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Datasheet for the decision of 5 April 2011

Case Number: T 1834/09 - 3.3.08

Application Number: 98931285.5

Publication Number: 1032661

IPC: C12N 15/12

Language of the proceedings: EN

Title of invention:
Apo-2DcR

Applicant:
Genentech, Inc.

Headword:
Apo-2DcR/GENENTECH

Relevant legal provisions:
EPC Art. 54(3), 87(1)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Main first and second auxiliary requests: entitlement to priority date (no)"
"Novelty (no)"

Decisions cited:
G 0002/98, T 0081/87, T 0077/97

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1834/09 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 5 April 2011

Appellant: Genentech, Inc.
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Representative: Kiddle, Simon John
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 27 April 2009 refusing European application No. 98931285.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: M. Wieser
Members: T. J. H. Mennessier
J. Geschwind

Summary of Facts and Submissions

I. The applicant (appellant) lodged an appeal against the decision of the examining division dated 27 April 2009, whereby European patent application No. 98 931 285.5 was refused. The application, entitled "Apo-2DcR", originated from an international application filed on 12 June 1998 and published as WO 98/58062. It claimed the priority date of 18 June 1997.

II. The decision was based on the set of claims 1 to 40 as identified in the letter of 15 February 2007. The refusal was decided for reasons of insufficiency of disclosure (Article 83 EPC in connection with Rule 31(2)(a) EPC), presence of added matter (Article 123(2) EPC), and lack of novelty (Article 54(3) EPC).

III. On 6 August 2009, the appellant filed a statement setting out the grounds of appeal which was accompanied by a new main request (claims 1 to 38), a first auxiliary request (claims 1 to 38) and a second auxiliary request (claims 1 to 26).

IV. The main request corresponded to the request refused by the examining division with changes to the dependency of the claims (see claims 15, 35 and 36) and the deletion of claims 37 and 38.

V. The first auxiliary request differed from the main request in that claims 22 to 27 and 29 to 34 had been amended. In the second auxiliary request these claims had been deleted.

VI. Claim 1 of each of the three requests read as follows:

"1. Isolated Apo-2DcR polypeptide having at least about 80% amino acid sequence identity with native sequence Apo-2DcR polypeptide comprising amino acid residues 1 to 259 of Fig. 1A (SEQ ID NO:1)."

VII. The examining division did not rectify its decision and referred the appeal to the board of appeal (Article 109 EPC).

VIII. On 8 December 2010, in an annex to the summons to oral proceedings issued under Article 15(1) of the Rules of Procedure of the Boards of Appeal, the board sent a communication containing its provisional and non-binding opinion on a number of issues. Amongst others the board expressed the view that the subject-matter of claim 1 of all requests on file was not new inter alia over D4, a document cited under Article 54(3) EPC.

IX. As announced in its letter of 7 March 2011, the appellant did not attend the oral proceedings which took place as scheduled on 5 April 2011.

X. The following document is referred to in the present decision:

(D4) WO 98/30693 (filed on 13 January 1998 and published on 16 July 1998; claiming the priority dates of 14 January 1997 and 7 August 1997).

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

Document D4 was not entitled to rely on its earliest priority date for two reasons.

First, for an invention relating to newly identified members of a protein family which was known to have a highly divergent range of biological activities, such as the TNRF superfamily to which the polypeptide of document D4 belonged, it was necessary to provide in the priority document a credible disclosure of an exploitable specific function or activity. This position was supported by decisions T 81/87 (OJ EPO 1990, 250) and T 77/97 of 3 July 1997. The earliest priority document of document D4 failed to disclose such a function.

Second, the failure to identify a specific function or activity of a protein in a previous application in a scientifically credible manner had the consequence that it was not possible to take advantage of the priority of that application as it did not disclose the industrial applicability of the protein as required by Article 57 EPC.

Since it was not entitled to its earliest priority date, document D4 was not relevant for the novelty assessment of the claimed polypeptide.

XII. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request or, in the alternative, on the basis

of one of the first and second auxiliary requests, all filed together with the statement of grounds of appeal on 6 August 2009.

Reasons for the Decision

Main request

1. Claim 1 is directed to any polypeptide characterised by having about 80% amino acid sequence identity with the native sequence Apo-2DcR polypeptide comprising amino acid residues 1 to 259 of Figure 1A as represented in SEQ ID NO:1. This sequence identity is the sole essential feature which is required for a polypeptide to fall within the scope of the claim. Claim 1 encompasses a polypeptide consisting of the sequence SEQ ID NO:1.

2. The examining division, finding that document D4 disclosed that particular polypeptide, concluded that claim 1 was not new. D4, which is a Euro-PCT application published after the international filing date of the application at issue, claims the priority dates of 14 January 1997 and 7 August 1997. It was cited under Article 54(3) EPC.

3. The appellant has argued that document D4 and its earliest priority document (application US 60/035,496 filed on 14 January 1997) did not describe the 'same invention', as a specific function of the polypeptide disclosed has been identified only in document D4. Therefore, document D4 was not entitled to claim priority from its earliest priority document. As the

application at issue was entitled to its priority date of 28 June 1997, document D4 did not belong to the state of the art for the novelty assessment of the subject-matter of claim 1.

4. The legal standard to be applied when assessing whether a claim is entitled to a priority date pursuant to Article 87(1) EPC is given by decision G 2/98 (OJ EPO 2001, 413; see the Conclusion) in the answer to the point of law referred to the Enlarged Board of Appeal which reads: "*The requirement for claiming priority of "the same invention", referred to in Article 87(1) EPC, means that priority of a previous application in respect of a claim of a European patent application in accordance with Article 88 EPC is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge from the previous application as a whole*".

5. The respective descriptions of document D4 and its earliest priority document (application US 60/035,496) are very similar, insofar as the polypeptide in question (denoted "TRID" in document D4 and "TNFR-5" in the priority document) and all aspects related thereto, including its preparation and its therapeutical uses, are concerned. The descriptions differ insofar as three experimental examples (Example 4 showing the tissue distribution of TRID mRNA expression, Example 5 showing that the extracellular domain of TRID binds the cytotoxic ligand-TRAIL and blocks TRAIL-induced apoptosis, and Example 6 showing that TRID protects cells from TRAIL-induced apostosis) have been added in document D4.

6. The earliest priority document of document D4 teaches that the TRID/TNRF-5 polypeptide is capable of interacting with a TNF-family ligand, i.e. a potent inducer of apoptosis, a function which qualifies said polypeptide as an appropriate compound for the treatment of immune system-related disorders associated with increased apoptosis or the inhibition of apoptosis (see pages 50 to 56 of the earliest priority document which correspond to pages 31 to 36 of document D4).

7. It has to be decided whether this teaching, which is not supported by experimental data, amounts to a credible disclosure rather than a pure speculation.

8. A significant statement in this respect can be found on page 4, lines 20 to 24, of the earliest priority document. There, it is stated that the TNFR-5 polypeptide shares sequence homology with other TNF receptors and that it shows the highest degree of sequence homology with the translation product for the human mRNA for nerve growth factor receptor, including multiple conserved cysteine rich domains.

9. According to a well established principle in the field of biology, an identified DNA sequence and the putative encoded protein are assigned to a known protein family or superfamily on the basis of sequence comparison - such as by degree of homology, the presence of highly conserved domains, motifs and/or signatures. Thus, once an unambiguous consensus sequence has been defined, the skilled person is prepared to accept that a peptide belongs to the family/superfamily, and performs the

same or similar biological function(s) as the other members thereof, if it exhibits this consensus sequence.

10. The board takes the view that the sequence homology disclosed in the earliest priority document of document D4 has to be considered as being a strong and reliable indication that the TNRF-5 polypeptide is capable of interacting with a member of the TNF ligand family. This is regarded as being a clear sign that the TNRF-5 polypeptide is useful in the treatment of a number of immune system-related disorders associated with increased apoptosis or the inhibition of apoptosis and is, therefore, susceptible of industrial application.

11. Appellant's argument that such prediction of a biological function or property based solely on sequence analysis and on the mere presence of a particular domain or motif in a polypeptide sequence cannot reasonably be made in case of the TNFR superfamily has not been substantiated by any sort of written evidence, and is to be considered as an unproven allegation only.

12. Based on the evidence on file, the board does not agree that the earliest priority document (US 60/035,496) and document D4 do not describe the 'same invention' in that only the latter discloses a specific function of the polypeptide in question.

13. The two decisions cited by the appellant in support of its position that document D4 was not entitled to its earliest priority date are not relevant for the present case as they were concerned with different technical situations. In decision T 77/97 (see *supra*) the

competent board had to decide whether claims referring to compounds not explicitly described in the priority document were entitled to the priority date, and in the case underlying decision T 81/87 (see *supra*) the decisive question to be answered was whether the priority documents disclosed all the 'critical' features of the claimed invention.

14. The board concludes that the 'same invention' (in accordance with decision G 2/98 (see *supra*)) is described in document D4 and its earliest priority document. Therefore, document D4 is entitled to the priority date of 14 January 1997 pursuant to Article 87(1) EPC and, as such, is part of the state of the art according to Article 54(3) EPC.

15. The sequence of the TRID polypeptide (identically contained as SEQ ID NO:2 in both document D4 and its earliest priority document) and the sequence of the Apo-2DcR polypeptide (see SEQ ID NO:1 of the application at issue) are identical. This fact is not contested by the appellant.

16. Therefore, a particular embodiment of claim 1 is explicitly disclosed in document D4. Thus, the subject-matter of claim 1 lacks novelty and the main request does not comply with the requirements of Article 54 EPC.

First and second auxiliary requests

17. As claim 1 of each of the first and second auxiliary requests is identical to claim 1 of the main request, the board concludes that, for the reasons explained at

points 1 to 16 above, also said requests do not comply with Article 54 EPC.

Other substantive issues

18. As already for reasons of non-compliance with Article 54 EPC none of the requests on file can be accepted, there is no need to examine the other grounds on which the examining division based its refusal.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar The Chairman

A. Wolinski M. Wieser