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Case Number: T 1815/06 - 3.3.04

Application Number: 01910476.9

Publication Number: 1263788

IPC: C07K 14/715

Language of the proceedings: EN

Title of invention:
Identification of a domain in the tumor necrosis factor receptor family that mediates pre-ligand receptor assembly and function

Applicant:
The Government of the United States of America, as represented by the Secretary, Department of Health and Human Services

Headword:
Pre-ligand association domain/THE GOVERNMENT OF THE UNITED STATES

Relevant legal provisions:
EPC Art. 83, 84, 123(2)

Keyword:
"Main request - reasons for refusal overcome - yes"

Decisions cited:
-

Catchword:
-

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Case Number: T 1815/06 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 1 July 2009

Appellant: The Government of the United States of America, as represented by the Secretary, Department of Health and Human Services
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 12 July 2006 refusing European patent application No. 01910476.9 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chair: U. Kinkeldey
Members: G. Alt
D. S. Rogers

Summary of Facts and Submissions

I. This is an appeal against the decision of the examining division to refuse the European patent application No. 01 910 476.9. The application has the title "Identification of a novel domain in the tumor necrosis factor receptor family that mediates pre-ligand receptor assembly and function".

II. The decision of the examining division was based on a main and an auxiliary request.

Claims 1, 5, 6 and 19 of the main request read:

"1. A polypeptide, comprising the isolated amino acid sequence of a pre-ligand assembly domain (PLAD) of p60 or p80, wherein the polypeptide is R_1-TNF p60 PLAD-R_2 or R_1-TNF p80 PLAD-R_2 and wherein R_1 and R_2 are H, acyl, NH_2 or a peptide of 2-25 amino acids in length.

5. A polypeptide comprising the isolated amino acid sequence of a pre-ligand assembly domain (PLAD) of a TNF-like receptor, wherein the polypeptide is R_1-p60 PLAD-R_2 or R_1-p80 PLAD-R_2 and wherein R_1 and R_2 comprise an amino acid sequence that does not flank the TNF-like receptor PLAD in a naturally occurring TNF-like receptor.

6. The polypeptide of claim 5, wherein R_1 or R_2 or both are peptide sequences from another TNF-like receptor.

19. A composition comprising an inhibitor of p60 PLAD association or an inhibitor of p80 PLAD association."

III. The examining division refused the main request for non-compliance with the requirements of Articles 83, 84 and 123(2) EPC.

IV. The reasons for refusal were as follows:

The examining division considered that claim 1 was not clear because the term "PLAD" had no well-recognized meaning in the art and there were no technical features of "PLAD" provided in the claim. Also the description could not add any clarification since two contradicting definitions for "PLAD" were given therein.

Moreover, the examining division found that the subject-matter of claim 1 did not fulfil the requirements of Article 83 EPC since "neither the application nor common general knowledge allow the skilled practitioner to identify PLAD of p60 and p80".

The examining division also held that claim 1 did not fulfil the requirements of Article 123(2) EPC because an indication of the total length of the peptide was missing from the claim.

Furthermore, the examining division was of the opinion that in claim 5 the phrase "does not flank the TNF-like receptor PLAD in a naturally occurring TNF-like receptor" was unclear because it was not clear "which technical features, ie which sequence, correspond, to said term".

In claim 19 the term "inhibitor" was objected to under Article 84 EPC and with reference to the Guidelines chapter C-III, 4.7 because the term was not defined by

clear and unambiguous technical features, but by the result to be achieved.

Finally, the examining division considered that the subject-matter of the claim 19, a composition comprising an inhibitor of p60 or p80 PLAD association was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art because "the only compound which is disclosed to be effective is an antibody that specifically binds to the PLAD of p60 or p80, i.e. the subject-matter of amended claim 20".

V. The auxiliary request was refused pursuant to Article 113(1) EPC because the appellant did not agree to its text.

VI. With the statement of the grounds of appeal the appellant filed a new main, and with a further letter, a new auxiliary request. Both requests were withdrawn at the oral proceedings which took place on 1 July 2009 and were replaced by a new and sole main request.

Claims 1, 4, 5 and 14 of this request read:

"1. A polypeptide having at least 50 amino acids, comprising an isolated amino acid sequence of p60 or p80, wherein the polypeptide has the sequence R_1-[CPQGKYIHPQNNSICCTKCHKGTYLYNDCPGPGQDTDC]-R_2 or R_1-[CRLREYYDQTAQMCCSKCSPGQHAKVFCTKTSDTVC]-R_2, respectively, or a modification thereof not altering the function of the polypeptide, and wherein R_1 and R_2 are H, acyl, NH_2, or a peptide of 1-25 amino acids in length.

4. A polypeptide comprising the isolated amino acid sequence of a TNF-like receptor, wherein the polypeptide is R_1-[CPQGKYIHPQNNSICCTKCHKGTYLYNDCPGPGQDTDC]-R_2 or R_1-[CRLREYYDQTAQMCCSKCSPGQHAKVFCTKTSDTVC]-R_2, wherein R_1 and R_2 are amino acid sequences and wherein R_1 or R_2 are full or partial sequences that normally flank this sequence in a naturally occurring TNF-like receptor.

5. The polypeptide of claim 4, wherein R_1 or R_2 are peptide sequences from another TNF-like receptor.

14. A composition comprising an inhibitor of p60 PLAD association or an inhibitor of p80 PLAD association, such inhibitor being selected from an antibody that specifically binds to the PLAD of p60 or p80, respectively, a ligand that binds to the PLAD of p60 or p80, respectively, a polypeptide that binds to the PLAD of p60 or p80, respectively, or a peptide mimetic based on the PLAD of p60 or p80, respectively."

VII. The appellant requested that the decision of the examining division be set aside and that a patent be granted in the version of claims 1-17 of the main request submitted at the oral proceedings.

VIII. At the end of the oral proceedings the board announced its decision.

IX. The appellant has argued in essence as follows:

Instead of referring to "PLAD", the polypeptide of claim 1 was now defined by an amino acid sequence. This

was an unambiguous definition and moreover related to subject-matter that was disclosed in a manner sufficiently clear and complete for it to be carried out by the skilled person. Also the maximum overall length of the polypeptide was within the range disclosed in the application. Hence, claim 1 fulfilled the requirements of Articles 83, 84, 123(2) EPC.

The expression objected to by the examining division in former claim 5 "that does not flank the TNF-like receptor PLAD in a naturally occurring receptor" had been replaced in the corresponding claim 4 by the expression "that normally flank this sequence in a naturally occurring TNF-like receptor". This expression was clear, since TNF-like receptors and their amino acid sequences were well-known.

The term "inhibitor" in claim 14 was clear because it was qualified by references to classes of compounds. Since the classes of compounds were well-known to the skilled person, the requirements of Article 83 were also fulfilled.

Reasons for the decision

Claim 1

Articles 83, 84 (clarity) and 123(2) EPC

1. The polypeptide according to present claim 1 is no longer defined by reference to "TNF-p60 PLAD" or "TNF-p80 PLAD" as in claim 1 which was before the examining division (see section II above). Instead, the

polypeptide is defined in that it has a defined sequence of thirty eight and thirty six amino acids, respectively (see section VI above) or modifications of that amino acid sequence that do not alter the function of the entire polypeptide (for a basis see page 13, lines 5 and 6 and lines 26 to 29). According to claim 1 the specific sequences are flanked by residues R_1 and R_2 which may by either H, acyl, NH_2 or any peptide having from 1 to 25 amino acids. Moreover, the polypeptide is defined by its length. The minimum length being 50 amino acids, this means that at least one of R_1 and R_2 must have the feature that it is "a peptide having 1-25 amino acids". The maximum number of amino acid residues results from the sum of amino acids of either of the indicated specific sequences with both R_1 and R_2 being twenty five amino acids. Finally, it is also stated that the so defined polypeptide comprises an amino acid sequence of p60 or p80. Thus, in the board's view, the meaning of the claim is clear per se. Moreover, since the polypeptide is now defined by structural features only and not by functional features, which functional features are described in the specification, the specification does not make the claim unclear. Therefore, this reason of the examining division for refusing claim 1 is no longer valid (see section IV above).

2. The description discloses techniques for obtaining the claimed polypeptides, for example by protein chemistry techniques (pages 14 and 15) or by synthesising DNA and expressing it in a suitable host (pages 20 to 26). Therefore, the disclosure in the application is clear and complete so that the subject-matter of claim 1 can be carried out by the person skilled in the art.

3. Finally, it is an easy calculation from the features of the claim that the entire length of the polypeptide is between fifty and eighty-eight (for a polypeptide with the amino acid sequence first mentioned in the claim and if R_1 and R_2 are each a peptide having 25 amino acids) or between fifty and eighty-six amino acids (for the a polypeptide with the second amino acid sequence in the claim and if R_1 and R_2 are each a peptide having 25 amino acids). Polypeptides having this length are disclosed in the description. It is stated for example on page 12, lines 6 and 7 that "R_1 and/or R_2 can be 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25 or more amino acids in length".

Claim 4

Article 84 (clarity) EPC

4. The expression objected to by the examining division in claim 5 before them "that does not flank the TNF-like receptor PLAD in a naturally occurring receptor" is in present claim 4 replaced by the expression "wherein R_1 and R_2 are amino acid sequences and wherein R_1 or R_2 are full or partial sequences that normally flank this sequence in a naturally occurring TNF-like receptor" in present claim 4 (for a basis in the application see page 12, lines 18-20). This feature is clear since TNF-like receptors and their amino acid sequences are known (see for example in the application page 2, lines 10-19, page 30, lines 15 to 20 and page 57).

Claim 5

5. Claim 5 relates to a polypeptide where "R_1 or R_2 are peptide sequences from another TNF-like receptor", i.e. from a receptor which is not the receptor from which the specific sequence indicated in claim 4 stems from. The meaning of this claim is thus clear.

Claim 14

Articles 83 and 84 (clarity) EPC

6. Claim 14 relates to "[a] composition comprising an inhibitor of p60 PLAD association or an inhibitor of p80 PLAD association, such inhibitor being selected from an antibody that specifically binds to the PLAD of p60 or p80, respectively, a ligand that binds to the PLAD of p60 or p80, respectively, a polypeptide that binds to the PLAD of p60 or p80, respectively, or a peptide mimetic based on the PLAD of p60 or p80, respectively."

7. In the board's view, the meaning of the term "inhibitor" in claim 14 is clear as such, i.e. it refers to compounds inhibiting the association of the TNF receptor family via the pre-ligand association domain. In the claim the term "inhibitor" is additionally qualified and thereby the compounds to which it refers are limited (for a basis in the description see 29, lines 1 to 4). Also the meaning of these other terms in the claim is clear to the skilled person who understands that, for example, "a polypeptide that specifically binds to the PLAD of p60 or p80" is a polypeptide that binds to the pre-ligand

assembly domain of the TNF-like receptor p60 or p80. Thus, there is no lack of clarity in this respect.

8. The examining division has raised an objection of lack of sufficiency of disclosure with regard to the subject-matter of claim 19 (corresponding to present claim 14; see section VI above) on the basis that only one compound falling under the terms of the claims is disclosed in the application, i.e. an antibody.

8.1 With respect to this argument the board first notes that the requirement of sufficiency of disclosure is not judged on the basis of the examples alone, but that account has to be taken of the entire disclosure in the application and also of the skilled person's common general knowledge (Case Law of the Boards of Appeal of the European Patent Office, 5th edition, II.A.3, third paragraph). Thus, the presence of only one example in an application is per se not a reason for denying sufficiency of disclosure. Second, if there are doubts with regard to the sufficiency of disclosure, this must be substantiated by evidence (Case Law of the Boards of Appeal of the European Patent Office, 5th edition, II.A.5.1, 6th paragraph). Thus, for an objection of lack of sufficiency to be successful in the present case there should be evidence, for example, that compounds structurally falling under the terms of the claim do not have the indicated function or that compounds having the indicated function could not be obtained in a straightforward manner. However, there is no such evidence on file.

9. It follows from the above that the amended claims of the main request overcome the objections that were the reason for the refusal. Therefore, the examination can proceed on the basis of these claims.

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 for further prosecution upon the basis of claims 1 - 17 of the main request submitted during the oral proceedings.

The Registrar: The Chair:

P. Cremona U. Kinkeldey