DECISION
of 7 February 2006

Case Number: T 0070/05 - 3.3.08
Application Number: 97917736.7
Publication Number: 0904366
IPC: C12N 15/12
Language of the proceedings: EN
Title of invention:
APO-2LI and APO-3 apoptosis polypeptides
Applicant:
GENENTECH, INC.
Opponent: -
Headword:
Apoptosis receptors /GENENTECH
Relevant legal provisions:
EPC Art. 54(3)(4), 123(2)
Keyword:
"Added subject-matter (no)"
"Novelty (yes) - intermediate document not entitled to priority"
Decisions cited:
G 0002/98, T 0081/87, T 0077/97, T 1127/00
Catchword:
-
Case Number: T 0070/05 - 3.3.08

DECISION of the Technical Board of Appeal 3.3.08 of 7 February 2006

Appellant: GENENTECH, INC.
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Decision under appeal: Decision of the Examining Division of the European Patent Office posted 16 August 2004 refusing European application No. 97917736.7 pursuant to Article 97(1) EPC.

Composition of the Board:
Chairman: L. Galligani
Members: P. Julià
          C. Rennie-Smith
Summary of Facts and Submissions

I. On 18 October 2004, the applicant (appellant) lodged an appeal against the decision of the examining division dated 16 August 2004 whereby the European patent application No. 97 917 736.7 was refused pursuant to Article 97(1) EPC. The European patent application originated from an international application published as WO 97/37020 (referred to in the present decision as "the application as filed") with the title "Apo-2LI and Apo-3 apoptosis polypeptides" and claiming the priorities of US 08/625,328 (1 April 1996) and of US 08/710,802 (23 September 1996).

II. As grounds for the refusal the decision under appeal stated that the request then on file, which contained 21 claims, lacked novelty (Article 54(3),(4) EPC) over document WO 97/33904 (D1) as far as this latter enjoyed priority rights from the document US 60/013,285 (D1a) (12 March 1996).

The examining division referred to decision G 2/98 (OJ EPO 2001, 413) as equating the term "the same invention" with "the same subject matter" and considered that under Article 54(3) EPC the priority document had to be assessed only for novelty but not for other requirements, such as for instance that in Article 57 EPC, which had been invoked by the applicant. However, for novelty purposes, it was established case law that the disclosure of the prior art or, as in the present case, the priority document had to be enabling.

Document D1a disclosed a DNA sequence encoding a death domain containing receptor (DDCR) with a specific amino
acid sequence shown in Figure 1, wherein residues 25 to 428 matched the residues 14 to 417 of the SEQ ID NO: 6 of the Apo-3 receptor of the application. Document D1a also disclosed the ligand binding domain of the DDCR receptor as an extracellular fragment from residues 30 to 215 in Figure 1, which was substantially identical to that covered by the claims in issue. This technical information was sufficiently clear and complete to put the skilled person in a position to express and isolate the indicated products.

The examining division considered, however, that document D1a did not disclose the claimed uses of the DDCR receptor in a manner sufficiently clear and complete to be carried out, since they were speculative and based only on the characterization of the DDCR receptor as a member of the TNF receptor superfamily.

III. On 23 December 2004, the appellant filed a statement of grounds of appeal.

IV. The examining division did not rectify its decision and remitted the appeal to the board of appeal under Article 109(2) EPC.

V. On 27 September 2005, the board sent a communication pursuant to Article 11(1) of the Rules of Procedure of the Boards of Appeal (RPBA) indicating its preliminary, non-binding opinion.

VI. In reply to the board's communication, the appellant filed further observations on 6 January 2006.
VII. Oral proceedings took place on 7 February 2006 during which the appellant filed a new claim request, which contained 19 claims and differed from the request before the examining division essentially by the deletion of two claims and of part of the claimed subject-matter and, where appropriate, by change or amendment of claim dependencies. Independent claims 1, 5, 6, 10 and 14 read as follows:

"1. An isolated polypeptide having at least 80% sequence identity with the polypeptide consisting of amino acid residues 1 to 181 of SEQ ID NO: 1 and having the biological activity of inhibiting apoptosis in at least one type of mammalian cell in vivo or in vitro."

"5. An isolated polypeptide consisting of amino acid residues 1 to 181 of SEQ ID NO: 1."

"6. An isolated polypeptide having at least 80% sequence identity with the polypeptide consisting of amino acid residues 1 to 417 of SEQ ID NO: 6 and having the biological activity of inducing apoptosis in at least one type of mammalian cell in vivo or in vitro."

"10. An isolated polypeptide comprising amino acid residues 25 to 417 of SEQ ID NO: 6."

"14. An isolated polypeptide consisting of amino acid residues 1 to 198 of SEQ ID NO: 6."

Claims 2 to 4 were dependent on claim 1 and further defined the degree of sequence identity (90%, 95%) and the presence of one or more cysteine rich domains. Claims 7 to 9 defined further embodiments of claim 6.
Claims 11 to 13 further defined the subject-matter of claim 10. Claims 15 to 19 were, respectively, directed to an isolated nucleic acid encoding any one of the polypeptides of claims 1 to 14, a vector comprising said nucleic acid, a host cell comprising said vector and a method of producing these polypeptides comprising culturing those host cells and recovering the polypeptides from the host cell culture.

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

D1: WO 97/33904 (filing date: 17 October 1996),

D1a: US 60/013,285 (filing date: 12 March 1996), priority of document D1,

P1: US 08/625,328 (filing date: 1 April 1996), first priority of the present application,

P2: US 08/710,802 (filing date: 23 September 1996), second priority of the present application.

IX. The appellant's arguments, insofar as they are relevant to the present decision, may be summarised as follows:

Article 123(2) EPC

Basis for the claimed subject-matter in the application as filed was found, in particular on pages 5, 7 to 8, 11 and 37 as well as in claims 1 to 4, 19 to 27 and 34 to 39 of the application as filed.
Article 54(3)(4) EPC

The claimed subject-matter enjoyed priority rights from the first priority document P1 or from the second priority document P2. Since the filing dates of both priority documents were earlier than the filing date of document D1, which for the same subject-matter was not entitled to the claimed priority from document D1a, the claimed subject-matter was novel.

The appellant referred to the differences between the sequences of the DDCR and the DR3-V1 receptors disclosed, respectively, in documents D1a and D1, while at the same time arguing that there was no disclosure of a credible biological function for the DDCR receptor in the priority document D1a.

Although document D1 disclosed the nucleotide and amino acid sequences of the DR3 and DR3-V1 receptors, only the latter receptor was disclosed in document D1a (referred to therein as DDCR). Thus, only subject-matter relating to the DR3-V1/DDCR receptor was relevant for the assessment of novelty. For the latter, which the examining division considered to be disclosed in an enabling manner, document D1a did not contain any data providing a credible functional characterization, i.e. it did not support any disclosure that needed to be taken into account under Article 54(3) EPC.

Document D1a identified only an open reading frame in a nucleic acid sequence which was said to encode the DDCR receptor, a new member of the TNFR superfamily. This was a mere piece of sequence structure information, not an actual characterization of the DDCR receptor. With
only this information and, in the light of the divergent biological properties of the TNFR superfamily members, the skilled person could not reasonably predict what the DDCR receptor could be used for. The mere presence of a death domain in a newly identified TNFR superfamily member was not indicative of any specific biological activity, since additional information derived from actual experimental testing was required. Document D1a itself referred to this TNFR superfamily as varied and influencing numerous biological functions both normal and abnormal, apoptosis being mentioned therein as just one of a whole variety of possible functions that the DDCR receptor could exhibit but without any experimental determination supporting this assertion. Thus, document D1a did not provide an enabling disclosure of the DDCR receptor nor did it identify a credible specific activity possessed by this receptor.

According to the established case law, in the absence of a disclosure of an essential element in the priority document, priority cannot be validly claimed. Gaps with regard to essential elements cannot be retrospectively filled by relying on knowledge not disclosed and only acquired later (cf. inter alia T 81/87, OJ EPO 1990, page 250 and T 77/97 of 3 July 1997). In the present case, the expression of the DDCR receptor and its actual characterization (i.e. isolation and biological activity) were such missing elements, which could not be added later. This failure implied also a failure to disclose an exploitable biological function of the DDCR receptor as well, which was an essential element of the invention. As stated in the case law (in particular decision T 77/97, supra), there was a distinction
between a purely intellectual content of a disclosure in a priority document and its actual teaching, the former being insufficient to provide a valid priority claim.

Thus, the disclosure of document D1 relating to the DR3-V1/DDCR receptor was not entitled to the claimed priority from document D1a, and consequently, the subject-matter claimed in the present request, which was entitled to priority from document P1 or from document P2, was novel.

X. The appellant (applicant) requested that the decision under appeal be set aside and that the case be remitted to the examining division for further prosecution on the basis of the set of claims filed during the oral proceedings.

Reasons for the Decision

Article 123(2) EPC

1. The examining division acknowledged that the set of claims then under consideration met the requirements of Article 123(2) EPC (cf. point 1 of the decision under appeal). The present set of claims is directly derivable from that before the examining division (cf. point VII supra). The appellant has indicated a basis in the application as filed for the amendments. The board is satisfied that the conditions of Article 123(2) EPC are complied with.
2. The key issue to be decided in the present case is whether the decision under appeal was correct in holding that document D1 is entitled to its claimed priority right from document D1a and, consequently, whether it is a prior art document under Article 54(3)(4) EPC that anticipates the subject-matter of the present application.

3. The criteria for assessing the right to priority have been laid down in the opinion of the Enlarged Board of Appeal G 2/98 (supra), which in point 9 of the Reasons for the Opinion states that "a narrow or strict interpretation of the concept of "the same invention", equating it to the concept of the "same subject-matter" referred to in Article 87(4) EPC ... is necessary to ensure a proper exercise of priority rights in full conformity inter alia with the principles of equal treatment of the applicant and third parties ... and legal certainty ... and with the requirement of consistency with regard to the assessment of novelty and inventive step". It is further stated "that priority of a previous application in respect of a claim in a European patent application in accordance with Article 88 EPC is to be acknowledged only if the person skilled in the art can derive the subject-matter of the claim directly and unambiguously using common general knowledge, from the previous application as a whole".

4. The criteria as defined in decision G 2/98 are to be applied both in assessing the right of document D1 to the claimed priority from document D1a and in assessing
whether the subject-matter of the request now under consideration is entitled to the claimed priority from documents P1 and P2. The same standard must apply both for the present application and for document D1.

5. Since the filing date of the present application (31 March 1997) is later than the filing date of document D1 (17 October 1996), the disclosure of document D1 - including subject-matter which is not entitled to the priority right from document D1a - may anticipate the subject-matter of the application that is not entitled to any priority right, i.e. neither from document P1 nor from document P2. Thus, the board deems it appropriate first to assess whether the request under consideration comprises subject-matter not entitled to the claimed priorities.

Entitlement of the request under consideration to the claimed priority date of documents P1 or P2

6. In the board's judgement, subject-matter related to an isolated "Apo-2 ligand inhibitor" (Apo-2LI) polypeptide consisting of amino acid residues 1 to 181 of SEQ ID NO: 1 and having the biological activity of inhibiting apoptosis in at least one type of mammalian cell in vivo or in vitro, i.e. the subject-matter of claims 1 to 5, as well as subject-matter related to an isolated nucleic acid encoding these polypeptides, i.e. the subject-matter of claims 15 to 19 as far as they are dependent on claims 1 to 5, is entitled to the first claimed priority date of document P1.

In fact, the first priority document P1 discloses in Figure 1 (SEQ ID NO: 1) the amino acid sequence of the
Apo-2LI polypeptide. Reference is made on page 9 of this document to this sequence and, as preferred embodiments, to biologically active variants having at least 90%, more preferably 95% sequence identity, and, optionally, to one or more cysteine-rich domains (cf. page 9, lines 8 to 24 and claims 1 to 4). Nucleic acids encoding the Apo-2LI polypeptides and related products (vectors, host cells) are also referred to in the description of document P1 (cf. inter alia page 11, line 5 to page 12, line 5, page 15, line 11 to page 32, line 13, page 54, examples and claims 17 to 20), including references to a signal sequence or pre-sequence of the Apo-2LI which directs its insertion in the membrane of human cells (cf. page 18, lines 6 to 9 and page 55, lines 30 to 32). A definition of the biological activity of these Apo-2LI polypeptides, namely the ability to reduce or inhibit apoptosis (cf. page 13, line 34 to page 14, line 11), as well as experimental demonstration of this activity is also found in document P1 (cf. pages 66 to 67, examples 10 and 11 and claim 23).

7. The board also considers that subject-matter related to an isolated Apo-3 polypeptide consisting of amino acid residues 1 to 417 of SEQ ID NO: 6 and having the biological activity of inducing apoptosis in at least one type of mammalian cell in vivo or in vitro, i.e. the subject-matter of claims 6 to 9, the corresponding mature Apo-3 polypeptide (residues 25 to 417 of SEQ ID NO: 6), i.e. the subject-matter of claims 10 to 13, or the extracellular domain consisting of residues 1 to 198 of SEQ ID NO: 6, i.e. the subject-matter of claim 14, as well as subject-matter related to an isolated nucleic acid encoding all these polypeptides,
i.e. the subject-matter of claims 15 to 19 as far as they are dependent on claims 6 to 14, is entitled to the second claimed priority date of document P2.

In fact, the second priority document P2 discloses in Figure 8 (SEQ ID NO: 10) the amino acid sequence of the Apo-3 polypeptide. Reference is made on page 12 of this document to the mature and the full-length native Apo-3 sequences and, as preferred embodiments, to biologically active variants having at least 90%, more preferably 95% sequence identity, and the possible presence of deletions of about one to 24 amino acid residues (including a single amino acid deletion at residue 236) (cf. page 12, lines 2 to 23 and claims 1 to 5). Document P2 further discloses an extracellular domain comprising residues 1 to 198 of Figure 8 (SEQ ID NO: 10) and a death domain comprising residues 338 to 417 of Figure 8 (SEQ ID NO: 10) (cf. inter alia page 7, lines 28 to 35, claims 6 to 7). Further domains are also identified, namely a signal sequence (residues 1-24), a transmembrane domain (residues 199-224) and an intracellular domain (residues 225-417) (cf. inter alia page 71, lines 6 to 10). Nucleic acids encoding the Apo-3 polypeptides and related products (vectors, host cells) are also referred to in the description of document P2 (cf. inter alia page 14, line 23 to page 15, line 21, page 18, line 24 to page 34, line 23, pages 70 to 77, examples 9 to 15 and claims 15 to 20), including a signal sequence or pre-sequence of the Apo-3 which directs its insertion in the membrane of human cells (cf. page 21, lines 2 to 4). A definition of the biological activity of these Apo-3 polypeptides, namely the ability to induce or stimulate apoptosis (cf. page 17, lines 14 to 26), as well as experimental
demonstration of this activity is also found in document P2 (cf. pages 72 to 75, examples 11 to 13). Document P2 also comprises the disclosure of the first priority document P1 as regards Apo-2LI referred to in point 6 supra and it clearly identifies the Apo-2LI polypeptides as specific fragments of the Apo-3 polypeptide (cf. page 71, lines 29 to 32).

In conclusion, whereas the subject-matter concerned with Apo-2L is entitled to the first claimed priority date of document P1 (1 April 1996), the subject-matter concerned with Apo-3 is entitled to the second claimed priority date of document P2 (23 September 1996).

8. Since all subject-matter of the request under consideration is entitled either to the first or the second claimed priority date - both earlier than the filing date of document D1 (17 October 1996), it is only the subject-matter of document D1 that is entitled to the priority date from document D1a which is relevant for the assessment of novelty.

The disclosure of document D1

9. Document D1 discloses two death-domain-containing receptors, namely the DR3-V1 (DR3 Variant 1) (Figure 1, SEQ ID NO: 1, 2) and the DR3 (Figure 2, SEQ ID NO: 3, 4) receptors, derived respectively from a human testis tumour cDNA library and a human HUVEC cDNA library. The amino acid sequences of these two receptors are identical except for their respective signal peptide which for DR3-V1 is predicted to consist of about residues 1-35 (Figure 1, SEQ ID NO: 2) and for DR3 of about residues 1-24 in Figure 2 (SEQ ID NO: 4), and
wherein residues 25-35 of DR3-V1 are identical to residues 14-24 of DR3 (cf. page 10, line 30 to page 11, line 14). Due to possible sequence errors and the known variability of cleavage sites, reference is made to a range of possible lengths for these signal sequences - in particular for DR3-V1 anywhere in the range of about 25 to about 45 (cf. page 11, lines 15 to 24).

10. Several domains of these receptors, DR3-V1 and DR3, are identified in document D1. In particular for DR3-V1 the ligand binding (extracellular) domain is identified within residues from about 36 to about 212, the transmembrane domain within residues from about 213 to about 235 and the intracellular domain within residues from about 236 to about 428, this latter domain including a death domain at residues from about 353 to about 419 (Figure 1, SEQ ID NO: 2) (cf. inter alia page 6, lines 15 to 19 and page 31, lines 18 to 25).

Reference is also made to fragments of these receptors, in particular fragments corresponding to the extracellular domains or to soluble polypeptides comprising all or part of the extracellular and intracellular domains but lacking the transmembrane domains (cf. inter alia page 30, lines 6 to 20, page 40, line 29 to page 41, line 5).

11. Based on the very specific nucleotide and amino acid sequences of these two receptors, document D1 refers to more generic products, such as polynucleotides hybridizing under stringent hybridization conditions to (a portion of) the disclosed nucleic acid sequences, allelic and non-naturally occurring variants which encode for fragments, analogs or derivatives of these receptors, isolated nucleic acid molecules or
polypeptides that are at least 90% identical to the disclosed sequences, etc. (cf. inter alia page 14, line 26 to page 15, line 25, page 16, lines 13 to page 20, line 14, page 28, line 11 to page 29, line 5, page 30, lines 15 to 20).

12. It is worth noting at this point that the amino acid sequence of the DR3 receptor disclosed in document D1 (Figure 2, SEQ ID NO: 4) corresponds exactly to the amino acid sequence of the Apo-3 receptor disclosed in the present application (Figure 4, SEQ ID NO: 6).

Entitlement of document D1 to the claimed priority date of document D1a

13. There is no reference to the DR3 receptor in the priority document D1a. The disclosure of document D1a relates only to DDCR (death-domain-containing receptor), which according to document D1 corresponds to the DR3-VR1 receptor (cf. page 4, line 22 and page 9, line 10 in document D1). However, the amino acid sequence of the DDCR receptor disclosed in document D1a is not identical to the amino acid sequence of the DR3-V1 receptor disclosed in document D1. The residues at positions 229, 232 to 240, 256 and 260 of the DDCR receptor in document D1a differ from the ones indicated in document D1 for the DR3-V1 receptor (cf. Figures 1 and SEQ ID NO: 1, 2 of documents D1 and D1a).

Thus, the specific full-length sequences of the DR3 and the DR3-V1 receptors of document D1 cannot enjoy priority from document D1a.
14. Document D1a also identifies several domains of the DDCR receptor, in particular the ligand-binding (extracellular) domain from about residue 30 to about 215, the transmembrane domain from about 215 to about 240 and the intracellular domain from about 240 to about 428, which includes the death domain from about 350 to about 420 (cf. page 11, lines 9 to 19). Although the definition of these DDCR domains is very similar to the one given in document D1 for the DR3-V1 domains, they are not strictly the same. In particular, the extracellular domain of the DR3-V1 receptor is identified as within residues from about 36 to about 212 (cf. point 10 supra), whereas the corresponding extracellular domain of the DDCR receptor is defined from about residue 30 to about residue 215.

Thus, in accordance with the "narrow or strict interpretation" laid down in decision G 2/98 (supra), the specific extracellular fragment of the DR3-V1 receptor as defined in document D1 cannot enjoy priority from document D1a.

15. It may be considered that the disclosure of document D1a relating to the extracellular domain of DDCR is not limited to a very specific extracellular fragment (from residue 30 to residue 215) but that it includes a group of possible DDCR extracellular fragments for which the exact location "may vary slightly (e.g.; the address may "shift" by 1 to 5 residues) depending on the criteria used to define the domain" (cf. page 11, lines 9 to 26). However, even in such a case the selection of the most appropriate lower limit of the range explicitly disclosed in document D1a (corresponding to the first residue of the DDCR
extracellular fragment), namely "residue 35", does not correspond to the specific one disclosed in document D1 for the DR3-V1 receptor, namely "residue 36".

16. Since in document D1 the length of the signal sequence of the DR3-V1 receptor is said to vary in the range of about 25 to about 45 amino acids (cf. page 11, lines 15 to 24), it may also be argued that the disclosure of document D1 is not limited to a specific extracellular fragment but that it discloses a group of possible DR3-V1 extracellular fragments for which the first residue might vary from about residue 26 to about residue 46 (the extracellular fragments extending further to about residue 212).

17. If only for the reason that, by the use of the word "about", the exact extent of both groups of DDCR and DR3-V1 extracellular fragments is left open-ended, it might also be envisaged that these two groups comprise a common subgroup of shared extracellular fragments. However, no matter its size (number of sequences) or importance, this subgroup of extracellular fragments is not disclosed as such in document D1a nor it is singled out as such in document D1. Moreover, precisely because of this open-ended formulation, the number of possible sequences belonging to this subgroup is clearly not limited. Nevertheless, the question arises whether such a subgroup of extracellular fragments in document D1 is entitled to claim priority from the corresponding subgroup in document D1a, even though the specific extracellular fragments and other possible subgroups - comprising non-shared sequences - do not enjoy such priority.
18. According to decision G 2/98 (supra), "the use of a generic term or formula in a claim for which multiple priorities are claimed ... is perfectly acceptable ... provided that it gives rise to the claiming of a limited number of clearly defined alternative subject-matters" (cf. point 6.7 of the Reasons for the Opinion). In the present case and for the reasons given above, the common subgroup is not clear by itself nor it is clearly limited in documents D1 or D1a. The fact that this common subgroup might be intellectually envisaged as falling within the disclosure of documents D1 and D1a does not in itself amount to a clear and unambiguous disclosure, i.e. individualized as such (cf. T 1127/00 of 16 December 2003, points 5 to 7 of the reasons). Nor can this common subgroup be derived directly and unambiguously as such from document D1a itself (cf. G 2/98, supra, point 9 of the Reasons).

Thus, in accordance with decision G 2/98 (supra), the generic extracellular fragments of the DR3-V1 receptor as defined in document D1 do not enjoy priority from document D1a.

19. A similar reasoning applies to the more generic products referred to in document D1, such as polynucleotides hybridizing under stringent hybridization conditions to (a portion of) the disclosed nucleic acid sequences, allelic and non-naturally occurring variants which encode fragments, etc. (cf. point 11 supra). The presence of a possible subgroup of generic products common to a corresponding subgroup in the priority document D1a - which is not, however, disclosed in document D1 nor in document D1a - cannot be an appropriate basis for acknowledging any
priority right. This criterion is also in line with the established case law of the Boards of Appeal for which the disclosure of a generic group in an earlier document does not entitle a specific member (in the present case a subgroup) of that generic group disclosed in a later application to priority from the earlier document (cf. "Case Law", supra, IV.B.1, page 236 and inter alia T 77/97 of 3 July 1997).

20. It is also the board's opinion that, based on a disclosure of a "wrong" nucleotide or amino acid sequence in the priority document - independently of the reasons for the possible mistakes, either arising from unintended sequencing or typing errors or else arising from a conscious choice to file an application at a very early stage and thus, comprising doubtful or incomplete data - it would not be fair to acquire a right over a broad area from which, only later on, the "correct" sequence might be selected and disclosed in a patent application. The possible advantages conferred by such a practice would only encourage and, in the long term, lead to a mischievous use of priority rights.

Thus, the board considers that the generic products of the DR3-V1 receptor as referred to in document D1 do not enjoy priority from document D1a.

21. In the present case and in view of the above considerations, it is not necessary for the board to enter into the merit of appellant's reasoning as regards the absence of a credible identification for an exploitable biological function or activity of the DDCR receptor in the priority document D1a (cf. Section IX supra).
Conclusion

22. Since document D1 does not contain any subject-matter entitled to the priority date of document D1a and all the subject-matter of the request under consideration enjoys earlier priority dates either from document P1 or document P2 (cf. points 6 to 8 supra), document D1 is not relevant for the assessment of novelty.

23. Since document D1 is the only document cited in the decision under appeal as anticipating the claimed subject-matter, novelty of this subject-matter is acknowledged.

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 on the basis of the set of claims filed during the oral proceedings.

The Registrar:    The Chairman:

A. Wolinski     L. Galligani