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**Datasheet for the decision
of 13 December 2019**

Case Number: T 1432/17 - 3.3.04

Application Number: 11188573.7

Publication Number: 2471813

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

Language of the proceedings: EN

Title of invention:
Optimized Fc variants

Patent Proprietor:
Xencor, Inc.

Opponent:
James Poole Limited

Headword:
Fc variants/ XENCOR

Relevant legal provisions:
EPC Art. 113(2)
RPBA Art. 12(4)

Keyword:
All requests - admitted into the proceedings (no)

Decisions cited:

Catchword:

-



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Case Number: T 1432/17 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 13 December 2019

Appellant: Xencor, Inc.
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Respondent: James Poole Limited
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Representative: Carpmaels & Ransford LLP
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 25 April 2017
revoking European patent No. 2471813 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chair G. Alt
Members: B. Claes
R. Romandini

Summary of Facts and Submissions

- I. The appeal of the patent proprietor (hereinafter "appellant") lies from the decision of the opposition division to revoke European patent No. 2 471 813, entitled "*Optimized Fc variants*".

Claim 1 of the patent as granted read:

"1. A polypeptide for use in a method of treatment comprising contacting effector cells expressing FcγRIIb with said polypeptide, wherein said polypeptide binds with greater affinity to the FcγRIIb receptor than a parent polypeptide and increases the inhibitory activity of the FcγRIIb receptor, and wherein said polypeptide comprises an Fc variant of said parent Fc polypeptide and wherein said Fc variant comprises an amino acid substitution S267E as compared to said parent Fc polypeptide, wherein said numbering is according to the EU index." (emphasis added by the board)

- II. In the decision under appeal the opposition division held *inter alia* that claim 1 of the main request and of auxiliary request 1 related to added subject-matter (Article 123(2) EPC). Auxiliary request 2, submitted during the oral proceedings, was not admitted into the opposition proceedings as it did not *prima facie* resolve the added subject-matter issues and introduced further problems.

Claim 1 of the main request was identical to claim 1 as granted with the exception that the method of treatment was qualified as "a method of treatment of autoimmune disease or inflammatory disease".

Claim 1 of auxiliary request 1 read:

"1. A polypeptide **for use in promoting anti-inflammatory activity or reducing autoimmunity** comprising contacting effector cells expressing FcγRIIb with said polypeptide, wherein said polypeptide binds with greater affinity to the FcγRIIb receptor than a parent polypeptide and increases the inhibitory activity of the FcγRIIb receptor, and wherein said polypeptide comprises an Fc variant of said parent Fc polypeptide and wherein said Fc variant comprises an amino acid substitution S267E as compared to said parent Fc polypeptide, wherein said numbering is according to the EU index." (emphasis added by the board)

III. With their statement of grounds of appeal the appellant submitted claims of a main request and five auxiliary requests - all these requests being newly filed in the proceedings - and arguments to the effect that claim 1 of the main request complied with the requirements of Article 123(2) EPC. It was also stated that auxiliary requests 1 to 5 satisfied the requirements of Article 123(2) EPC for at least the same reasons as those applying to claim 1 of the main request.

Claim 1 of the main request, which was based on claim 1 of the main request before the opposition division (see section II), read:

"1. A polypeptide for use in a method of treatment of autoimmune disease or inflammatory disease comprising contacting effector cells expressing FcγRIIb with said polypeptide, wherein said polypeptide binds with greater affinity to the FcγRIIb receptor than a parent

polypeptide and increases the inhibitory activity of the FcγRIIb receptor, and wherein said polypeptide comprises an Fc variant of said parent Fc polypeptide and wherein said Fc variant comprises an amino acid substitution S267E as compared to said parent Fc polypeptide, wherein said numbering is according to the EU index, **wherein said polypeptide is prepared for administration to a patient.**" (emphasis added by the board)

Claim 1 of auxiliary request 1, which was based on claim 1 of auxiliary request 1 before the opposition division (see section II), read:

"1. A polypeptide for use in promoting anti-inflammatory activity or reducing autoimmunity comprising contacting effector cells expressing FcγRIIb with said polypeptide, wherein said polypeptide binds with greater affinity to the FcγRIIb receptor than a parent polypeptide and increases the inhibitory activity of the FcγRIIb receptor, and wherein said polypeptide comprises an Fc variant of said parent Fc polypeptide and wherein said Fc variant comprises an amino acid substitution S267E as compared to said parent Fc polypeptide, wherein said numbering is according to the EU index, **wherein said polypeptide is prepared for administration to a patient.**"

Claim 1 of auxiliary request 2 was identical to claim 1 of the main request but with the alternative "or inflammatory disease" deleted.

Claim 1 of auxiliary request 3 was identical to claim 1 of the main request but with the alternative "autoimmune disease or" deleted.

Claim 1 of auxiliary request 4 was identical to claim 1 of auxiliary request 1 but with the alternative "or reducing autoimmunity" deleted.

Claim 1 of auxiliary request 5 was identical to claim 1 of auxiliary request 1 but with the alternative "in promoting anti-inflammatory activity or" deleted.

- IV. With their reply to the appeal, the respondent (opponent) requested *inter alia* that the new requests not be admitted into the proceedings and submitted arguments to the effect, *inter alia*, that the claims of the newly filed requests did not comply with the requirements of Articles 84 and 123(2) EPC.
- V. The board issued a communication pursuant to Article 15(1) RPBA in preparation for oral proceedings, informing the parties of the board's preliminary assessment of the appeal. It expressed the preliminary opinion that claim 1 of the main request lacked clarity (Article 84 EPC) and related to added subject-matter (Article 123(2) EPC). The same applied to claim 1 of each of the auxiliary requests. The board further stated that, on the basis of the parties' written submissions, it was provisionally inclined not to admit the new requests into the proceedings pursuant to Article 12(4) RPBA.
- VI. The appellant was neither present nor represented at the oral proceedings, as announced beforehand in writing. At the end of the oral proceedings the chair announced the board's decision.
- VII. The appellant requested in writing that the decision under appeal be set aside and that the claims of the main request and, alternatively, the claims of any of

auxiliary requests 1 to 5 be found to comply with the requirements of Article 123(2) EPC. They further requested that, if any new request was found to comply with the requirements of Article 123(2) EPC, the case be remitted to the opposition division for further prosecution.

The respondent (opponent) requested that the new main request and auxiliary requests 1 to 5 not be admitted into the proceedings and the appeal consequently be dismissed. As an auxiliary request, for the event that the board were to decide that the appeal were allowable, the respondent requested that the case be remitted to the opposition division for further prosecution.

Reasons for the Decision

1. The appeal is admissible.
2. The duly summoned appellant was not present or represented at the oral proceedings, as announced in writing. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the board continued with the proceedings in the appellant's absence and the party was treated as relying on their written submissions.

The board's communication pursuant to Article 15(1) RPBA

3. In its communication pursuant to Article 15(1) RPBA (see section V) the board informed the parties, in relation to the requirements of Article 123(2) EPC (see point 10 and 11), that it agreed with the opposition division that the feature "comprising contacting effector cells expressing FcyRIIb with said

polypeptide" meant that claim 1 of the main request as considered by the opposition division (see section II) related to *ex vivo* treatment methods (see decision under appeal, page 5, first full paragraph) because from a technical point of view the feature could not be equated with the administration of the polypeptide to a patient in order "*to allow it to contact in vivo to the receptor*" in question, as the appellant had argued in the opposition proceedings. The board also noted that the appellant had not presented any arguments to the effect that the application as filed disclosed *ex vivo* methods.

4. Claim 1 of each and every claim request submitted in the appeal proceedings (see section III) still comprised the same feature, albeit supplemented by the feature "**wherein said polypeptide is prepared for administration to a patient**".
5. As concerns this amendment the board noted in its communication (see point 12) that the standards for preparing polypeptides for administration to a patient and for *ex vivo* treatments did not necessarily differ. The added feature therefore did not imply any characteristics that altered the meaning of the feature "comprising contacting effector cells expressing FcγRIIb with said polypeptide" such that it was now, in context, limited to *in vivo* patient administrations of the claimed polypeptide. The board therefore held that claim 1 of the main request related to added subject-matter and did not comply with the requirements of Article 123(2) EPC (see point 15).
6. The board also noted in its communication (see point 16) that in view of its finding in point 12, claim 1 was unclear within the meaning of

Article 84 EPC. Whereas the appellant had argued that "Ex vivo methods are no longer embraced within claim 1" due to the amendment (see statement of grounds of appeal, page 7, point 4.3, second paragraph), the board considered that the skilled person was unable to discern which characteristics of the polypeptide prepared for administration to the patient could support this contention.

7. As claim 1 of each of the auxiliary requests likewise referred to the same contentious features as claim 1 of the main request, the board held that these requests did not comply with the requirements of Articles 84 and 123(2) EPC either (see point 17 of the communication).
8. After having noted that i) the board's findings on clarity and added subject-matter of the newly filed requests concurred with the respondent's submission that the new claim requests were not clearly allowable, ii) the newly filed claim requests could and should have been filed during the opposition proceedings because all the arguments on which the opposition division had based its decision had been discussed at the latest during the oral proceedings, and iii) the appellant had not presented any arguments in response to the respondent's request that the new requests not be admitted into the proceedings, the board announced that it was inclined not to admit the new requests into the proceedings pursuant to Article 12(4) RPBA (see points 19 to 22).

Main request and auxiliary requests 1 to 5 filed with the statement of grounds of appeal - admission into the proceedings (Article 12(4) RPBA)

9. Pursuant to Article 12(4) RPBA, the board has the discretion to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first-instance proceedings. The board thus has discretion to admit requests which could have been presented to the first instance but were not.
10. The six claim requests at issue (see section III) were all submitted for the first time in these appeal proceedings with the appellant's statement of the grounds of appeal. They all comprise the same inserted feature **"wherein said polypeptide is prepared for administration to a patient"**, which allegedly overcomes the opposition division's finding that the feature "comprising contacting effector cells expressing FcγRIIb with said polypeptide" related to added subject-matter (see point 3 above).
11. It needs to be established, therefore, whether or not the appellant could have been expected to have presented the claims of the auxiliary requests filed with the statement of grounds of appeal in the proceedings before the opposition division.
12. The factual situation as regards the objection under Article 123(2)EPC was identical at the time the appellant filed auxiliary request 2 (which was not admitted into the proceedings; see section II) during the oral proceedings before the opposition division, after the division had announced its opinion that the claims of the main request and auxiliary request 1 before it did not comply with these requirements, and

at the time the appellant filed the statement of grounds of appeal.

13. Thus, in the board's view, the claim requests submitted with the statement of grounds of appeal and on the basis of which the appellant is requesting the board to set aside the decision under appeal could - and should - have been filed during the opposition proceedings, at the latest during the oral proceedings.
14. The appellant has not provided any justification for not submitting the new claim requests until the appeal stage, and the appellant has not presented any arguments in response to the respondent's request in its reply to the appeal for the board not to admit the new claim requests into the proceedings.
15. In addition to the above procedural considerations, the board also abides by its finding in the communication pursuant to Article 15(1) RPBA that claim 1 of each and every claim request submitted with the statement of grounds of appeal fails to meet the requirements of Articles 84 and 123(2) EPC (see points 3 and 5 to 7 above). The appellant has not presented any arguments in this context either, or in response to the board's communication expressing these findings.
16. In view of the above considerations the board decided not to admit the main request and auxiliary requests 1 to 5, all filed with the statement of grounds of appeal, into the proceedings.
17. Since there were no pending claim requests in the appeal proceedings (Article 113(2) EPC), the board decided to dismiss the appeal.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



I. Aperribay

G. Alt

Decision electronically authenticated