 90, pages 176-182 (1997);

D35 Hazama M. et al., Immunology, Vol. 78, pages 643-649 (1993).

VIII. The submissions by appellant I (patentee) in writing and at the oral proceedings, insofar as they are relevant to the present decision, can be summarized as follows:

Article 123(2) EPC
Claims 4 and 8

– The expression "mucosal adjuvant" used without being limited to a "non-toxic mucosal adjuvant" had a basis in the application as filed.

Novelty

Claims 4 and 8

– The authors of documents D2 and D3 were not able to detect any adjuvant effect of the Glu 112 -> Lys LT mutant, contrary to the requirements of claims 4 and 8, according to which this technical effect had to be achieved.

– Document D29 did not disclose any adjuvant effect for the mutants of CT subunit A.

Inventive step (Article 56 EPC)

– The closest prior art was represented by documents D2/D3. The problem to be solved was the provision of a non-toxic adjuvanticious LT or CT toxin in a composition (vaccine) for mucosal administration.

– The skilled person would have concluded from the failure by the experiments described in documents D2/D3 to show adjuvant activity that CT or LT mutants with mutant A subunit were unsuitable as mucosal adjuvants.

– Moreover, in the light of the state of the art in December 1993, there was a conviction that adjuvanticity and toxicity were intimately linked.

– Even if document D35 suggested that LTB had adjuvant activity, this had to be balanced by document D2, teaching the opposite, and by further documents questioning the adjuvant properties of the B subunit alone.

Sufficiency of disclosure

– The patent (see paragraphs [0028] to [0032]) gave sufficient information for the skilled person to arrive at detoxified mutants of LT or CT.

– Later document D31 showed that the mutant E112K described in documents D2 and D3 as ineffective had indeed adjuvant properties.

IX. The submissions in writing by appellant II (opponent 02) and the other party (opponent 03), insofar as they are relevant to the present decision, can be summarized as follows:

Article 123(2) EPC
Claims 4 and 8

– The expression "mucosal adjuvant" in these claims found basis in the original application only in the context of "non-toxic mucosal adjuvant". The omission of the term "non-toxic" thus offended Article 123(2) EPC.

Novelty
Claims 4 and 8

– Document D3 disclosed the generation of a Glu 112 -> Lys mutant of the *E. coli* heat labile toxin (LT) subunit A and investigation on the potential adjuvant effect of such a mutant (termed "mLT"). As part of that investigation, mice were immunized three times by the peroral route with an antigen

admixed with mLT. Therefore, the Glu 112 -> Lys LT mutation fell within the scope of claim 1 and the route of administration was mucosal. A similar teaching could be found in document D2. In conclusion, these prior art disclosures anticipated claim 4 and 8 because the Glu 112 -> Lys LT mutant was inherently being used as a mucosal adjuvant by the authors of documents D3 and D2, regardless of the actual adjuvant activity of the mutant.

– Document D29 described mutants of cholera toxin (CT) subunit A and their use in vaccines. On page 11, lines 31 to 35 of this document it is stated: "the toxin analogs of the present invention can be formulated into vaccine compositions or used in combination with other immunogenic agents in a multicomponent vaccine". Therefore, claims 4 and 8, relating to the use of a mutant subunit A toxin in admixture with a second antigen were anticipated by the disclosure in document D29.

Inventive step (Article 56 EPC)

– Document D30 disclosed the use of LT as mucosal adjuvant together with a second viral or bacterial antigen. Document D29 disclosed the use of detoxified CT mutant toxin subunit A in combination with other immunogenic agents in a multicomponent vaccine (see page 11, lines 31-35). Therefore, a skilled person coming across document D29 would recognise the benefit of using detoxified CT or LT toxin instead of LT in the vaccine of document D30 and arrive at the claimed subject-matter.

– Contrary to appellant I's opinion, the prior art did not suggest that adjuvanticity and toxicity were intimately linked. On the contrary, the fact that document D35 taught that subunit B of LT (LTB) had mucosal adjuvant properties without being toxic was a proof that adjuvanticity and toxicity could be separated. Therefore the skilled person would expect LT holotoxin with a mutated A subunit to also be adjuvantitious.

– Document D2 invited the skilled person to investigate whether defined mutations in the A subunit could give a non-toxic, yet adjuvant-active molecule.

Sufficiency of disclosure

– It would place an undue burden on the skilled person to carry out the invention across the whole scope of the claims.

– The claims encompassed non-workable mutants such as those described in documents D2, D3 or D20.

X. Appellant I (patentee) requested that the decision under appeal be set aside and that the patent be maintained upon the basis of claims 1 - 12 of the Main Request submitted at the oral proceedings.

Appellant II (opponent 02) requested in writing, by letter dated 21 April 2006 (reiterated in letters dated 1 June 2007 and 20 February 2008) that the decision under appeal be set aside and that the European patent No. 0732 937 be revoked.

Reasons for the Decision

1. The appeal is admissible.

Article 123(2) EPC
Claims 4 and 8

2. Appellant II and the other party (opponent 03) have raised an objection under Article 123(2) EPC arguing that the expression "mucosal adjuvant" in these claims found basis in the original application only in the context of a "non-toxic mucosal adjuvant" and that the omission of the term "non-toxic" in claims 4 and 8 offended Article 123(2) EPC.

3. However, the expression "mucosal adjuvant" used without being limited to a "non-toxic mucosal adjuvant" has a basis on page 7, line 19 and page 9, lines 18-19 of the application as filed and in claims 6 and 15 as filed.

Article 123 (3) EPC
Claims 1 to 12

4. The claims differ from the corresponding granted claims in that they have been restricted to mutants of *E. coli* heat labile toxin (LT) and/or cholera toxin (CT). In view of this restriction to only two defined toxins, the omission of the disclaimer in the granted claims to only the double mutant of pertussis toxin (PT) from an otherwise unrestricted, general toxin does not extend the scope of protection of the granted claims. Therefore, no objection under Article 123(3) arises.

Article 84 EPC
Claims 1 to 12

5. Appellant II and the other party (opponent 03) have raised objections under this Article against the claims as maintained by the opposition division. However, since the current wording of the claims presently before the board does not differ in material respects from the wording in the claims as granted (see point 3 supra), there is no legal basis to examine them for compliance with Article 84 EPC.

Novelty (Article 54(1)-(4) EPC and Article 54(4), (5) EPC 1973)
Claims 1 to 3 and 10 to 12

6. No prior art document discloses any pharmaceutical composition comprising a detoxified mutant A subunit of *E. coli* heat labile toxin (LT) non-toxic mucosal adjuvant in admixture with a second antigen according to claim 1 or 10, or a process for its manufacture according to claim 11. The subject-matter of claims 1, 10 and 11 and dependent claims 2, 3 and 12 is thus novel.

Claims 4 to 9

7. Appellant II maintains that documents D2 and D3 anticipate claims 4 and 8 because the Glu 112 -> Lys LT mutant disclosed in these documents was inherently being used as a mucosal adjuvant by the authors of documents D3 and D2, regardless of the actual adjuvant activity of the mutant.

8. Documents D2 and D3 indeed disclose the generation of a Glu 112 -> Lys LT subunit A mutant (see document D3, page 2278, section 2.1) and the investigation of the potential adjuvant effect of such a mutant. As part of that investigation, mice were immunized three times via the peroral route with keyhole limpet haemocyanin (KLH) admixed with the LT mutant Glu 112 -> Lys (termed "mLT") (see document D3, page 2280, l-h column: "...we investigated the adjuvant activity of these proteins..."). The function of an adjuvant is to help (from "adjuvare") a second antigen increase its antigenicity, as shown in paragraphs [0063] to [0071] of the patent.

9. For a prior art document to anticipate the use of claims 4 or 8, it must make available to the public the direct relationship between using a non-toxic mutant A subunit of CT or LT and obtaining a mucosal adjuvant effect. In contrast to this, documents D2 and D3 provide the opposite teaching, stating that their authors could not detect any adjuvant effect of the Glu 112 -> Lys LT mutant (see document D3, page 2280, l-h column, second paragraph and document D2, page 1183, l-h column, lines 10-19). Therefore, documents D2 and D3 do not anticipate claims 4 and 8.

10. The subject-matter of claims 4 to 9 is thus also novel.

Document D29

11. It was also argued by appellant II that the disclosure of document D29 anticipated claims 4 and 8, relating to the use of a mutant subunit A toxin in admixture with a second antigen.

12. Document D29 in fact describes mutants of cholera toxin (CT) subunit A (see e.g. Table 4 on page 40) and their use in vaccines (see e.g. page 42, lines 1 to 13). On page 11, lines 31 to 35 of this document it is stated:

"the toxin analogs of the present invention can be formulated into vaccine compositions or used in combination with other immunogenic agents in a multicomponent vaccine."

13. However, this document does not address the adjuvant properties of the mutants of cholera toxin (CT) subunit A. The skilled person is thus also not taught by this document the direct relationship between using a non-toxic mutant A subunit of CT and obtaining a mucosal adjuvant effect. On page 43, lines 14-15 of document D29, reference is made to "protection at mucosal surfaces", however, this occurs in the context of eliciting antibodies against the mutant, i.e., the antigenic rather than the adjuvant properties of the mutant are meant.

Inventive step (Article 56 EPC)

14. To summarize, claims 1 to 3 and 10 to 12 relate to a pharmaceutical composition comprising a non-toxic mutant A subunit of E. coli heat labile toxin (LT) and a second antigen and to a method for the manufacture of a vaccine comprising these components (claim 11). Claims 4 to 9 relate to medical uses relying on the newly discovered pharmaceutical properties (mucosal adjuvanticity) of the non-toxic mutant A subunit of cholera toxin (CT) or E. coli heat labile toxin (LT).

Closest prior art and problem to be solved

15. Wild type LT and CT, comprising each A and B subunits were known to act as adjuvants (see e.g. document D30). However, CT and LT were potent enterotoxins which could not be used in vivo. In document D35, adjuvant effects based on the use of LT subunit B (LTB) as a mucosal adjuvant are reported, i.e. an approach similar to that taken in the prior art to overcome the problem of CT toxicity discussed in paragraphs [0012] and [0016] of the contested patent, consisting in using the non-toxic portion (subunit B) of the toxin. As regards subunit A, the most relevant documents are documents D2, D3 and D29. Document D29 pertains to non-toxic CT having a mutant A subunit to be used as antigen. However, this document does not disclose any mucosal adjuvant effect associated with this mutant (see point 13 supra). Document D3 discloses the generation of a Glu 112 -> Lys LT subunit A mutant (see page 2278, section 2.1) and the investigation of the potential adjuvant effect of such a mutant. As part of that investigation, mice were immunized three times via the peroral route with keyhole limpet haemocyanin (KLH) admixed with the LT mutant Glu 112 -> Lys (termed "mLT") (see document D3, page 2280, l-h column: "...we investigated the adjuvant activity of these proteins..."). Document D2 (a review document published 3 months before the earliest priority date of the patent in suit) also addresses the problem of LT toxicity by mutating the subunit A in the LT holotoxin, i.e., the same type of approach followed in the contested patent (see paragraph [0021]), although it gives less details than document D3. For

these reasons, the board considers document D3 as the closest prior art.

16. The problem to be solved is the provision of a non-toxic adjuvanticious LT or CT toxin in a composition (vaccine) for mucosal administration. The solution proposed is CT or LT toxins having a mutated A subunit. In view of the results of Table 2 (see page 8) of the patent, the board is satisfied that the above problem has indeed been solved.

17. The relevant question for assessing inventive step is whether or not the skilled person would have turned to CT or LT toxins having a mutated A subunit for solving the above problem.

18. The authors of document D3 were not able to detect any adjuvant effect of the Glu 112 -> Lys LT mutant A subunit (see page 2280, l-h column, second paragraph, as confirmed in document D2, page 1183, l-h column, lines 10-19). The skilled person would have thus concluded from the experiments disclosed in document D3 that CT or LT mutants with mutant A subunit were unsuitable as mucosal adjuvants. Moreover, neither documents D29, D35 (see points 13 and 15 supra) nor any prior art document disclosed or suggested any mucosal adjuvant effect associated with non-toxic CT or LT having a mutant A subunit. It is therefore the board's view that the skilled person looking for non-toxic adjuvanticious LT or CT toxins would have prima facie not turned to CT or LT toxins having a mutated A subunit.

19. Further, in the light of the state of the art in December 1993, there was a conviction that adjuvanticity and toxicity were intimately linked. For instance, when discussing the adjuvant activity of wild-type CT and LT, the abstract of document D2 states: "...This adjuvant activity appears to be closely linked to the ADP-ribosylating action of CT and LT associated with enhanced cyclic AMP formation in the affected cells and thus it may prove difficult to eliminate the enterotoxic activity without loss of adjuvanticity". On page 1182, l-h column of document D2, the question "Can adjuvanticity be separated from enterotoxicity?" arises. The answer to this question is in the negative (see page 1183, l-h column, lines 10-19) since the authors of document D2 conclude that whereas the wild-type LT had an oral adjuvant effect, the lack of adjuvant effect for the mLT mutant was "clear-cut". Finally, the title itself of document D3 ("The adjuvant effect of *Vibrio Cholerae* and *Escherichia coli* heat-labile enterotoxin is linked to their ADP-ribosyltransferase activity") also supports the conclusion that adjuvanticity and toxicity were considered to be intimately linked.

20. Therefore, the board concludes that it was not obvious for the skilled person to separate adjuvanticity from toxicity and arrive at the presently claimed pharmaceutical compositions and medicinal applications.

21. The other party (opponent 03) argued that document D35 taught that subunit B of LT (LTB) had mucosal adjuvant properties without being toxic. Hence the prior art suggested that adjuvanticity and toxicity could be separated. Therefore the skilled person would expect LT

holotoxin with a mutated A subunit to be also adjuvantitious.

22. However, even assuming in the favour of the other party that document D35 suggested that LTB had adjuvant activity, this has to be balanced by document D2, teaching the opposite (see page 1182, r-h column, first full paragraph). Further documents questioning the adjuvant properties of the B subunit alone are referred to in paragraphs [0018] of the patent. Therefore, the disclosure in document D35 could not alter the prevailing conviction that adjuvanticity and toxicity could not be separated. In conclusion, the board is not convinced that the skilled person would have expected LT holotoxin with a mutated A subunit to be also adjuvantitious.

23. Appellant II maintains that it would have been obvious to arrive at the claimed subject-matter by combining the teachings of documents D30 and D29. Document D30 disclosed the use of LT as mucosal adjuvant together with a second viral or bacterial antigen, whereas document D29 disclosed the use of a detoxified CT mutant A subunit toxin in combination with other immunogenic agents in a multicomponent vaccine (see page 11, lines 31-35). Therefore, a skilled person would have recognised the benefit of using the detoxified CT toxin A subunit of document D29 instead of LT in the vaccine of document D30.

24. In the board's judgement, turning to the detoxified CT toxin A subunit of document D29 was contrary to the findings in documents D2/D3, according to which a previous attempt to achieve the same result (adjuvant

effect) with the "mLT" mutant toxin had failed with "clear-cut" results. Moreover, document D29 did not suggest any mucosal adjuvant effect associated with this mutant. On page 43, lines 14-15 of this document, reference is merely made to "protection at mucosal surfaces" in the context of eliciting antibodies against the mutant, i.e., the antigenic rather than the adjuvant properties of the mutant are meant. Under these circumstances, the skilled person would have reasonably expected that using the detoxified CT toxin A subunit of document D29 instead of LT in the vaccine of document D30 would have cancelled its adjuvant properties.

25. Finally, appellant II argues that document D2 (see page 1183, l-h column, lines 21-23 from the bottom) suggested to investigate whether defined mutations in the A subunit other that the one then tested ("mLT") could give a non-toxic, yet adjuvant-active molecule. The board observes that this suggestion ("(i)") was only one of the four ("i" to "iv") made under the heading "Perspectives: use in humans?". Therefore, investigating mutants was not the only route open to the skilled person. Moreover, formulating a possible future strategy, namely investigating mutants to find a non-toxic, yet adjuvant-active molecule, does not mean that the skilled person had a high expectation of success in entering this route. The conclusions arrived at by the board under point 18 and 19 supra rather show that the contrary was true.

26. The board concludes that the subject-matter of claims 1 to 12 satisfies the requirement of Article 56 EPC.

Sufficiency of disclosure (Article 83 EPC)

27. In the view of appellant II and the other party (opponent 03), it would place an undue burden on the skilled person to carry out the invention across the whole scope of the claims.

28. However, the patent (see paragraphs [0028] to [0032]) provides sufficient information for the skilled person to select suitable detoxified mutants of LT or CT, either among the numerous examples of suitable detoxified CT and LT mutant toxins which have been already published or by investigating new mutants as to whether they exhibit the required adjuvanticity applying the tests disclosed in paragraphs [0063] to [0071] of the patent. Later documents D33 and D34 show that new mutants of LT endowed with adjuvant properties have indeed been selected by following the instructions provided by the patent in suit.

29. It was also argued by appellant II that the claims encompass non-workable mutants such as those described in documents D2, D3 or D20. However, the claims are limited to situations where "a detoxified bacterial ADP-ribosylating toxin (CT or LT) having a mutant A subunit" functions as a mucosal adjuvant. Therefore, none of the claims covers situations where a detoxified CT/LT mutant does not provide an adjuvant effect. In view of the present formulation of the claims, the toxic LT mutants listed in Table 1 (page 55) of document D20 are also excluded from the claims.

As for appellant II's opinion that the claims cover the mutant Glu 112 -> Lys (termed "mLT") described in

documents D2 and D3, which does not function as a mucosal adjuvant, post-published document D31 (see page 2072, l-h column) demonstrates that this mutant (denoted "LT-E112K" in this document) does possess mucosal adjuvant activity. The reported failure by the authors of documents D2 and D3 thus merely shows that one group failed in an attempt to use Glu 112 -> Lys LT mutant as an oral adjuvant for KLH protein in mice. In the light of the results in document D31, these investigations seem to have had a different (and/or possibly poorer) experimental design.

30. In view of the foregoing, the board concludes that no case of insufficiency of disclosure has been made out.

Order

For these reasons it is decided that:

1) The decision under appeal is set aside.

2) The case is remitted to the department of first instance with the order to maintain the patent as amended in the following version:

1. Description: pages 2 and 7 of the patent specification, pages 3, 3a, 4, 5, 6 and 8 submitted during oral proceedings of 3 April 2008.

2. Claims: 1 - 12 of the Main Request submitted during oral proceedings of 3 April 2008.

3. Figures: 1 - 3 of the patent specification.

The Registrar: Chair:

P. Cremona U. Kinkeldey