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Case Number: T 0516/11 - 3.3.04

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Title of invention:
Anticarcinoma antibodies and uses thereof

Applicant:
Ottawa Health Research Institute

Headword:
Anticarcinoma antibodies/OTTAWA HEALTH

Relevant legal provisions:
EPC Art. 56, 87, 111(1), 113(1)

Keyword:
Remittal to the department of first instance - (yes)
Substantial procedural violation (no)
Appealed decision sufficiently reasoned (yes)

Decisions cited:
T 0367/91, T 0939/92, T 0890/02, T 0411/04

Catchword:

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Case Number: T 0516/11 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 7 May 2015

Appellant: (Applicant)	Ottawa Health Research Institute 725 Parkdale Avenue Ottawa, Ontario K1Y 4E9 (CA)
Representative:	Fleuchaus, A. Fleuchaus & Gallo Partnerschaft mbB Patent- und Rechtsanwälte Steinerstrasse 15/A 81369 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 22 October 2010 refusing European patent application No. 04761652.9 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairwoman	G. Alt
Members:	A. Chakravarty
	M.-B. Tardo-Dino

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division refusing European patent application No. 04761652 entitled "*Anticarcinoma antibodies and uses thereof*".

II. The only ground for refusal of the application was that the subject-matter of claims 4 and 6 to 8 of the sole claim request was obvious in the light of the disclosure of Zhang J. et al., *J. Mol. Biol.*, vol. 341, no. 1., pages 161 - 169, published 30 July 2004 (document D1). Specifically, the subject-matter of claims 4 and 6 to 8 relating to a single domain antibody (sdAb) of claim 1 conjugated to an enzyme, a cytotoxic agent or an apoptosis inducer was not entitled to priority. As a result of this, the disclosure of document D1 represented the closest prior art for said subject-matter of claims 4 and 6 to 8 (points 11 to 14 of the decision under appeal).

Document D1 disclosed a single domain antibody, termed AFAI, which fell within the ambit of claim 1. A conjugate comprising this antibody and an enzyme, a cytotoxic agent or an apoptosis inducer was said to be a "*straightforward alternative*", not associated with any surprising or unexpected technical effects (point 16 of the decision under appeal). The conjugation of an antibody such as that disclosed in document D1 to an enzyme, a cytotoxic agent or an apoptosis inducer was also part of the "*common technical knowledge*" of the skilled person. The disclosure of document D1 provided an "*implicit incentive*" to the skilled person to make the claimed conjugates. Thus, the disclosure of document D1 need not be combined with another prior art document to lead to the conclusion that the claimed

subject-matter lacked an inventive step (points 19 and 20 of the decision under appeal).

III. With the statement setting out the grounds of appeal, a main and seven auxiliary requests were filed.

IV. In a communication pursuant to Article 15(1) RPBA, the board informed the appellant of its preliminary appreciation of substantive and legal matters concerning the appeal.

V. Oral proceedings before the board were held on 7 May 2015. At these proceedings, the appellant submitted a sole claim request, replacing all previously pending requests.

VI. Claims 1 and 4 to 6 of the sole request read:

"1. An isolated single domain antibody (sdAb) characterized by complementary determining region (CDR) 1 sequence KNLMG, CDR2 sequence TISGSGGTNYASSVEG, and CDR3 sequence AFAI and having an amino acid sequence of at least 90% sequence identity to SEQ ID NO. 1, and at least 90% sequence identity of the remaining portions of SEQ ID NO. 1 and wherein the isolated sdAb binds to non-small cell lung carcinoma A549 cell line.

4. A conjugate comprising the antibody of claim 1 or 2 and a molecule selected from the group consisting of a radio isotope, a therapeutic or a toxin.

5. A conjugate comprising the antibody of claim 1 or 2 and a radio isotope for use in the diagnosis of lung carcinoma in mammalian tissue.

6. The antibody according to claim 1 or 2 or the conjugate of claim 4 comprising the antibody of claim 1 or 2 and a molecule selected from the group consisting of a radio isotope, a therapeutic and a toxin, for the use in the treatment of lung carcinoma".

VII. The claims of this sole request differ from those of the request considered by the examining division, in that all subject-matter relating to a conjugate comprising the antibody of claim 1 or 2 and a molecule selected from the group consisting of an enzyme, a cytotoxic agent or an apoptosis inducer (i.e. the subject-matter of former claim 4 and the corresponding subject-matter of former claims 5 and 6) has been deleted.

VIII. The appellant's arguments may be summarised as follows:

Taking account of the examining division's decision on inventive step, all subject-matter relating to conjugates comprising the antibody of claim 1 or 2 and a molecule selected from the group consisting of an enzyme, a cytotoxic agent or an apoptosis inducer had been removed from the claims. As a result, the reasons for the refusal of the application were moot.

With respect to the request for reimbursement of the appeal fee, the examining division based its finding of lack of inventive step on the disclosure of document D1 combined with common general knowledge.

When challenged to substantiate this common general knowledge at the oral proceedings, the examining division did not cite a relevant document, in breach of practice set out in the Guidelines for Examination (G-VII, 3.1) and also in decision T 939/92 of

12 September 1995. The lack of substantiation, with common general knowledge being neither specified nor substantiated, meant that it had not been possible to properly defend the case.

Thus, the appellant's right to be heard was not respected, this amounting to a substantial procedural violation which should lead to the appeal fee being reimbursed.

IX. The appellant's final requests were that the decision under appeal be set aside, that the case be remitted to the examining division for further prosecution on the basis of the request filed during the oral proceedings and that the appeal fee be reimbursed.

Reasons for the Decision

Right to priority - Article 87 EPC/
Inventive step - Article 56 EPC

1. The claim request considered in the decision under appeal and that presently pending differ in that all references to "*A conjugate comprising the isolated antigen binding fragment [...] and a molecule selected from the group consisting of an enzyme, a cytotoxic agent or and apoptosis inducer*" have been deleted from the claims.

2. Only this subject-matter was objected to as lacking the right to priority and consequently was found to lack an inventive step. Since this subject-matter is not present in the claims of the claim request, the reasons of the appealed decision supporting the objection for

lack of inventive step no longer apply. Hence, the appeal is allowable.

Request for reimbursement of the appeal fee - Rule 103(1)(a) EPC

3. Rule 103(1)(a) EPC stipulates that the appeal fee shall be reimbursed in full where the Board of Appeal deems an appeal to be allowable, if such reimbursement is equitable by reason of a substantial procedural violation.

4. The prerequisite that the appeal be allowable is met.

5. Pursuant to the provisions of Article 113(1) EPC, that concern the right to be heard, "*the decisions of the European Patent Office may only be based on grounds or evidence on which the parties concerned have had an opportunity to present their comments*". The "*grounds or evidence*" are to be understood as meaning the essential legal and factual reasoning on which the EPO has based its decision. This right encompasses the parties being given an opportunity to comment on the material facts of the case relevant to the decision and therefore to the outcome of the case. Non-compliance with Article 113(1) EPC may amount to a substantial procedural violation and thus may require the reimbursement of the appeal fee pursuant to Rule 67 EPC (cf. for example decision T 411/04 of 15 June 2007, point 5 of the reasons).

6. In the present case, the appellant has argued that the examining division committed a substantial procedural violation by depriving it of its right to be heard in failing to cite a document to substantiate what it considered common general knowledge. This failure was

said to put the appellant into a position in which it did not know what the common general knowledge actually was and therefore meant that it was not possible to properly defend the application.

7. On the issue of inventive step, the minutes of the oral proceedings before the examining division contain the following statements:

"*The ED further objected that since the priority document does not disclose conjugates with an enzyme, a cytotoxic agent or an apoptosis inducer, claims 4, 6 and 7 could not be considered inventive in view of D1*" (point 38).

"*The R did not dispute the lack of priority but argued that D1 does not teach or suggest any of these conjugates and that the reference of the use of the antibody for therapy refers to the antibody itself, not conjugates thereof. The R further stated that the ED should provide another document to combine with D1 for the inventive step objection*" (point 39).

"*After the break, the ED explained that it considered the MR as not meeting the requirements of Article 56 EPC because claims 4 and 6-8 could not be considered inventive in view of D1, which already discloses drug delivery in the abstract and on page 166, right column*" (point 41).

8. These statements satisfy the board that the examining division had explained to the appellant the "*legal and factual reasoning*" on which its decision of lack of inventive step was based.

9. It is evident from the minutes of the oral proceedings (see point 41) that the examining division explained to the appellant why it considered document D1 to be relevant in its consideration of obviousness stating, "*After the break, the ED explained that it considered the MR as not meeting the requirements of Article 56 EPC because claims 4 and 6-8 could not be considered inventive in view of D1, which already discloses drug delivery in the abstract and on page 166, right column*".

10. Turning to the decision under appeal, in points 14 to 16 (section II, above) the subject-matter of claim 4 was considered to have been obvious to the person skilled in the art in view of the disclosure of document D1 alone. Document D1 disclosed a single domain antibody (AFAI) comprising the same CDRs recited in claim 1. The antibodies of claim 4 differed from those disclosed in document D1 in that the AFAI single domain antibody was conjugated to one of an enzyme, a cytotoxic agent or an apoptosis inducer. Such conjugation was said to be a "*straightforward alternative*". The examining division regarded said conjugation of an antibody to a an enzyme, a cytotoxic agent or an apoptosis inducer as one of the straightforward technical options which the skilled person, aware of the teaching of D1, would have selected without requiring the use of inventive skill.

11. Thus, not only did the examining division take the appellant's arguments regarding the common general knowledge (point 7, above) into account but it also gave reasons for finding of lack of inventive step independent of the prior general knowledge (point 10, above). It is true that in point 19 of the decision under appeal (section II, above), the examining

division when answering the appellant's arguments referred to the prior art in these terms: "*The examining division takes the view that the use of said molecules attached to cancer specific antibodies to form conjugate suitable for use in the diagnosis or treatment is part of common technical general knowledge and thus the disclosure of D1 need not be combined with another prior art document to support the lack of inventive step*". However this remark was in response to the appellant's arguments and has no bearing on the reason given earlier in the decision that D1 alone deprived the claimed subject-matter of inventive step.

12. Even if the examining division's reasoning was not to the appellant's satisfaction or if it was incorrect in its assessment of the closest prior art, such a lapse would constitute a substantive issue, but not a procedural error, let alone a substantial one (see decisions T 367/91 of 14 December 1992, Reasons 7 and T 890/02 of 14 October 2004, Reasons 34).

13. In summary, the alleged deficiency of not providing any evidence of the common general knowledge has no causal link on the outcome of the decision (point 10, above) and the appellant's arguments were taken into consideration but not accepted by the examining division (point 11, above). The appellant's objections to this pertain to the merits of the case rather than to the right to be heard (point 12, above).

14. Consequently, the procedure before the examining division complied with the requirements of Article 113(1) EPC. In the absence of a substantial procedural violation, the request for reimbursement of the appeal fee cannot be allowed.

Remittal - Article 111(1) EPC

15. The decision under appeal only gave reasons as to why the subject-matter of the then pending claims 4 and 6 to 8 was not allowable for reason of lack inventive step pursuant to Article 56 EPC and did not come to a decision on whether any of the other pending claims met the requirements of this article, nor whether any claim met any other provision of the EPC. The board therefore deems it appropriate to exercise its power under Article 111(1) EPC and to remit the case to the examining division for further examination of whether the amended claims comply with the requirements of the EPC.

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 for further prosecution.

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

The Registrar: The Chairwoman:

P. Cremona G. Alt

Decision electronically authenticated