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**Datasheet for the decision
of 18 July 2022**

Case Number: T 0523/19 - 3.3.04

Application Number: 10184742.4

Publication Number: 2364996

IPC: A61K39/00, C07K16/32,
C07K16/24, C07K16/00, C07K16/28

Language of the proceedings: EN

Title of invention:
Optimized Fc variants and methods for their generation

Patent Proprietor:
Xencor Inc.

Opponent:
Pohlman, Sandra M.

Headword:
Optimized Fc variants/XENCOR

Relevant legal provisions:
EPC Art. 123(3)

Keyword:
Amendments - extension beyond the content of the application
as filed (yes)



Beschwerdekammern

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Case Number: T 0523/19 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 18 July 2022

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 18 December
2018 revoking European patent No. 2364996
pursuant to Article 101(3) (b) EPC.**

Composition of the Board:

Chair M. Pregetter
Members: A. Chakravarty
 P. de Heij

Summary of Facts and Submissions

- I. The appeal of the patent proprietor (appellant) is directed against the decision of the opposition division to revoke the European patent No. 2 364 996, entitled "*Optimized Fc variants and methods for their generation*".
- II. The patent had been opposed by an opponent (respondent) on grounds for opposition under Article 100(a) EPC, in conjunction with Articles 53(b) and 56 EPC, Article 100(b) and Article 100(c) EPC.
- III. In the decision under appeal, the opposition division considered sets of claims of a main request and two auxiliary requests. It held that claim 1 of the main and auxiliary request 1 did not meet the requirements of Article 123(2) EPC. It did not admit auxiliary request 2 into the proceedings as "*there is no change of subject matter and so no actual amendment or limitation has taken place*" and therefore there was a lack of compliance with Rule 80 EPC.
- IV. With the statement of grounds of appeal, the appellant re-filed sets of claims of the main and auxiliary requests 1 and 2 considered by the opposition division.
- V. Claim 1 as granted reads:

"1. A protein comprising an Fc variant of a parent IgG Fc polypeptide, said Fc variant comprising an amino acid substitution in the Fc region, wherein said amino acid substitution is 243L and wherein numbering is according to the EU index."

Claim 1 of the main request reads:

"1. A protein comprising an IgG Fc variant of a parent Fc polypeptide, said Fc variant comprising an amino acid substitution in the Fc region, wherein said amino acid substitution is F243L and wherein numbering is according to the EU index".

Claim 1 of auxiliary request 1 reads:

"1. A protein comprising an IgG Fc variant of a parent Fc polypeptide, said Fc variant comprising an amino acid substitution in the Fc region, wherein said amino acid substitution is F243L and wherein numbering is according to the EU index, wherein said protein is an Fc fusion or an antibody".

Claim 1 of auxiliary request 2 reads:

"1. An antibody or an Fc fusion comprising an IgG Fc variant of a parent Fc polypeptide, said Fc variant comprising an amino acid substitution in the Fc region, wherein said amino acid substitution is F243L and wherein numbering is according to the EU index".

VI. In the statement of grounds of appeal, the appellant addressed the opposition division's decision on the requirements of Article 123(2) and Rule 80 EPC. As far as relevant to this decision it argued as follows.

Auxiliary request 2

Admission (Rule 80 EPC)

Auxiliary Request 2 complied with the requirements of Rule 80 EPC. It had been submitted during the oral proceedings before the opposition division in direct

response to an objection made by the respondent regarding basis for the term "protein". This objection had been raised for the first time during the oral proceedings. The amendment removed the term to which the objection was raised and thus complied with the requirements of Rule 80 EPC.

VII. In its reply, the respondent maintained its objection under Article 123(3) EPC which it had advanced in the proceedings before the opposition division against the main request and the auxiliary requests and argued that the decision of the opposition division not to admit auxiliary request 2 into the proceedings was correct. The respondent's arguments relevant to the decision are summarised as follows:

Main request and auxiliary request 1 - claim 1

Amendments (Article 123(3) EPC)

The opposition division's decision that claim 1 of the main request did not infringe Article 123(3) EPC was incorrect. In the amended claim, the Fc variant no longer had to be derived from an IgG parent Fc polypeptide but may now be derived from any parent Fc polypeptide. The term Fc, referred to the last constant region immunoglobulin domains of IgA, IgD and IgG, and the last three constant region domains of IgE and IgM, and the flexible hinge N-terminal to these domains (see paragraph [0047] of the patent) and was in no way limited to the IgG Fc region. In the amended claim, the parent molecule could thus be any Fc precursor comprising an F at position 243. The claim therefore included a host of possible parent molecules, which were clearly not encompassed by granted claim 1.

Auxiliary request 2

Admission (Rule 80 EPC)

In auxiliary request 2 as submitted during oral proceedings before the opposition division, the general term "protein" was replaced with the specific terms "antibody" or "Fc fusion". Since these terms were already present in claim 1 of auxiliary request 1, limiting the scope of 'protein', the opposition division had been right to hold that "there is no change of subject-matter and no actual amendment or limitation has taken place". Thus, this amendment did not address any "objection made by the Opponent." and for that reason did not comply with Rule 80 EPC.

- VIII. The appellant made no submissions in reply to the respondent's reply to the statement of grounds of appeal and made no submissions on the topic of compliance with Article 123(3) EPC.
- IX. The board appointed oral proceedings. Subsequently, the appellant informed the board that it would not attend the scheduled oral proceedings, implying that it withdrew its request for oral proceedings. The respondent announced that they would not attend the oral proceedings either. It maintained its request that the appeal be dismissed and made a conditional request for oral proceedings in case its request for dismissal of the appeal was not allowed.
- X. The board cancelled the oral proceedings and informed the parties that the decision would be issued in due course.

XI. The appellant's requests as understood by the board are as follows:

- that the decision under appeal be set aside and that the set of claims of the main request or, alternatively, auxiliary requests 1 or 2, be acknowledged as complying with the requirements of Article 123(2) EPC;

- that the case be remitted to the opposition division to consider the requirements of Articles 83, 54 and 56 EPC.

XII. The respondent's requests as understood by the board are as follows:

- that the appeal be dismissed,

- that auxiliary request 2 not be admitted into the appeal proceedings;

- that the case not be remitted to the opposition division.

Reasons for the Decision

Main request - claim 1

Amendments (Article 123(3) EPC)

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

2. Claim 1 has been amended from the granted claim 1 in that term "IgG" has been moved such that the claim is

for an "IgG Fc variant of a parent Fc polypeptide..." instead of "A protein comprising an Fc variant of a parent IgG Fc polypeptide..". The board construes that granted claim as relating to variants of a "parent" polypeptide where said parent polypeptide is an IgG polypeptide. On the other hand, claim 1 as amended relates to variants of any "parent" Fc polypeptide. As such, the pool of "parent" polypeptides referred to in the amended claim is not restricted to IgG Fc polypeptides. This difference alone results in the amended claim including within its ambit, proteins not included within the ambit of the claim as granted, contrary to Article 123(3) EPC.

3. In the board's view, the (new) indication that the claimed protein comprises an "IgG Fc variant" is not an equivalent limitation to the claim. Rather, this feature is understood as indicating that the claimed protein has some characteristics of an IgG. However, as these 'characteristics' are neither defined nor delimited they encompass an essentially unlimited degree of variation. The feature "IgG Fc variant" therefore does not compensate for the extension of scope of the claim caused by the change in definition of the parent polypeptide.
4. It follows from the above that the main request is not allowable.

Auxiliary request 1 - claim 1

5. Like claim 1 of the main request, this claim refers to "A protein comprising an IgG Fc variant of a parent Fc polypeptide" and fails to meet the requirements of Article 123(3) EPC for the same reasons as claim 1 of the main request.

Auxiliary request 2

6. The board admits the claim request into the proceedings. However, given that the claim request is not allowable (see point 7, below), the reasons for this are moot.
7. The board agrees with the opposition division that claim 1 of auxiliary request 2 relates to the same subject-matter as claim 1 of auxiliary request 1, since the only amendment vis-à-vis claim 1 of auxiliary request 1 is the placement in the claim of the indication that the claimed protein is an antibody (see page 7 of the decision under appeal). The claim therefore fails the requirements of Article 123(3) for the same reasons as the main request and auxiliary request 1.
8. No claim request is allowable and therefore the appeal must be dismissed. Under these circumstances remittal of the case need not be considered.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



I. Aperribay

M. Pregetter

Decision electronically authenticated