

Internal distribution code:

- (A) [] Publication in OJ
(B) [] To Chairmen and Members
(C) [X] To Chairmen
(D) [] No distribution

**Datasheet for the decision
of 7 October 2011**

Case Number: T 1172/08 - 3.3.08

Application Number: 99918575.4

Publication Number: 1073754

IPC: C12N 15/57, C12N 15/63,
C12N 9/54, C12N 1/21

Language of the proceedings: EN

Title of invention:
Process for the preparation of protein mutants having lower
allergenic response in humans

Patentee:
GENENCOR INTERNATIONAL, INC.

Opponent:
Merck Patent GmbH

Headword:
Method for determining T-cell epitopes/GENENCOR

Relevant legal provisions:
EPC Art. 123(3), 69
EPC R. 80
Protocol on the Interpretation of Article 69 EPC

Keyword:
"Extension of protection conferred - all requests (yes)"

Decisions cited:
T 0175/84, T 0371/88, T 0108/91, T 0140/99, T 0314/03

Catchword:
-



Case Number: T 1172/08 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 7 October 2011

Appellant I:
(Patent Proprietor) GENENCOR INTERNATIONAL, INC.
925 Page Mill Road
Palo Alto
California 94304 (US)

Representative:
G. Forrest
Mewburn Ellis LLP
33 Gutter Lane
London EC2V 8AS (GB)

Appellant II:
(Opponent) Merck Patent GmbH
Postfach
Frankfurter Strasse 250
D-64293 Darmstadt (DE)

Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
6 June 2008 concerning maintenance of European
patent No. 1073754 in amended form.

Composition of the Board:

Chairman: M. Wieser
Members: B. Stolz
R. Moufang

Summary of Facts and Submissions

I. European Patent EP No. 1073754 was granted with claims 1 to 6 and was opposed on the grounds of Articles 100(a) and 100(b) EPC.

II. Claim 1 of the granted patent read:

"A method for determining T-cell epitopes within a protein comprising the steps of:

(a) obtaining from a single human blood sample a solution of dendritic cells and a solution of naïve CD4+ and/or CD8+ T-cells;

(b) promoting differentiation in said solution of dendritic cells;

(c) combining said solution of differentiated dendritic cells and said naïve CD4+ and/or CD8+ T-cells with a peptide of interest;

(d) measuring the proliferation of T-cells in said step (c)."

III. The opposition division decided that the main request before it did not fulfil the requirements of Article 123(2) EPC, but that auxiliary request 1, filed at the oral proceedings on 9 April 2008, met all requirements of the EPC.

IV. Claim 1 of Auxiliary request 1 read as follows:

"A method for determining T-cell epitopes within a protein comprising the steps of:

(a) obtaining from a single human blood sample a solution of monocyte cells and a solution of naive CD4+ T-cells;

(b) promoting differentiation of said monocyte cells to dendritic cells by a method as described in Example 1;

(c) combining said solution of dendritic cells and said naive CD4+ T-cells with a peptide of interest;

(d) measuring the proliferation of T-cells in said step (c).

V. The patentee (appellant I) and the opponent (appellant II) filed an appeal against the interlocutory decision of the Opposition Division.

VI. Appellant I requested that the decision under appeal be set aside and that the patent be maintained on the basis of its main request filed with letter dated 8 February 2008 during opposition proceedings.

VII. Appellant II requested that the decision under appeal be set aside and that the patent be revoked, and filed new prior art documents D20 to D26.

- VIII. Both parties filed further submissions in response to each other's grounds of appeal. Appellant II raised a new objection under Rule 80 EPC and filed additional prior art documents D27 to D29.
- IX. The board summoned the parties to oral proceedings. A communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) dated 26 April 2011, annexed to the summons, informed the parties of the preliminary non-binding opinion of the board on some of the issues of the appeal proceedings.
- X. Both parties filed additional comments in response to the board's communication.
- XI. Oral proceedings were held on 7 October 2011. In the course of the oral proceedings, appellant I withdrew its main request filed with letter dated 8 February 2008.
- XII. The final requests of the parties were:
- Appellant I requested, as its main request, to dismiss the appeal of appellant II and to maintain the patent on the basis of claims 1 to 6 filed as auxiliary request 1 at the oral proceedings in opposition on 9 April 2008, or in the alternative, to set aside the decision under appeal and to maintain the patent on the basis of claims 1 to 6 filed as auxiliary request 2 with letter of 2 March 2009.
- Appellant II requested that the decision under appeal be set aside and that the patent be revoked.

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

- D3: Lisa A. Williams et al., 1994, International Review of Cytology, 153, 41 - 103,
- D4: ^Annapurna Vyakarnam et al., 1991, International Immunology, 3, No. 10, 939-947,
- D5: Macatonia, S. E. et al., Immunology, 1991, 74, 399-406,
- D6: Helga Bernhard et al., 1995, Cancer Research, 1099- 1103,
- D7: Nikolaus Romani et al., 1996, Journal of Immunological Methods, 196, 137-151,
- D8: Penelope A. Bedford et al., 1997, Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology, 14, No. 4, 301 -306,
- D9: Van Tsai et al., 1997, The Journal of Immunology, 1997, 158, 1796-1802,
- D10: Ichiro Kawashima et al., 1998, Human Immunology, 59, 1-14.

XIV. Appellant I's arguments, insofar as they are relevant for the present decision, may be summarized as follows:

The objection under Rule 80 EPC was unjustified. The amendments to claim 1 addressed problems in relation to the inventive step objection raised by appellant II.

The amendments of claim 1 were in line with the requirements of Article 123(3) EPC. The extent of protection conferred by a claim was not determined merely by the words of a claim, and an amendment to a claim to clarify an inconsistency between the claim and the description did not contravene Article 123(3) EPC.

XV. Appellant II's arguments can be summarised as follows:

The amendment to claim 1 was not occasioned by a ground of opposition and as such not admissible under Rule 80 EPC.

The method of claim 1 of the main request differed from the method of claim 1 as granted. Monocytes and dendritic cells were not equal. There was no immediately obvious error in claim 1 as granted that would have prompted the skilled person to interpret claim 1 in the way appellant I would like to have it.

Reasons for the decision

Documents D20 to D29

1. Appellant II filed documents D20 to D26 with its grounds of appeal to support its arguments against the interlocutory decision of the opposition division, and documents, D27 to D29, to address arguments raised in appellant I's grounds of appeal.

Appellant I considered the exact publication dates of documents D21 and D22 unclear and requested that document D24 not be admitted in appeal proceedings because it was not admitted in opposition proceedings and in any case irrelevant because it was not written by a person skilled in the art.

2. In the light of the fact that the reasoning of this decision does not rely on any of these documents, the board sees no necessity to decide on this issue.

Main request

Rule 80 EPC

3. During opposition proceedings, on 9 April 2008, the patentee (now appellant I) filed an auxiliary request (now the main request) comprising claims 1 to 6 (for claim 1, cf. section IV above). While parts (a) and (b) of claim 1 as granted referred to obtaining dendritic cells and the differentiation of dendritic cells (cf. section II above), the respective parts of claim 1 of the auxiliary request referred to obtaining monocyte cells and the differentiation of monocyte cells to dendritic cells.
4. According to Rule 80 EPC (Rule 57a EPC 1973), the description, claims and drawings of a European patent may be amended provided that the amendments are occasioned by a ground of opposition.

Thus, in order to be allowable, the board has to be satisfied that the amendments resulted from a bona fide attempt to overcome a ground of opposition.

5. In its opposition brief of 22 June 2005, appellant II attacked inventive step of the granted claims *inter alia* on the basis of document D3, disclosing antigen uptake and antigen processing of dendritic cells, in combination with any one of documents D4 to D10 disclosing the identification of primary CD4+ T cell epitopes using various assays comprising dendritic cells.

In its response to the summons to oral proceedings in opposition, appellant I filed several requests comprising the same amendment of claim 1 as the current main request. It stated in essence that claim 1, comprising this amendment, met the requirements of Article 56 EPC because the skilled person would have had no reason to believe that DCs obtained according to the amended claim, i.e. obtained by in vitro differentiation of isolated monocytes, would work in a method of determining T-cell epitopes (cf. e.g. page 8, paragraph 4).

The board is therefore satisfied that the amendments of claim 1 of the main request were intended to overcome an inventive step objection, i.e. were occasioned by a ground of opposition.

Articles 123(3) and 69 EPC

6. According to Article 123(3) EPC, "the European patent may not be amended in such a way as to extend the protection it confers".

According to Article 69(1) EPC, "the extent of protection conferred by the patent ... shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims."

7. The interpretation of the protection conferred by a patent according to Article 69 EPC is in general not one of the duties of the boards of appeal (cf. e.g. decision T 175/84, OJ EPO 1989, 71). For the purpose of establishing whether the amendments of the main request fall foul of the provisions of Article 123(3) EPC, it is however necessary to do so.

8. Parts (a) and (b) of claim 1 as granted referred to obtaining dendritic cells from a human blood sample and to promoting the differentiation in said solution of dendritic cells, while the respective parts of claim 1 of the main request refer to obtaining monocyte cells and to promoting the differentiation of said monocyte cells to dendritic cells.

It is evident, and it has not been contested by the parties, that obtaining a solution of monocyte cells from a blood sample is not the same as obtaining a solution of dendritic cells from a blood sample. Thus, claim 1 as granted and claim 1 of the main request, when read on their own, provide protection for different subject matter.

9. Appellant I agreed that normally such a shift in the extent of protection would not be allowable. It argued however that the case at issue was very particular because the claims as granted did not embrace the subject matter of the only example of the patent

specification. Under such circumstances, the skilled reader would have realised that the claim language was inconsistent with the patent specification, and that what the patentee really wanted was protection for the method described in Example 1.

10. It has therefore to be established whether the amendments of claim 1 result in an extension of the scope of protection conferred by the patent as a whole.
11. According to the protocol on its interpretation, "Article 69 EPC should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims" (Protocol on the interpretation of Article 69 EPC, Article 1, first sentence).
12. From this, appellant I concluded that what determined the scope of protection in the present case was not the literal meaning of the term dendritic cells. Since the literal meaning of the term dendritic cells was not consistent with Example 1, in which monocytes were isolated, the skilled person would have concluded that the granted patent conferred protection for a method for determining T-cell epitopes comprising the steps of obtaining monocyte cells and differentiating those monocyte cells to dendritic cells. Thus, on a proper construction of claim 1, there was no extension of the scope of protection.

13. The board agrees with appellant I only insofar as the protocol on the interpretation of Article 69 EPC states that the description and drawings should be used for interpreting the claims even if there is no ambiguity in the meaning of the claims. But Article 1 of the protocol also makes reference to the balance that has to be struck between the interests of the patent proprietor in obtaining fair protection and a reasonable degree of legal certainty for third parties (Protocol on the interpretation of Article 69 EPC, Article 1, third sentence). To give some guidance in this respect, it also explicitly states that Article 69 EPC should not "be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated" (Protocol on the interpretation of Article 69 EPC, Article 1, second sentence).

14. The board has no doubts and the parties have not disputed that dendritic cells and monocytes are different cell types characterized by different features. Both cell types can be distinguished by morphological features as well as phenotypic and molecular markers, and the isolation of enriched dendritic cell fractions from blood samples was for instance disclosed in prior art document D8.

Thus, the skilled person would a priori not have had any reason to read a different technical meaning into the term "obtaining from a blood sample a solution of dendritic cells". Had he wondered, as argued by appellant I, what sublineage of dendritic cells was

used for the differentiation in said solution of dendritic cells, he might have turned to the description and Example 1 and would have found that monocytes were isolated and in vitro differentiated into dendritic cells. He might have wondered why the claim referred to isolating dendritic cells, but in the board's opinion, the protocol on the interpretation of Article 69 EPC does not leave room for going a step further and reading appellant I's interpretation into claim 1. Doing so would require the skilled reader to completely ignore the wording of granted claim 1, which per se was not technically meaningless, with the consequence that the wording of claim 1 would merely serve as an empty shell.

This is clearly not in the sense of Article 69 EPC nor in the sense of the protocol on its interpretation. Moreover, the interest of third parties in legal certainty would be completely ignored, if appellant I's interpretation were found to be acceptable.

15. Appellant I repeatedly referred to the amendments in claim 1 as removing an inconsistency between the claims and the description. To support its case, it cited several decisions from the boards of appeal relating to this issue.

In decision T 108/91 of 17 September 1992, the competent board stated that the amendment of a granted claim to replace an inaccurate technical statement, which was evidently inconsistent with the totality of the disclosure of the patent, by an accurate statement of the technical features involved, did not infringe Article 123(3) EPC. Importantly, in said case the technical term used in the claims was inconsistent with

the totality of the disclosure of the patent. This is however not comparable to the present case where the general parts of the description of the application documents define the invention exactly as in granted claim 1 (cf. e.g. p. 4, lines 20-24; p. 7, lines 33-34, of the published international application), and the term monocytes is used only in Example 1 but nowhere else in the description.

In decision T 140/99 of 27 March 2001, the meaning of a literally clear term in a claim was altered by adding a statement how the term had to be interpreted. The board accepted this amendment because it considered it to remove an inconsistency between the claim and the description. This is also not comparable to the present case where a literally clear technical term was not altered by stating how it had to be interpreted but instead was removed and replaced by a term with an equally clear but distinct technical meaning.

In decision T 371/88 of 29 May 1990, the replacement of a restrictive term, which in its strict literal meaning did not clearly embrace a further embodiment of the description, by a less restrictive term clearly embracing also this embodiment was held to be permissible if two conditions are met. The conditions are: a) the restrictive term is not so clear in its technical meaning in the given context that it could be used to determine the extent of protection without interpretation by reference to the description and drawings of the patent, and b) it is quite clear from the description and the drawings of the patent and also from the examination procedure up to grant that the further embodiment belongs to the invention and that it

was never intended to exclude it from the protection conferred by the patent. The present case differs from the case underlying decision T 371/88 because already the first condition is not met. The replacement of the terms "obtaining dendritic cells" and "promoting differentiation in said solution of dendritic cells" by "obtaining monocyte cells" and "promoting differentiation of said monocyte cells" cannot be regarded as the replacement of a more restrictive term by a less restrictive term. The term monocytes does not embrace dendritic cells.

In decision T 314/03 of 24 May 2005, the replacement of a feature of the claim in plural form by the same feature in singular form, was considered to remove an inaccuracy or inconsistency which was said to be obvious to the skilled person upon reading the description. The present case is however about replacing a technically meaningful term with a technically entirely different and equally meaningful term. This constitutes an entirely different situation.

In conclusion, the board does not agree with appellant I's interpretation of the cited decisions and their applicability to the present case.

16. In view of the above considerations, the board comes to the conclusion that the amendment of claim 1 extends the protection conferred by the granted patent. The main request does not meet the requirements of Article 123(3) EPC.

Auxiliary request

17. Claim 1 of the auxiliary request also comprises the steps of "obtaining from a single human blood sample a solution of monocyte cells" and "promoting differentiation of said monocyte cells to dendritic cells". For the same reasons as given for the main request, it does not meet the requirements of Article 123(3) EPC.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is revoked.

The Registrar:

The Chairman:

A. Wolinski

M. Wieser