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D E C I S I O N
of 9 March 2005

Case Number: T 0010/01 - 3.3.8

Application Number: 85309454.8

Publication Number: 0187041

IPC: C12N 15/48

Language of the proceedings: EN

Title of invention:
Fusions of AIDS-related polypeptides

Patentee:
GENENTECH, INC.

Opponent:
Chiron Corporation

Headword:
AIDS polypeptides/GENENTECH

Relevant legal provisions:
EPC Art. 54, 123(2)

Keyword:
"Main request - novelty - no"
"First to third auxiliary requests - admissibility of
disclaimer - no"

Decisions cited:
G 0001/03

Catchword:
-



Case Number: T 0010/01 - 3.3.8

D E C I S I O N
of the Technical Board of Appeal 3.3.8
of 9 March 2005

Appellant: GENENTECH, INC.
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
25 October 2000 concerning maintenance of
European patent No. 0187041 in amended form.

Composition of the Board:

Chairman: L. Galligani
Members: F. L. Davison-Brunel
M. B. Günzel

Summary of Facts and Submissions

I. European patent No. 0 187 041 with the title "Fusions of AIDS-related polypeptides" was granted with 15 claims for the designated Contracting States BE, CH, DE, FR, GB, IT, LI, LU, NL, SE and 15 claims for AT on the basis of the European patent application No. 85 309 454.8, claiming priority from US 685272 of 24 December 1984 and US 805069 of 4 December 1985.

Granted claim 1 for all designated States except AT read as follows:

"1. A fusion polypeptide comprising (a) a first polypeptide sequence of an AIDS associated retrovirus E', env or gag polypeptide having at least one antigenic determinant capable of specifically binding complementary antibody and (b) a second polypeptide sequence which is not an AIDS associated virus polypeptide; wherein said E' polypeptide of AIDS-associated retrovirus is defined as the 206 residue polypeptide designated "E'" in Fig.2, its naturally-occurring alleles, or its amino acid sequence variants which are immunologically cross-reactive with antisera capable of binding the E' polypeptide produced in cells infected with AIDS-associated retrovirus."

Claims 2 to 14 related to further features of the said fusion polypeptide and claim 15 related to a composition comprising the polypeptide of any of claims 1 to 14.

The corresponding claims were filed as "process" claims for AT.

- II. An opposition was filed on the grounds of Article 100(a) and (b) EPC, lack of novelty and inventive step, lack of sufficient disclosure. The opposition division maintained the European patent in amended form on the basis of the third auxiliary request then on file.
- III. The appellant (patentee) lodged an appeal against this decision. He submitted a statement of grounds of appeal identifying his main request, first and a second auxiliary requests, as being respectively to the granted claims, the first and second auxiliary requests refused by the opposition division. He filed therewith claim 1 of the third auxiliary request, the remaining claims being said to be the same as in the second auxiliary request.

Claim 1 of the **first auxiliary request** for all designated Contracting States except AT read as follows:

"1. A fusion polypeptide comprising (a) a first polypeptide sequence of an AIDS associated retrovirus E', env or gag polypeptide having at least one antigenic determinant capable of specifically binding complementary antibody and (b) a second polypeptide sequence which is not an AIDS associated virus polypeptide; wherein said E' polypeptide of AIDS-associated retrovirus is defined as the 206 residue polypeptide designated "E'" in Fig.2, its naturally-occurring alleles, or its amino acid sequence variants which are immunologically cross-reactive with antisera capable of binding the E' polypeptide produced in cells infected with AIDS-associated retrovirus; **provided the**

fusion polypeptide is not a fusion of a gag or env region or portion thereof to HbsAg or pre-S HbsAg gene or an immunogenic portion thereof." (emphasis added by the board).

The same disclaimer "provided..." was also introduced in claim 1 of the second and third auxiliary requests.

No corresponding claim requests were on file for AT.

- IV. The opponent also initially filed an appeal and submitted a statement of grounds of appeal.
- V. Both parties sent further submissions with comments on their respective appeals.
- VI. On 23 September 2004, the board sent a communication under Article 11(1) EPC of the Rules of Procedure of the Boards of Appeal, stating its preliminary, non-binding opinion.
- VII. On 9 February 2005, the opponent sent further submissions in advance of the forthcoming oral proceedings.
- VIII. By letter dated 25 February 2005, the appellant informed the board that he withdrew his request for oral proceedings and that he would not attend the proceedings.
- IX. By fax dated 7 March 2005, the opponent withdrew his appeal. He attended oral proceedings which took place as scheduled on 9 March 2005.

X. The following document is mentioned in the present decision:

(1): EP-A-0 181 150 claiming priority from US 667501 of 31 October 1984, US 696534 of 30 January 1985 and US 773447 of 6 September 1985.

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

Main request; novelty of claim 1

Document (1) was to be taken into consideration under Article 54(3)(4) EPC. Only the passage on page 5, lines 1 to 3 of the granted patent:

" Another alternative is to join the gag, env or pol regions or portions thereof to HBsAg gene or pre-S HBsAg gene or immunogenic portions thereof, which portion is capable of forming particles in a unicellular microorganism host, e.g., yeast or mammalian cells."

had been relied on to challenge novelty.

It was evident that this passage related specifically and exclusively to genes and gene portions, namely to DNA constructs. This was consequent with the previous passage which equally related to DNA sequences. When denying novelty, the opposition division had presumably felt that this passage "ought" to refer to proteins. In fact, it was just a muddle that could hardly be said to disclose anything. Surely, it could not be said to be a clear and unambiguous disclosure of fusion proteins

according to claim 1, as it should be in order to affect novelty. Furthermore, also in accordance with the case law, a prior art document must describe the invention sufficiently for the skilled person to be able to carry it out. Document (1) did not affect novelty.

The disclaimer in claim 1 of all auxiliary claim requests

The disclaimer was aimed at excluding from claim 1 the passage on page 5 of document (1) in case that passage would be found to prejudice novelty. Its wording was based on the wording used in document (1). The thus amended claim was novel.

- XII. The respondent's arguments in writing and during oral proceedings insofar as they are relevant to the present decision may be summarised as follows:

Main request; novelty of claim 1

The passage on page 5, lines 1 to 3 of document (1) was prejudicial to the novelty of claim 1. The patentee had referred to the case law which held that novelty-only citations must be interpreted narrowly. A narrow interpretation was not the same as an over-pedantic or an obscurantist interpretation. The skilled person would not interpret the passage as requiring DNA to be joined to protein; he/she would instead understand that a HIV gene should be ligated to a HBsAg gene and that the resulting gene fusion would be used to generate a fusion protein. This was all the more true that the following passage stated that:

"Thus, particles are formed which will present the HIV-1 immunogen to the host...",

ie it was a clear reference to using HBsAg's ability to self-assemble to present HIV immunogens on the surface of particles. This meant that a HIV-HBsAg fusion protein was contemplated.

The disclaimer in claim 1 of all auxiliary claim requests

The disclaimer which was present in claim 1 of all auxiliary claim requests related to any portions of the HBsAg or pre-S HBsAg gene whereas document (1) only disclosed such portions of the gene as were capable of forming particles in a unicellular host. Its scope was, thus, broader than necessary to establish novelty. For, inter alia, this reason and in accordance with the Enlarged Board of Appeal decision G 1/03 (OJ EPO 2004, 413, points 2.6.5 and 3 of the Reasons), the disclaimer and, consequently, claim 1 were not allowable under Article 123(2) EPC.

The three auxiliary requests had to be rejected.

XIII. The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, alternatively, on the basis of the first or second auxiliary requests refused by the opposition division, or on the basis of the third auxiliary request filed on appeal.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

Main request

Article 54(3)(4) EPC; novelty of the subject-matter of claim 1

1. Document (1) is a European patent published on 14 May 1986, ie later than the filing date of the patent in suit (23 December 1985) and claiming priority, in particular, from the priority document US 667501 which was filed on 31 October 1984, ie earlier than the earliest priority date of the patent in suit (24 December 1984). It is thus relevant to novelty pursuant to Article 54(3)(4) EPC insofar as its content corresponds to that of its priority document. It is concerned with providing recombinant DNA constructs capable of expressing an env, gag or pol polypeptide of AIDS virus, for example, for vaccination. It is mentioned in the passage bridging pages 4 and 5 (page 11, lines 11 to 26 in the priority document US 667501) that:

"Particularly, the DNA sequence of the viral antigen may be inserted into the vaccinia virus at a site where it can be expressed, so as to provide an antigen of HIV-1 recognized as an immunogen by the host. The gag, pol, or env genes or fragments thereof that encode immunogens can be used.

Another alternative is to join the gag, env, or pol regions or portions thereof to HBsAg gene or pre-S HBsAg gene or immunogenic portions thereof, which portion is capable of forming particles in a unicellular microorganism host, e.g., yeast or mammalian cells. Thus, particles are formed which will

present the HIV-1 immunogen to the host in immunogenic form, when the host is vaccinated with assembled particles."

Where there can be no doubt that the first paragraph relates to DNA and the last sentence of the second paragraph relates to protein fusions comprising a HIV-1 part and a HBsAg part, the first sentence of the second paragraph is somewhat confusing insofar as it refers to "... HBsAg gene ... or immunogenic portions thereof...", which is obviously not possible since DNA is not immunogenic.

2. However, reading the first sentence as a part of the two above mentioned paragraphs, its meaning becomes evident in spite of the "short-cut" produced by attributing to the gene a property (immunogenicity) of the protein it encodes. In the Board's judgment, the skilled person at the priority date would not have had any difficulty in understanding the sentence as disclosing, in particular, polypeptides comprising (a) a portion of the AIDS virus gag or env proteins fused to (b) a second polypeptide being a portion of the HBsAg protein which is capable of forming particles, these polypeptides resulting from the expression of a composite DNA consisting of DNA encoding a part of the AIDS virus gag or env proteins fused to DNA encoding a particle forming part of the HBsAg or pre-S HBsAg protein. Thus, the teaching of document (1) is considered to be clear and unambiguous for the skilled person willing to understand.

3. Claim 1 of the main request now under consideration discloses amongst other embodiments a fusion polypeptide comprising (a) an env or gag polypeptide which may carry less than the total number of antigenic determinants of the gag or env proteins ie consisting of a portion of the gag or env proteins and (b) a second polypeptide which is not an AIDS associated virus.
4. The fused polypeptide described in document (1), thus, falls within the scope of the claim, the second polypeptide being identified as a portion of the HBsAg protein, which is capable of forming particles. The subject-matter of claim 1, thus, lacks novelty.
5. In his written submissions relative to novelty, the appellant mentioned case law establishing that in order to be novelty destroying, a prior art document must give sufficient instructions for the skilled person to be able to reproduce its teachings. The matter was not pursued any further and, thus, the board can only consider the reference to this case law as somehow implying that, at the priority date, the skilled person would not have been able to construct DNA fusions comprising AIDS and HBsAg DNA. In the absence of any evidence to sustain this argument, it can only be considered as an unproven allegation with no technical basis and, thus, of no relevance.
6. The main request is rejected for failing to comply with the requirements of Article 54(3)(4) EPC.

First to third auxiliary requests; claim 1; allowability of the disclaimer

7. In claim 1 of these three auxiliary requests, an attempt was made to delimitate the claimed subject-matter from the teachings of document (1) by introducing into the claim the disclaimer:

".. provided the fusion polypeptide is not a fusion of a gag or env region or portion thereof to HBsAg or pre-S HBsAg gene or an immunogenic portion thereof."

The respondent has inter alia criticized this wording as being broader than was necessary to restore novelty.

8. In accordance with the Enlarged Board of Appeal decision G 1/93 (supra, point 2.1 of the Order), disclaimers may indeed be used to restore novelty by delimiting a claim against state of the art under Article 54(3)(4) EPC. Yet, in order to be allowable, the disclaimer must fulfil a number of criteria. Point 2.6.5 of the decision states that:

"... a disclaimer may serve exclusively the purpose for which it is intended and nothing more. In the case of a disclaimer concerning conflicting applications, its purpose is to establish novelty with respect to a prior application in the sense of Article 54(3) EPC... If a disclaimer has effects which go beyond its purpose as stated above, it is or become inadmissible."

In point 3., it is further specified:

"The necessity for a disclaimer is not an opportunity for the applicant to reshape his claims arbitrarily. Therefore, the disclaimer should not remove more than necessary to restore novelty..."

9. The present disclaimer corresponds to the first part of the first sentence in the second paragraph of document (1) (see point 1, *supra*). The second part of this sentence, however, is missing:

"...which portion is capable of forming particles in a unicellular microorganism host, e.e. yeast or mammalian cells."

Otherwise stated, what is disclaimed is a fusion protein comprising any portion of the HBsAg protein irrespective of whether or not it is capable of forming particles whereas document (1) discloses fusion proteins comprising only these portions of the HBsAg protein which are capable of forming particles. Thus, the scope of the disclaimer is wider than that necessary to restore novelty. It can also be inferred from the said decision (point 3, third paragraph of the reasons) that a disclaimer being broader than strictly necessary to restore novelty may, depending on the circumstances of the case be allowed, if this turns out to be necessary to avoid an otherwise resulting unclarity of the claim. However, in the present case there is no apparent justification for the disclaimer being broader than the disclosure in document (1). In the view of the Board no lack of clarity objection would have resulted from the insertion in the

disclaimer of the above cited second part of the sentence of document (1). Accordingly, the disclaimer fails to fulfil the criteria enounced in points 2.6.5 and 3 of the Enlarged Board of Appeal decision G 1/03 (*supra*). It is, thus, concluded that this disclaimer is not allowable.

10. Claim 1 of each of the three auxiliary requests contains an unallowable disclaimer. Consequently, these requests are rejected under Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

A. Wolinski

L. Galligani