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Case Number: T 1414/05 - 3.3.04

Application Number: 95930790.1

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Title of invention:
MHC complexes and uses thereof

Patentee:
Sunol Molecular Corporation

Opponent:
Corixa Corporation

Headword:
MHC complexes/SUNOL

Relevant legal provisions:
EPC Art. 54(3)

Relevant legal provisions (EPC 1973):
EPC Art. 150(3), 158(1)(2)

Keyword:
"Priority (no)"
"Novelty (yes)"

Decisions cited:
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Case Number: T 1414/05 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 29 April 2008

Appellant: (Patent Proprietor)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 13 September 2005 concerning maintenance of European patent No. 0776339 in amended form.

Composition of the Board:

Chairman: R. Moufang
Members: G. Alt
R. Gramaglia

Summary of Facts and Submissions

I. The appeal was lodged by the patent proprietor (appellant) against the decision of the opposition division, according to which European patent No. 0 776 339, entitled "MHC complexes and uses thereof" could be maintained in amended form pursuant to Article 102(3) EPC 1973.

II. Claims 1 and 3 as granted read:

"1. A MHC fusion complex comprising a MHC class II molecule that contains a peptide-binding groove, and a presenting peptide covalently linked to the MHC molecule,
wherein the α and β chain subunits are linked as a single chain fusion protein with the presenting peptide,
wherein the presenting peptide and the fusion complex is capable of modulating the activity of a T cell receptor,
wherein a linker sequence is interposed between the MHC molecule and the presenting peptide,
wherein a second linker sequence ("single chain linker sequence") is used to link the α and β chains and
wherein both linker sequences are flexible to permit folding of the single chain molecule to an active form.

3. A method for identification of a peptide that can modulate the activity of T cells, comprising:
introducing into host cells cloning vectors that each contain DNA constructs that code for a MHC fusion complex according to claim 1;

culturing the host cells under conditions suitable for expression of the MHC fusion complex; and
selecting host cells that express MHC fusion complex that modulates the activity of T cells."

III. The opposition was based on Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC), lack of inventive step (Article 56 EPC) and lack of invention (Article 52 EPC).

The opposition division decided that the subject-matter of the main request (claims as granted) was not novel, that claim 1 of the first and third auxiliary request did not comply with the requirements of Article 84 EPC and that claim 1 of the second auxiliary request did not fulfil the requirements of Article 123(2) EPC. The single claim of the fourth auxiliary request was found to comply with the requirements of the EPC.

IV. The only submission of the respondent during the appeal proceedings was a letter informing the board that it would not attend oral proceedings.

V. Oral proceedings took place on 29 April 2008 in the absence of the respondent. At the end of the proceedings the board announced the decision.

VI. The appellant requested that the decision of the opposition division be set aside and that the patent be maintained on the basis of the main request submitted at the oral proceedings before the board.

Claims 1 and 3 of the main request read:

"1. A MHC fusion complex comprising a MHC class II molecule that contains a peptide-binding groove, and a presenting peptide covalently linked to the MHC molecule,
wherein the α and β chain subunits are linked as a single chain fusion protein with the presenting peptide,
wherein the presenting peptide and the fusion complex is capable of modulating the activity of a T-cell receptor to induce T-cell proliferation,
wherein a linker sequence is interposed between the MHC molecule and the presenting peptide,
wherein a second linker sequence ("single chain linker sequence") is used to link the α and β chains and
wherein both linker sequences are flexible to permit folding of the single chain molecule to an active form.

3. A method for identification of a peptide that can modulate the activity of T cells to induce T-cell proliferation, comprising:
introducing into host cells cloning vectors that each contain DNA constructs that code for a MHC fusion complex according to claim 1;
culturing the host cells under conditions suitable for expression of the MHC fusion complex; and
selecting host cells that express MHC fusion complex that modulates the activity of T cells."

The request contained five further claims relating to a DNA construct, an expression vector, a pharmaceutical composition and the use of a DNA sequence or the MHC

fusion complex in the preparation of a medicament. All of these claims refer to claim 1.

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

The patent was entitled to its two priority dates. Therefore, the international application PCT/US96/10102 (hereinafter referred to as the international application D2) published as WO 96/40944 did not form part of the state of the art in accordance with Article 54(3) EPC. In particular, the priority documents disclosed that the alpha and beta chains were joined together by a flexible linker.

The international application D2 was not entitled to the priority date of US 08/480,002 (document D1), since the structure of a fusion protein containing a flexible linker between the alpha and beta chains and between one of the chains and a peptide was not unambiguously disclosed therein (see pages 4 and 5). Also it was not clearly and unambiguously derivable from document D1 whether truncated or complete chains were fused (see page 9, lines 35-37).

The international application D2 related to the treatment of autoimmune diseases by suppressing T-cell proliferation and therefore did not disclose the feature in claim 1 "capable of modulating the activity of a T-cell receptor to induce T-cell proliferation".

VIII. The relevant arguments submitted by the respondent during the opposition proceedings are as follows:

The passages relating to a single-chain major histocompatibility (MHC) fusion complex were missing from the priority documents of the patent, which therefore did not disclose such a complex. Therefore, these priorities were not valid.

The subject-matter of claim 3 of the patent as granted did not relate to a patentable invention and did not solve any problem.

Reasons for the Decision

Articles 84, 123(2) and (3) EPC

1. Since the requirements of Article 84 EPC are not a ground for opposition and the ground for opposition under Article 100(c) EPC has not been invoked, the examination of the requirements of Articles 84 and 123(2) EPC is restricted to amendments made over the patent in its granted form.

2. The new feature in claim 1 "is capable of modulating the activity of a T-cell receptor to induce T-cell proliferation" and corresponding features in claims 3, 5 and 6 have a basis throughout the application document as filed, for example on page 3 last line continued on page 4, lines 1 and 2; page 31, lines 26 to 30; page 41, lines 5 to 15.

3. The scope of protection is not extended by the amendment. The scope of the claims is limited to major histocompatibility (MHC) fusion complexes which have the said capability.

4. The board sees no objections under Article 84 EPC arising from the amendment.

5. Hence the amendments comply with the requirements of Articles 84, 123(2) and (3) EPC.

Novelty

6. The international application PCT/US96/10102 (hereinafter referred to as "the international application D2") designates, inter alia, the European Patent Office. The application has entered the European phase. All states designated by the patent in suit are also designated by the international application D2.

6.1 The two priority dates of the patent (29 July 1994 and 1 February 1995) are prior to the earliest priority date of the international application D2 (7 June 1995). The appellant argues that the subject-matter of claim 1 of the main request can validly claim the priority dates of the patent and that, therefore, the international application D2 does not belong to the state of the art. In particular, the appellant argues that the priority documents, which as submitted by the appellant both have the same disclosure with respect to the relevant passages, disclose a single-chain MHC fusion complex wherein the two chains are linked by a flexible linker. The appellant relies on the following passage on page 13 of the first priority document US 283302: "[d]ifferent linker sequences could be used including any of a number of flexible linker designs

that have been used successfully to join antibody variable regions together..."

6.2 However, this statement is part of a description, starting on the top of page 12, of the linker inserted between the presenting peptide and one of the MHC chains. Therefore, in the board's view, a skilled person would derive from the above statement that linkers such as those used for joining antibody variable regions together may also be used for joining the presenting peptide with one of the MHC chains, but not that alpha and beta chains may be joined by a linker.

6.3 Such a disclosure is also not found on page 4, lines 25 to 27 of the first priority document, which refer to a DNA expression vector coding for the MHC fusion complex, or in claim 28 of the second priority document relating to a DNA vector encoding alpha and beta chains. In the board's view, the skilled person would derive from either passage that the complete MHC molecule is encoded by a single vector. However, the skilled person would not be able to derive from such a disclosure that the vector contains a DNA fragment coding for linked alpha and beta chains and even less the presence of a flexible linker between the two chains in the MHC fusion complex.

6.4 Hence, the board concludes that claim 1 is not entitled to either of the priority dates. Consequently, the relevant date for the assessment of novelty is the filing date of the patent, i.e. 31 July 1995, which is after the earliest priority date of the international application D2. Therefore, this application belongs to

the state of the art pursuant to Article 54(3) EPC in connection with Articles 150(3) and 158(1)(2) EPC 1973 insofar as its subject-matter is entitled to any of its own priority dates.

7. The appellant argues that the international application D2 does not anticipate the subject-matter of claim 1 because the MHC complexes disclosed therein had a property which was opposite to that required by claim 1, namely that of being "capable of modulating the activity of a T-cell receptor **to induce T-cell proliferation**".

7.1 The disclosure in the international application D2 is restricted to the use of MHC complexes for the treatment of autoimmune diseases, which treatment relies on the suppression of T-cell proliferation. There is no disclosure in this application that MHC complexes with this activity are at the same time capable of fulfilling the opposite activity, i.e. of inducing T-cell proliferation.

8. The appellant submitted at the oral proceedings with reference to paragraph [0057] of the patent that the functional feature "capable of modulating the activity of a T-cell receptor to induce T-cell proliferation" also had a structural implication, namely, that for being capable of fulfilling this function the peptide presented by the MHC complex must be properly positioned. In view of this submission the board considers it plausible that the T-cell modulating activity of an MHC complex is inter alia dependent on the position of the presenting peptide and that therefore, due to this structural requirement, the same

MHC complex is not capable of inducing and suppressing T-cell proliferation. Consequently, it cannot be assumed that the MHC complexes disclosed in the international application D2 are capable of inducing T-cell proliferation. This has also never been argued by the respondent.

8.1 The international application D2 also alludes to screening T-cell receptors for corresponding MHC-peptide complexes (for example page 21). While it is conceivable that during such a screening procedure MHC complexes with T-cell proliferating capability may be found, it is noted that such complexes are not disclosed in document D2. A successful novelty objection cannot however be based on assumptions.

8.2 In summary, the board comes to the conclusion that MHC complexes capable of modulating the activity of a T-cell receptor to induce T-cell proliferation are not disclosed in the international application D2.

8.3 Thus, for that reason alone the subject-matter of claim 1 and also of claims 2 to 7, which all contain a reference to claim 1 (see section VI above), is novel over the disclosure in the international application D2. Therefore, the appellant's further arguments need not be considered, in particular the question whether or not the international application D2 can validly claim the priority date of the application US 08/480,002 (document D1).

Claim 3

9. Claim 3 as granted relates to a method for the identification of a peptide that can modulate the activity of T cells and requires that DNA constructs which code for the fusion complex according to claim 1 are introduced and cultured into host cells (see section II above).

9.1 During opposition proceedings the respondent submitted that, due to the reference to claim 1 relating to MHC complexes capable of modulating T-cell activity, claim 3 as granted did not in fact relate to a screening method revealing the appropriate products, but instead only to a method of confirming the property of the initial product. For that reason the subject-matter of claim 3 was neither a patentable invention within the meaning of Article 52(1) EPC nor did it involve an inventive step pursuant to Article 56 EPC, because it did not provide a solution to any problem.

9.2 Present claim 3 differs from granted claim 3 only by the feature "to induce T-cell proliferation". Therefore, since the above-outlined objection is in principle applicable to present claim 3, the board has considered whether or not it could be successful.

9.3 The meaning of a claim is determined from the viewpoint of the skilled person reading said claim, in the light of the description and with common general knowledge. In the board's view, in the present case, the skilled person would, in view of its preamble, recognize that claim 3 relates to a screening method. Consequently he/she would interpret the expression "MHC fusion complex according to claim 1" as referring to MHC complexes according to claim 1 except however that

their functional properties are not yet determined at the outset of the screening method.

9.4 The board thus considers that the respondent's interpretation of the meaning of claim 3 is not appropriate. Therefore, the argument fails.

Inventive step

10. The international application D2 is the only document submitted by the respondent in these proceedings. It can only be prior art according to Article 54(3) EPC and is therefore not available for the assessment of inventive step. The opposition division did not introduce any document of its own motion into the proceedings when it considered the inventive step of the fourth auxiliary request. Thus, the board, not having at its disposal any document on the basis of which inventive step could be assessed, has to conclude that the subject-matter of claims 1 to 7 fulfils the requirements of Article 56 EPC.

Further objections

11. The board also sees no further objections against the amended 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 with the order to maintain the patent in amended form on the basis of claims 1 to 7 of the main request as submitted at the oral proceedings and a description yet to be adapted.

The Registrar: The Chair:

P. Cremona R. Moufang