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Datasheet for the decision of 13 October 2008

Case Number: T 0240/08 - 3.3.08

Application Number: 93903129.0

Publication Number: 0625203

IPC: C12N 15/31

Language of the proceedings: EN

Title of invention:
Synthetic Haemophilus Influenzae Conjugate Vaccine

Applicant:
Aventis Pasteur Limited

Headword:
Haemophilus conjugate/AVENTIS

Relevant legal provisions:
EPC Art. 54, 56, 83, 84, 123
EPC R. 103(1)(a)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Main request: added matter (no)"
"Clarity (yes)"
"Sufficiency of disclosure (yes)"
"Novelty (yes)"
"Inventive step (yes)"
"Reimbursement of the appeal fee (no)"

Decisions cited:
T 0800/99, T 0989/99

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0240/08 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 13 October 2008

Appellant: Aventis Pasteur Limited
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 13 August 2007 refusing European application No. 93903129.0 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: L. Galligani
Members: T. J. H. Mennessier
C. Heath

Summary of Facts and Submissions

I. The applicant (appellant) lodged an appeal against the decision of the examining division dated 13 August 2007, whereby the European patent application No. 93 903 129.0 with publication number 0 625 203 was refused. The application, entitled "*Synthetic Haemophilus Influenzae Conjugate Vaccine*", originating from an international application published as WO 93/15205 (which will be referred to in the "Reasons" as the application as filed).

II. Basis for the refusal was the main request filed with the letter of 4 November 2002 (claims 1 to 18) and the auxiliary request filed with the letter of 22 April 2005 consisting of a newly filed claim 1 and claims 2 to 18 of the main request.

Claim 1 of that main request read:

"1. An immunogenic conjugate, consisting of a synthetic carbohydrate antigen linked to a synthetic peptide containing at least one T-cell epitope, wherein said carbohydrate is a synthetic ribosylribitol phosphate (PRP) oligomer, **wherein said peptide and said carbohydrate antigen are selected and linked to enhance the immunogenicity of said carbohydrate antigen**."

(emphasis added by the board)

Claim 1 of the auxiliary request differed therefrom in that the sentence "*wherein said peptide is synthesised using a peptide synthetiser*" had been added at the end of the claim.

III. The main request was refused for reasons of the presence of added matter in claim 1 (Article 123(2) EPC, lack of clarity of claim 1 (Article 84 EPC) and lack of inventive step of claim 1 (Article 56 EPC) in view of document D5 taken alone or in combination with document D3 (for documents D3 and D5, see Section X *infra*). The auxiliary request was refused for the same reasons. Furthermore, it was considered that the added feature "*wherein said peptide is synthesized using a peptide synthesiser*" in claim 1 did not contribute to the inventive step of the claimed subject-matter.

IV. On 13 December 2007, the appellant filed a statement setting out the grounds of appeal which was accompanied by a new main request (claims 1 to 18), the claims rejected by the examining division being maintained as an auxiliary request. Furthermore, the appellant complained that there had been multiple procedural violations involved in the handling of the application prior to rejection by the examining division.

V. The examining division did not rectify its decision and referred the appeal to the Board of Appeal (Article 109 EPC 1973).

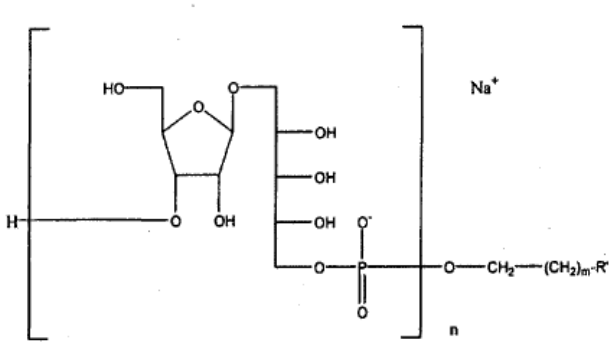
VI. On 2 June 2008, a communication under Article 15(1) of the Rules of Procedure of the Boards of Appeal presenting some preliminary and non-binding views of the board was sent to the appellant. The board was of the preliminary view that a person skilled in the art, in the apparent absence of any prejudice or technical difficulty, would have regarded it as obvious to try to replace in the immunogenic conjugate of document D3 the

KLH moiety by a synthetic peptide containing a T-cell epitope as described in document D1 with a reasonable expectation of obtaining an immunogenic conjugate capable of eliciting the production of anti-PRP antibodies.

VII. In reply to the board's communication, the appellant filed together with a letter dated 5 August 2008 a new main request (claims 1 to 12) to replace the previous main request. Furthermore, the appellant withdrew its request for oral proceedings.

Claim 1 of the present main request read:

"1. An immunogenic conjugate, for use in producing anti-PRP antibodies, consisting of a synthetic carbohydrate antigen linked to a carrier, said carrier being a synthetic peptide containing at least one T-cell epitope, wherein said carbohydrate is a synthetic ribosylribitol phosphate (PRP) oligomer which is a linear homopolymer of alternating molecules of ribose and ribitol joined by a phosphodiester linkage represented by the formula:



wherein n is an integer from 3 to 20 and m is an integer from 3 to 5, and R' is the synthetic peptide containing at least one T-cell epitope."

Claims 2 to 12 were dependent on claim 1 and directed to particular embodiments thereof.

VIII. On 14 August 2008, in a telephone conversation, the Rapporteur informed the appellant's representative that the board was of the opinion that the main request could form a basis for the grant of a patent and invited him to specify its present requests.

IX. With a letter dated 14 August 2008, the appellant withdraw the auxiliary request and maintained its request for reimbursement of the appeal fee. Amended description pages were enclosed.

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

(D1) WO-A-91/06652 (published on 16 May 1991)

(D3) EP-A2-0 320 942 (published on 21 June 1989)

(D5) G.J.P.H. Boons et al., Bioorganic & Medicinal Chemistry Letters, Vol. 1, No. 6, 1991, pages 303 to 308

XI. The submissions made by the appellant, insofar as they are relevant to the present decision, may be summarised as follows:

As regards the procedural aspects

The examining division committed multiple procedural violations, including:

(i) wrong refusal to entry into the proceedings of replacement claims filed on 10 July 2001 (see the communication of 14 January 2002) and to the slightly amended version of those claims filed on 4 November 2002 (see the communication of 19 December 2002);

(ii) failure to make clear in each of the summons to oral proceedings of 15 March 2004 and 28 November 2006 what reasons underlay the non-acceptance of arguments put forward by the applicant in relation to the objections and failure to include in the decision a reasoned discussion of the passages of the description principally relied upon by the applicant as offering support for the amendment objected to under Article 123(2) EPC;

(ii) refusal to clarify what objections were outstanding in answer to the applicant's request as formulated in the letter of 18 April 2007; and

(iv) rejection of the application in part on the ground of lack of inventive step over document D5 in the decision under appeal.

As regards the substantial aspects with respect to the main request

Articles 84 and 123(2) EPC

The feature reading "*wherein said peptide and said carbohydrate antigen are selected and linked to enhance the immunogenicity of said carbohydrate antigen*", on the presence of which the examining division had based its objections of added matter and lack of clarity, had been deleted from claim 1 now in issue. Thus, the requirements of Articles 84 and 123(2) EPC were now met.

Article 56 EPC

Document D5 disclosed conjugation of a B-epitope-containing phosphorylated disaccharide from the inner core of Neisseria meningitidis immunotype lipopolysaccharide 6 via an artificial spacer to an elongated T-cell epitope-containing peptide sequence of meningococcal outer membrane protein (OMP). It was simply an account of the making of a conjugate and did not provide evidence that it had any ability to raise antibodies and to serve as a vaccine.

A reader of document D5 would have appreciated that the ability of a designed conjugate to produce bactericidal antibodies against Neisseria meningitidis was hard to predict and that it was in reality entirely unknown whether the conjugation of a peptide to an oligosaccharide of Neisseria meningitidis would produce something useful in a vaccine or not, despite the optimistic statement at the very end of the document, according to which the immunological properties of the conjugate described therein might be of a great value for the future design and development of a broadly protective synthetic vaccine against Neisseria meningitidis.

Whilst document D5 disclosed the concept, but no verification of the actual effect, of conjugating an oligosaccharide of Neisseria meningitidis to a T-cell epitope-containing peptide of Neisseria meningitidis, document D3 disclosed the making of synthetic ribosylribitol phosphate (PRP) oligomer and its conjugation to a protein such as tetanus toxin.

Contrary to the examining division's contention, it would not have been obvious to modify the teaching of document D5 by substituting the synthetic PRP oligomer of document D3 for the Neisseria meningitidis oligosaccharide of document D5 so as to obtain a vaccine against Haemophilus inflenzae type b (Hib).

A skilled person would not have considered such a conjugate comprising by design a B-cell epitope from Hib and a T-cell epitope from Neisseria meningitidis, i.e. containing epitopes from two different organisms to be one that could be expected to work. In document D5 it was explicit that the T-cell epitope was selected from a meningococcal OMP in order that it would provide a homologous T-helper response, i.e. it was deliberately from the same organism.

Both documents D1 and D3 described using KLH to render immunogenic another component, be it a PRP oligomer or a synthetic peptide. Neither of the documents suggested that a synthetic peptide was capable of making something else immunogenic.

XII. The appellant requests that the decision under appeal be set aside, that a patent be granted on the basis of

the main request of 5 August 2008 and that the appeal fee be reimbursed.

Reasons for the Decision

Main request

Article 123(2) EPC

1. The immunogenic conjugate of claim 1 is described from line 29 of page 11 to line 11 of page 12, taken together with lines 13 to 15 of page 11 in the application as filed.

2. The immunogenic peptide of claim 2 is the subject-matter of claim 26 as filed.

3. The passages, tables and claims of the application as filed as referred to at points 1 and 2 *supra* provide an appropriate support for the conjugates of claims 3 to 5 which are dependent on claim 1 or claim 2, account being taken of the following additional parts of the application as filed:

3.1 As regards claim 3

Claim 27 as filed which refers to a conjugate of claim 25 as filed, wherein the synthetic peptide contains the amino acid sequence GPKEPFRDYVDRFYK from the HIV-1 gag p24 protein.

3.2 As regards claim 4

Page 20, lines 4 to 25, Tables 1 to 3 (see pages 47 to 51) and Table 11 (see page 59) which describe the synthetic peptides referred to in the claim.

3.3 As regards claim 5

Claim 28 as filed.

4. The passages, tables and claims of the application as filed as referred to at points 1 to 3 *supra* provide an appropriate support for the conjugates of claims 6 to 9 which are dependent on claim 5, account being taken of the following additional parts of the application as filed:

4.1 As regards claim 6

Page 12, lines 16 to 28 which describes conjugates, wherein the synthetic peptide has an amino acid sequence corresponding to an epitope of the P1 outer membrane protein of Haemophilus influenzae and having one of the sequences referred to in the claim.

4.2 As regards claim 7

The paragraph bridging page 12 (from line 29) and page 13 (to line 4) which describes conjugates, wherein the synthetic peptide has an amino acid sequence corresponding to an epitope of the P2 outer membrane protein of Haemophilus influenzae and having one of the sequences referred to in the claim.

4.3 As regards claim 8

Page 13, lines 5 to 16 which describes conjugates, wherein the synthetic peptide has an amino acid sequence corresponding to an epitope of the P6 outer membrane protein of Haemophilus influenzae and having one of the sequences referred to in the claim.

4.4 As regards claim 9

Claim 17 as filed which is directed to a synthetic peptide comprising at least one T-cell epitope (T) and at least one neutralisation B-cell epitope (B).

5. The passages, tables and claims of the application as filed as referred to at points 1 to 4 *supra* provide an appropriate support for the conjugates of claims 10, 11 and 12 which are dependent on claim 9, 10 and 11, respectively, account being taken of the following additional parts of the application as filed:

5.1 As regards claim 10

Claim 18 as filed which is directed to a synthetic peptide in the form of a chimeric T-B peptide.

5.2 As regards claim 11

Claim 19 as filed which is directed to a synthetic peptide of claim 18 as filed comprising at least one T-cell epitope of P1, P2 or P6 protein of Haemophilus influenzae type b and at least one neutralisation B-cell epitope of P1, P2 or P6 protein of Haemophilus influenzae type b.

5.3 As regards claim 12

Claim 20 as filed which is directed to a synthetic peptide of claim 18 as filed, wherein the chimeric T-B peptide is selected from P1-P2 chimeric synthetic peptides having an amino acid sequence as set forth in Table 11 in which peptides with SEQ ID NO: 42 to 49 are referred to.

6. In view of the above remarks, the conclusion is reached that the main request as a whole meets the requirements of Article 123(2) EPC.

Article 84 EPC

7. In the decision under appeal the clarity objection raised against claim 1 of the main request then on file was directed to the expression "*wherein said peptide and said carbohydrate antigen are selected and linked to enhance the immunogenicity of said carbohydrate antigen*" (see Section II *supra*). This expression is no longer present in claim 1 of the present main request. Thus, the opposition division's objection needs not be considered.

8. Having reviewed in detail the claims, the board reaches the conclusion that they clearly and concisely define the matter for which protection is sought. Thus, the main request meets the clarity requirement of Article 84 EPC.

Article 83 EPC

9. Compliance with the requirement of providing a sufficient disclosure was not disputed by the examining division in its decision.

10. Indeed, the application as filed provides a complete disclosure teaching the skilled person how to prepare the claimed conjugates (see Examples 1 to 12 on pages 32 to 39) and how to test the same (see Examples 13 to 20). Therefore, it is the board's view that the various aspects of the invention are disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Thus, the main request meets the requirements of Article 83 EPC.

Article 54 EPC

11. No novelty objection was raised in the decision under appeal.

12. It is also the board's view that none of the documents on file discloses an immunogenic conjugate for use in producing anti-PRP antibodies according to claim 1. Thus, the main request meets the requirements of Article 54 EPC.

Article 56 EPC

13. Claim 1 is directed to an immunogenic conjugate for use in producing anti-PRP antibodies, consisting of a synthetic carbohydrate antigen linked to a carrier, said carrier being a synthetic peptide containing at least one T-cell epitope, wherein said carbohydrate is

a particular synthetic ribosylribitol phosphate (PRP) oligomer.

14. Following the established practice of the EPO, the assessment of inventive step is performed by way of the problem-solution approach, starting with the determination of the document representing the closest prior art.

15. According to the case law of the EPO (see e.g. decision T 800/99 of 17 January 2001), the closest prior art is normally represented by a document which comes closest to disclosing the claimed subject-matter and is directed to the same purpose or effect of the invention and requires the minimum of structural and functional modifications. In the present case, two documents have to be considered first, namely D3 and D5, as either of them has been regarded by the examining division in the decision under appeal as a suitable document.

16. In the board's judgment, document D3 is better appropriate than document D5 to represent the closest prior art. This is because document D3 describes conjugates which are made of **a synthetic PRP oligomer**, as the polysaccharide antigen moiety of the conjugate of claim 1, and **a macromolecule** moiety, consisting of a protein such as e.g. the tetanus toxin or toxoid, the diphtheria toxin or toxoid, **KLH** or the outer membrane porin protein, which is capable of inducing a T-cell dependent response to that synthetic PRP oligomer. In contrast, document D5 describes a conjugate between a particular phosphorylated dissacharide from the inner core region of Neisseria meningitidis immunotype lipopolysaccharide 6, a polysaccharide which has

structurally speaking nothing to do with the PRP oligomer of the conjugate of claim 1 and a T-cell epitope-containing peptide of a meningococcal outer membrane protein.

17. The only difference between the conjugates of document D3 and the one of claim 1 resides in the moiety which is capable of inducing a T-cell dependent response to the synthetic PRP oligomer moiety, this being a protein in the first and a synthetic peptide in the latter.

18. In view of said difference the objective technical problem is regarded as the provision of an alternative conjugate. The solution to that technical problem being a conjugate according to claim 1.

19. The question to be answered is whether any of the prior art documents on file would have induced the skilled person to replace in the conjugate of document D3 the macromolecule moiety, which is a protein, by a synthetic peptide containing at least one T-epitope having the same capability of inducing a T-cell dependent response to the synthetic PRP oligomer.

20. The other document referred to in the decision under appeal for the assessment of inventive step is document D5. On page 303, the authors explain that, as part of a program to develop a broadly protective synthetic vaccine against Neisseria meningitidis, they were reporting the preparation of a particular sugar-peptide conjugate, in which a fragment of the inner core region of Neisseria meningitidis immunotype lipopolysaccharide 6 to function as the B-epitope and a T-cell epitope-containing peptide of a meningococcal outer

membrane protein to elicit a homologous T-helper response are covalently anchored by an artificial spacer. The document does not contain any guidance as to any proved ability to raise antibodies and to serve as a vaccine. The rather speculative last sentence on page 306, stating that "*the immunological properties of [the conjugate] may be of great value for the future design and development of a broadly protective synthetic vaccine against N. meningitidis*" only confirms the purpose of the search program. The skilled person may only derive from document D5 that a construct has been prepared which comprises a T-cell epitope-containing peptide expected to elicit a T-helper response to a disaccharide which is a fragment of lipopolysaccharide found in Neisseria meningitidis and unrelated with the PRP polysaccharide. Thus, the skilled person facing the objective technical problem as defined at point 18 *supra*, i.e. as the provision of an alternative conjugate capable of inducing a T-cell dependent response to PRP, will simply ignore document D5.

21. Document D1 has been referred to in the board's communication of 2 June 2008 (see Section VI *supra*). It refers to a link between the carrier outer membrane protein P1 and a PRP molecule of 20,000 to 2,000 000 daltons prepared by controlled acid hydrolysis (see Example IV on pages 9 to 10), in order to render the latter immonogenic, which is a teaching in the same line as that of document D3. It further describes immunogenic conjugates consisting of (i) **synthetic peptide** derived from the said outer membrane protein P1 of Haemophilus influenzae and **containing a potent T-helper determinant**, a preferred peptide being **HIBP1-4**

(see page 6, lines 2 to 24, in particular line 13, in combination with Figure 1b) which is one of the most preferred peptides of the application on issue (see page 29 and Figure 1) and (ii) **KLH** (see page 7, lines 1 to 20 and Example V on pages 10 to 11). The latter conjugates and the free peptides were assessed for their immunogenicity (see page 7, lines 1 to 20). Since the peptides contained a potent T-helper determinant and the peptide-KLH conjugates induced a strong antibody response in rabbits, the conclusion was reached that such a peptide could act as an antigen in a vaccine preparation against the disease caused by Haemophilus influenzae type b. However, the concept of using the synthetic peptides containing at least one T-cell epitope to render immunogenic a synthetic PRP oligomer is absent from document D1 and could only be derived therefrom with hindsight because the proposed course of action with the PRP molecule is the use of a link with a macromolecule not with a fragment thereof.

22. In view of the above analysis of documents D1 and D5, the board is of the view that the skilled person would have not found any incentive in the state of the art to arrive at the conjugate of claim 1. Therefore, claim 1 involves an inventive step. As claims 2 to 12 are dependent on claim 1 the same conclusion also applies to them. Thus, the main request as a whole meets the requirements of Article 56 EPC.

Adaptation of the description

23. The appellant has filed amended description pages intended to bring the description into conformity with the main request claims. Having considered them, the

board decides to leave the task of examining in depth the proposed amendments to the first instance as, firstly, the deletion of pages and passages of the description requires a renumbering of the remaining pages (and thus possibly the filing of a complete description) and, secondly, it will have to be established whether the embodiment at the bottom of page 13 of the application as filed in relation to a lipopeptide is in line with the claims of the main request.

Procedural aspects: request for reimbursement of the appeal fees

24. In order for the appeal fee to be reimbursed where the board of appeal deems an appeal to be allowable, such reimbursement should be equitable by reason of substantial procedural violation (see Rule 103(1)(a) EPC).

25. The appellant has used essentially four arguments in its attempt to demonstrate that the examination division committed a substantial procedural violation. The first line of argument is based on the assumption that the examining division misused its discretional power to admit or refuse amendments into the proceedings in its communications of 14 January 2002 and 19 December 2002. The second line of argument is based on the assumption that the examining division made erroneous or insufficient comments in the communications accompanying each of the summons to oral proceedings of 15 March 2004 and 28 November 2006, the communications of 14 January 2002 and 19 December 2002 as well as in the decision under appeal. The third line

of argument is based on an alleged refusal of the examining division to clarify what objections were outstanding in answer to its request as formulated in its letter of 18 April 2007, and the last line of argument concerns the use of D5 in the decision in order to justify a lack of inventive step.

26. In its communication of 14 January 2002, the examining division declined to allow amended claims 1 to 18 filed on 10 July 2001 into the proceedings. The amendments had been made in answer to the communication of 26 September 2000 at point 4 of which the appellant had been "given a final opportunity to amend the claims in a proper manner". The same occurred when, in its communication of 19 December 2002, the examining division again refused to enter into the proceedings the claims filed with the letter of 4 November 2002 which were in answer to the communication of 14 January 2002, whereas at point 4 of that communication the examining division was implicitly offering the appellant to make further amendments (see the sentences "*Thus, when making acceptable amendments (see above) which should form the basis of a discussion during oral proceedings*").

27. While refusing the above sets of claims looks erroneous in view of the decision T 989/99 of 14 December 2000, the board notes that, first, the examining division did respond to the amendments by way of citing new documents, and grounds for refusal under Article 123(2) EPC, and, second, the examining division indicated in the summons to oral proceedings of 15 March 2004 that they would allow a new set of claims. Therefore, the appellant no doubt has suffered a certain delay from

the initial refusal to admit an amended set of claims, but such delay has not been the reason for filing this appeal (which would have been difficult anyway in view of the appellant's own conduct that contributed to the length of proceedings), and the decision to refuse the patent is not based on such refusal, either. For that reason, the appellant's first point must fail.

28. The second line concerns allegedly insufficient or unclear comments made by the examining division in each summons to oral proceedings. The first summons of 15 March 2004 makes reference to previous communications as regards the issues of Article 123(2) EPC and clarity. In the board's view, this allowed the appellant to understand what would be discussed in oral proceedings, and prepare accordingly. In fact, the summons appears to have been clear enough for the appellant to withdraw its request for oral proceedings. It further appears that the examining division regarded oral proceedings as the most appropriate and efficient way to clarify all outstanding issues, as can be taken from the subsequent communication of 20 December 2005. In the following summons to oral proceedings of 28 November 2006, the division set out the three issues to be discussed: Article 123(2) EPC, Article 84 EPC and Article 56 EPC in light of document D3 and/or document D4. In the appellant's view, these remarks do not demonstrate that its arguments were sufficiently taken into account.

29. The board agrees. But a summons to oral proceedings is not a decision, and is rather meant to give the applicant the opportunity to prepare itself for oral proceedings by an indication of the scope of

subject-matter to be discussed. There is no requirement for the examining decision to write out a summons as if it were a preliminary decision. Mention of the three points to be discussed may well indicate that the examining division had taken the appellant's arguments into account, yet failed to be convinced thereby up to a point where a discussion in oral proceedings would no longer appear necessary. For that reason, the appellant's second point must fail as well.

30. The appellant's third line of argument is that the examining division failed to provide the appellant with an answer to its letter of 18 April 2007. It should be recalled that this letter was written as a response to the above summons of 28 November 2006. Not satisfied by the note of summons, the appellant had contacted the examiner by telephone on 19 March 2007 in order to request further and better particulars regarding those issues mentioned in the above summons. Apparently, no such particulars were provided, and the appellant was informed that oral proceedings would go ahead as scheduled.

31. While the board sympathises with the appellant in that the latter felt insufficiently informed by the examining division, it is difficult to see how, after a summons to oral proceedings has been issued, there should be a duty of the examining division to provide an applicant with more information regarding these proceedings than was furnished by the summons itself. Although unsatisfactory in the appellant's view, the only way of clarifying such outstanding issues would have been to attend oral proceedings and discuss matters then and there, a course of events the

appellant declined to follow. For these reasons, also the appellant's third point must fail.

32. Finally, the appellant objects to the reliance on document D5 for a refusal of the application. It appears from the decision that the examining division in its refusal of the main request relied on Articles 123(2), 84 and 56 EPC, rather than on Article 56 EPC alone. Failure to properly communicate its view on document D5 therefore is not an error on which the decision is based. The auxiliary request was refused for lack of inventive step, which indeed makes the argument on Article 56 EPC more relevant. In the above summons to oral proceedings of 28 November 2006, inventive step was mentioned as one issue to be discussed, albeit in connection with document D3 and/or document D4. Yet document D5 was in the proceedings and had previously been mentioned as a possible obstacle to inventive step. Mention of D5 in the oral proceedings would therefore not have been an "ambush" on the appellant, and neither can its reliance in the decision be considered as such. Thus, also this point must fail.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division with the order to grant a patent on the basis of the main request of 5 August 2008 together with a description and drawings to be adapted thereto.

3. The request for reimbursement of the appeal fee is refused.

The Registrar: The Chairman:

A. Wolinski L. Galligani