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Datasheet for the decision of 26 May 2021

Case Number: T 2248/18 - 3.3.04

Application Number: 12158424.7

Publication Number: 2468302

IPC: A61K39/395, C07K16/24, A61P37/06

Language of the proceedings: EN

Title of invention:
New indications for anti-IL-1beta therapy

Applicant:
Novartis AG

Headword:
TRAPS therapy/NOVARTIS

Relevant legal provisions:
EPC Art. 84
RPBA 2020 Art. 13(2)

Keyword:
Main request - amendment after expiry of period in R. 100(2)
EPC communication - cogent reasons (no)
Claims - clarity (no)

Decisions cited:
J 0027/94, T 1707/17

Catchword:
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Case Number: T 2248/18 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 26 May 2021

Appellant: (Applicant)	Novartis AG Lichtstrasse 35 4056 Basel (CH)
Representative:	Rouquayrol, Céline Hélène Novartis Pharma AG Patent Department 4002 Basel (CH)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 13 April 2018 refusing European patent application No. 12158424.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The appeal is by the applicant (appellant) against the decision of the examining division to refuse European patent application No. 12158424.7, published as EP 2 468 302 ("the application") and entitled "*New indications for anti-IL-1beta therapy*". The application was filed as a divisional application of European patent application No. 08760116.7, published as EP 2 152 308.

II. The examining division refused the application for the sole reason that it did not disclose the claimed invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC).

Independent claim 1 and dependent claim 2 of the main request (ten claims) considered by the examining division read:

"1. A medicament for use in the treatment of an auto-inflammatory syndrome in a patient in need thereof, the medicament comprising a human IL-1 beta binding antibody, the antibody comprising:
a first domain having an amino acid sequence as shown in SEQ ID NO:1 and
a second domain having an amino acid sequence as shown in SEQ ID NO:2 and
wherein said auto-inflammatory syndrome is Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), and wherein said antibody is parenterally administered at a dose between 0.1-50 mg of said antibody per kg body weight of the patient.

2. The medicament for use according to claim 1, wherein said antibody is **ACZ885**." (emphasis added by the board)

III. With the statement of grounds of appeal, the appellant re-submitted the set of claims of the main request and submitted sets of claims of five auxiliary requests. They argued in favour of sufficiency of disclosure, in particular that the application disclosed the suitability of the antibody ACZ885 as a medicament for use in the treatment of TRAPS. They requested *inter alia* that the decision under appeal be set aside and oral proceedings on an auxiliary basis.

Claim 1 of auxiliary request 1 read:

"1. A medicament for use in the treatment of an auto-inflammatory syndrome in a patient in need thereof, the medicament comprising the human IL-1beta binding antibody **ACZ885** and wherein said auto-inflammatory syndrome is Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), and wherein said antibody is parenterally administered at a dose between 0.1-50 mg of said antibody per kg body weight of the patient." (emphasis added by the board)

Claim 1 of auxiliary request 2 was identical to claim 1 of auxiliary request 1 but for the insertion of the further wording "and wherein said antibody is administered once every week or less frequently" at the end of the claim.

Claim 1 of auxiliary request 3 further specified the administration to be "once every three weeks or less frequently".

Claim 1 of auxiliary request 4 was identical to claim 1 of auxiliary request 1 but for the amendment that the antibody was administered at a dose "between 1-10 mg" instead of "between 0.1-50 mg".

Claim 1 of auxiliary request 5 combined the amendments of claim 1 of auxiliary requests 2 and 4.

IV. The board issued a communication pursuant to Rule 100(2) EPC, accompanying the summons to oral proceedings, specifying that any reply thereto had to be filed within a period of 2 months.

In the communication, the board expressed the preliminary view that the application met the requirements of Article 83 EPC with respect to the main request. The board thus envisaged allowing the appeal. The board then gave reasons why it did not intend to grant the appellant's request for the case to be remitted to the examining division in this procedural situation, and stated that "*22. In the present communication therefore the board addresses the requirement of inventive step*". The board subsequently noted that "*23. Furthermore, in the context of the auxiliary requests (see further) certain further requirements of the EPC are addressed which also appear to apply,* mutatis mutandis*, to the claims of the main request*". Thereafter, the board expressed the preliminary opinion that the subject-matter of claim 1 of the main request did not involve an inventive step (Article 56 EPC). In relation to the auxiliary requests, the board expressed a number of further concerns, *inter alia* that, owing to the term "antibody ACZ885", claim 1 of each auxiliary request lacked clarity (Article 84 EPC).

V. The arguments submitted with the appellant's due reply of 18 December 2020 to the board's communication were limited to addressing the board's negative preliminary opinion on inventive step. The appellant concluded that the claimed invention met the requirements of the EPC. New auxiliary requests 1 and 2 were submitted and former auxiliary requests 1 to 5 (see section III) were re-numbered as auxiliary requests 3 to 7, respectively.

Although claim 1 of both new auxiliary requests comprised amendments as compared to claim 1 of the main request, claim 2 of each of the new auxiliary requests was identical to claim 2 of the main request (see section II).

VI. During oral proceedings the appellant submitted a set of claims of a new main request (eight claims). The former main request was re-numbered auxiliary request 1 and the former auxiliary requests 1 to 7 (see section V) were re-numbered as auxiliary requests 2 to 8, respectively. The claims of the new main request were identical to the claims of the former main request but for the deletion of the former dependent claims 2 and 10. At the end of the oral proceedings the chair announced the board's decision.

VII. The appellant's arguments relevant to this decision may be summarised as follows:

Main request - admittance into the proceedings (Article 13(2) RPBA 2020)

That the new main request had not been filed earlier was due to an oversight on the part of the appellant that the board's concerns on the clarity of the term

"antibody ACZ885" expressed in the communication pursuant to Rule 100(2) EPC also applied to dependent claim 2 of the pending main request. The board could have emphasised these concerns more clearly and prominently in the communication in order to facilitate an appropriate and timely reaction by the appellant.

Compared with the set of claims of the former main request, in the new main request the dependent claims referring to the term "antibody ACZ885" had been deleted.

For reasons of overall efficiency it was "*better*" to obtain a decision of the board in respect of the invention of independent claim 1 (which lacked any reference to the term "antibody ACZ885"), since most likely, in an appeal relating to a divisional application of the application underlying the present case, the board would need to decide whether the subject-matter of claim 1 was allowable.

Not taking into account the main request pursuant to Article 13(2) RPBA 2020 and subsequently dismissing the appeal for this reason alone was "*unproportionate*".

Auxiliary requests 1 to 8 - clarity (Article 84 EPC)

The appellant did not submit arguments dissenting from the board's preliminary opinion expressed in this context (see section IV).

VIII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims of the main request filed during the oral proceedings or, alternatively, on the basis of the set of claims of auxiliary request 1, which was the

request underlying the decision under appeal, or of auxiliary requests 2 and 3, which were filed as auxiliary requests 1 and 2 with the letter of 18 December 2020, or of auxiliary requests 4 to 8, which were filed as auxiliary requests 1 to 5 with the statement setting out the grounds of appeal.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is admissible.

Main request - admittance into the proceedings (Article 13(2) RPBA 2020)

2. The claims of the main request are identical to the claims of the former main request (now auxiliary request 1) except that the former dependent claims 2 and 10, which included the term "antibody ACZ885", have been deleted. The request was filed by the appellant at the beginning of the oral proceedings after the board had invited the appellant to comment on the opinion which the board had expressed in the communication pursuant to Rule 100(2) EPC accompanying the summons to oral proceedings (see section IV), in particular on the issue that the term "antibody ACZ885" recited in the claims of the former main request was not clear (Article 84 EPC). The appellant has not disputed this preliminary opinion.

3. The new request constitutes an amendment to the appellant's appeal case made after the expiry of the period specified in a communication pursuant to Rule 100(2) EPC (here 2 months). Furthermore, it was filed in a late phase of the already advanced stage of

the proceedings, namely at the hearing, see Article 13(2) RPBA 2020.

4. Such an amendment to a party's appeal case shall in principle not be taken into account in the appeal proceedings unless there are "exceptional circumstances which have been justified with cogent reasons by the party concerned" (Article 13(2) RPBA 2020). This provision has two implications: it requires the party firstly to explain what the "exceptional circumstances" are and secondly to provide cogent reasons both for the content and for the timing of the amendment, i.e. why the amendment represents a justified response to those circumstances and why it was not possible to file such an amendment earlier (see also decision T 1707/17, point 2.2).

5. The appellant declared at the oral proceedings that they had overlooked the fact that the board's concerns on the clarity of the term "antibody ACZ885" expressed in the communication pursuant to Rule 100(2) EPC in the context of the auxiliary requests also applied to dependent claim 2 of the pending main request. Although the appellant expressed that the board could have emphasised these concerns more clearly and prominently in the communication in order to facilitate an appropriate and timely reaction, they acknowledged in the same context that the board's concerns in relation to clarity doubtless also concerned the claims of the then-pending main request, and not only claim 1 of this request.

6. The board does not consider an oversight of a relevant fact by an appellant to consititute an exceptional circumstance which can justify filing the new main request only at the hearing. This is true at least when

the board has not contributed to such an oversight, for instance in the case where a communication contains no ambiguities. In fact, to find otherwise would deprive communications sent under Rule 100(2) EPC of any practical and legal significance. Indeed, with the communication at hand, the board intended primarily to solicit a reaction on the part of the appellant within the time limit set in the communication. In view of this background, the new requests not only could but should have been presented prior to the oral proceedings.

7. The appellant's argument that the request should be admitted into the proceedings because a divisional application was pending and a decision on the merits of this request in the case at hand would promote "overall efficiency" is not persuasive for two reasons.

8. Firstly, the existence of a divisional application is not an exceptional circumstance within the meaning of Article 13(2) RPBA 2020. By contrast, it is a rather common occurrence.

9. Secondly, procedural economy may be a relevant criterion in exercising the discretion conferred under Article 114 EPC, even at such a late stage of the proceedings. However, the criterion refers to the very procedure in which a discretionary decision is to be made, and not to other proceedings, albeit related.

10. Moreover, it is at least questionable that a decision on the parent application would have a *res judicata* effect in subsequent proceedings concerning a divisional application, and *vice versa*. This is true even where the claimed subject-matter and the state of the art cited are identical. Indeed, the EPC deals only

with the binding effect of the *ratio decidendi* of a decision within the same proceedings (see Article 111(2) EPC).

11. The appellant's argument that it was not proportionate not to admit the new requests and to reject the appeal for this reason alone cannot convince the board either. While it may remain undecided whether the board should apply a "proportionality test" in deciding whether or not to admit a new request, this principle cannot imply that a board is obliged to consider late-filed requests if they overcome issues previously identified in the proceedings. This would be in conflict with the Boards' Rules of Procedure, which under Article 13(2) RPBA require "exceptional circumstances" for the admittance of late-filed amendments. Under this provision, clear allowability of a request is therefore not sufficient. Only for the sake of completeness, therefore, the board refers to the fact that the communication sent pursuant to Rule 100(2) EPC also contained the board's preliminary opinion that the claimed subject-matter lacked inventive step (Article 56 EPC).

12. For the reasons set out above the board, in accordance with Article 13(2) RPBA, did not consider the amended main request filed during the oral proceedings.

Auxiliary requests 1 to 8 - clarity (Article 84 EPC)

13. Claim 2 of auxiliary requests 1 to 3 and claim 1 of auxiliary requests 4 to 8 relates to an anti-human IL-1 beta antibody designated "ACZ885".

14. In paragraph [0021] the application refers to ACZ885 as an antibody being "*hereinafter described in the Examples and in WO 02/16436*". Example 1 of the

application makes a reference to the same patent document for the structure and making of ACZ885 and states that "[i]*n short, the amino-terminal sequences of heavy and light chain variable domains (...) are given in SEQ ID NO:1 and SEQ ID NO:2 below ...*" (see paragraph [0056]). The amino acid sequences of SEQ ID NO:1 and SEQ ID NO:2 are depicted in paragraphs [0057] and [0058], respectively.

15. The limited size of SEQ ID NO:1 (118 amino acids) and SEQ ID NO:2 (107 amino acids) reveals that they represent only parts of the complete sequence of the (monoclonal) antibody designated ACZ885. The application does not define the antibody designated by "ACZ885" precisely, but rather refers to an earlier international patent application WO 2002/16436.

16. However, WO 2002/16436 contains only a structural definition of the antibody which does not go beyond a reference to the same partial sequences as disclosed in the application. Furthermore, the document does not disclose that the hybridoma-producing monoclonal antibody "ACZ885" has not been deposited.

17. The board therefore concludes that the term "ACZ885" does not have a precise and unambiguous technical meaning. The term "antibody ACZ885", and thus claim 2 of auxiliary requests 1 to 3 and claim 1 of auxiliary requests 4 to 8, lacks clarity (Article 84 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

A. Chavinier Tomsic G. Alt

Decision electronically authenticated