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**Datasheet for the decision
of 28 February 2020**

Case Number: T 0756/16 - 3.3.04

Application Number: 06800000.9

Publication Number: 1896073

IPC: A61K39/395, G01N33/567,
C07H21/04, C12P21/06, C07K16/24

Language of the proceedings: EN

Title of invention:
Anti-IL-23 antibodies, compositions, methods and uses

Patent Proprietor:
Janssen Biotech, Inc.

Opponents:
Boehringer Ingelheim Pharma GmbH & Co. KG
Merck Sharp & Dohme Corp.
Eli Lilly and Company

Headword:
Anti-IL-23 antibodies/JANSSEN

Relevant legal provisions:
RPBA Art. 13

Keyword:
Late-filed request - admitted (no)

Decisions cited:

Catchword:



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Case Number: T 0756/16 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 28 February 2020

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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
28 January 2016 concerning maintenance of the
European Patent No. 1896073 in amended form.

Composition of the Board:

Chairman B. Claes
Members: A. Chakravarty
G. Decker

Summary of Facts and Submissions

- I. European patent No. 1 896 073, entitled "*Anti-Il-23 antibodies, compositions, methods and uses*" was opposed by three opponents under Article 100(a) EPC 1973 in conjunction with Articles 54 and 56 EPC 1973 and under Articles 100(b) and (c) EPC 1973.
- II. The patent proprietor (appellant I) and all three opponents (appellants II, III and IV, respectively) filed appeals against the interlocutory decision of the opposition division that, account being taken of the amendments in the form of auxiliary request 3, the patent and the invention to which it related met the requirements of the EPC (Article 101(3) (a) EPC).
- III. Opponents 2 and 3 subsequently withdrew their oppositions and appeals. The patent proprietor and opponent 1 (appellants I and II) remain parties to the appeal.
- IV. In its decision, the opposition division, *inter alia*, held that the subject-matter of claim 1 of the main request did not comply with the requirements of Article 123(2) EPC. The subject-matter of claims 3 to 7 of auxiliary request 1 also did not comply with the requirements of Article 123(2) EPC, while claim 1 of auxiliary request 2 lacked clarity (Article 84 EPC 1973).
- V. The board appointed oral proceedings and subsequently issued a communication pursuant to Article 15(1) RPBA 2007, setting out its preliminary and non-binding appreciation of the substantive and legal matters concerning the appeals.

- VI. In response to this communication, with a letter dated 31 December 2019, appellant I submitted further auxiliary requests 4a to 11a.
- VII. At the oral proceedings appellant I designated auxiliary request 4a, filed with the letter dated 31 December 2019, as the main request and withdrew all other pending claim requests. At the end of the oral proceedings, the Chair announced the decision of the board.
- VIII. Appellant I requested that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims of the main request, filed as auxiliary request 4a with the letter dated 31 December 2019.
- IX. Appellant II requested that the decision under appeal be set aside and that the patent be revoked.
- X. Claim 1 as granted reads:

"1. An isolated IL-23p19 antibody, wherein said antibody binds to human IL-23p19 or a fragment thereof at an epitope comprising portions of SEQ ID NO: 1 comprising amino acid residues 93-102, 93-110, and 127-137 of SEQ ID NO: 1."

Claim 1 of the main request reads:

"1. An isolated IL-23p19 antibody, wherein said antibody binds to human IL-23p19 or a fragment thereof at one or more of amino acid residues 93-102, one or more of amino acid residues 93-110, and one or more of amino acid residues 127-137 of SEQ ID NO: 1".

XI. The arguments of appellant I relevant to the decision are summarised as follows.

Admittance of the main request (formerly auxiliary request 4a, filed with the letter dated 31 December 2019), into the appeal proceedings - Article 13(1) and (3) RPBA 2007, Article 25(3) RPBA 2020

This request should be admitted into the proceedings because the deletions made in claim 1 over the claim 1 as granted were occasioned by developments during the written phase of the appeal proceedings. In particular, they were a direct response to a new point raised by the board in its communication pursuant to Article 15(1) RPBA 2007 of 13 December 2019 (see paragraph 23). The request met all the requirements of Article 13(1) and (3) RPBA 2007 in that they did not raise issues which the board or the other party could not reasonably be expected to deal with without adjournment of the oral proceedings. They in fact did not extend the scope of discussion as determined by the grounds of appeal, thus they were not complex and therefore also met the need for procedural economy.

The claim request was clearly allowable since the amendments successfully addressed the added subject-matter issue raised by the board without giving rise to new ones. The amendments to claim 1 did not add matter as the claimed subject-matter had a basis in claim 1 as filed.

The deletion of the "epitope language" in the claim resulted in a narrower scope of protection than that of claim 1 as granted. The antibodies included in the

scope as now claimed had also been included in the scope of the claim granted, however they were now its sole subject-matter. Thus the claim request met the requirements of Article 123(3) EPC. Finally, the amendments did not introduce any unclarity *vis-à-vis* claim 1 as granted.

XII. The arguments of appellant II relevant to the decision are summarised as follows.

Admittance of the main request into the appeal proceedings

The claim request was not clearly allowable in the sense that it could be quickly ascertained that it overcomes all outstanding issues without raising new ones. Moreover, the "epitope language" had been objected to under Article 123(2) EPC by all opponents earlier in the appeal proceedings and had been under debate throughout the entire opposition proceedings. The request therefore could and should have been filed earlier.

Amended claim 1 further significantly increased the complexity of the issues to be discussed at the oral proceedings, including the new objection under Article 123(3) EPC.

The amendments in claim 1 did not address the other outstanding issues under Articles 54, 56 and 83 EPC 1973.

Consequently, the new claim request should not be admitted into the proceedings under Article 13 RPBA 2007.

Article 123(3) EPC

If there was the slightest risk that deletion of the epitope language extended the scope of protection, then the claim was not allowable under Article 123(3) EPC.

Removal of the "epitope language" from the claim removed certain limitations regarding the binding characteristics of the claimed antibody. For example, Appellant I had, in the written submissions on novelty over the disclosure in document D25, emphasised that certain amino acid residues could be bound by an antibody without these being part of an epitope. Such binding was previously excluded but now included in the scope of protection of the claim. Moreover, the requirement of binding a single amino acid in each of the three segments recited in claim 1 of the main request was clearly different from binding at least five amino acids of an epitope (this had been the proprietor's definition of an epitope).

For these reasons there was a significant danger that the claim as amended included subject-matter not encompassed by the claim as granted and contravened the requirements of Article 123(3) EPC.

Thus, the claim request was not clearly allowable.

Reasons for the Decision

1. The appeals comply with Articles 106 to 108 and Rule 99 EPC and are therefore admissible.
2. An amended version of the Rules of Procedure of the Boards of Appeal (RPBA 2020) came into force on 1 January 2020. The transitional provisions are set out in Article 25 RPBA 2020. In the present case, the parties were notified of the summons to oral proceedings before 1 January 2020. Therefore, Article 13(2) RPBA 2020 does not apply to the present case and instead Article 13 RPBA 2007 continues to apply (see Article 25(3) RPBA 2020).

Admissibility of the main request Article 13(1) and (3) RPBA 2007

3. The main request was filed after the summons to oral proceedings had been issued and the board's subsequent communication pursuant to Article 15(1) RPBA 2007 (see section V). No request in this form was previously filed in the appeal proceedings.
4. Pursuant to Article 13(1) RPBA 2007, "*any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the Board's discretion. The discretion shall be exercised in view of inter alia the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy*". For requests which are filed after oral proceedings have been arranged, Article 13(3) RPBA 2007 applies in addition. The boards regularly apply the criterion that a new request filed

after the summons to oral proceedings will only be admitted if the board is satisfied that it is clearly allowable, in the sense that it can be quickly ascertained that it overcomes all outstanding issues without raising new ones (see Case Law of the Boards of Appeal of the European Patent Office, 9th Edition 2019, V.A.4.5.1).

5. Claim 1 of the main request differs from claim 1 as granted in that the target of the claim antibody is defined differently. Specifically, instead of binding "to human IL-23p19 or a fragment thereof at an epitope comprising portions of SEQ ID NO: 1 comprising amino acid residues 93-102, 93-110, and 127-137 of SEQ ID NO: 1", the antibody now binds "to human IL-23-19 or a fragment thereof at one or more amino acid residues 93-102, one or more amino acid residues 92-110 and one or more amino acid residues 127-137 of SEQ ID NO: 1" (see section X above). In other words, the amendment replaces the feature that the claimed antibody binds *anywhere* in the human IL-23p19 molecule or a fragment thereof at an epitope comprising the recited amino acid segments, with the feature of binding *only* to the one or more amino acids within the particular recited segments.

6. The question to be answered is whether or not the claim request is clearly allowable. The board, without coming to a final view on the matter, considers, however, that the objections raised at least under Article 123(3) EPC (see section XII above) cannot be dismissed out of hand, i.e. without detailed consideration, since they are not spurious or *prima facie* incorrect. Thus, for this reason alone, the claim request is held to be not clearly allowable.

7. The board has also considered whether or not the main request could exceptionally be admitted into the proceedings at this stage, in view of its filing by appellant I (see section VI above) to address objections which, in appellant I's view, were first raised in the board's earlier communication pursuant to Article 15(1) RPBA 2007 (see section V above). The board notes, however, that the particular objection which the amendment in claim 1 seeks to overcome, i.e. that of added subject-matter pursuant to Article 123(2) EPC, was already raised in the statement of grounds of appeal of appellant II (see point 8.1.3). The board can therefore also see no exceptional reason for admitting the claim request into the proceedings.
8. Finally, the board notes that admitting the claim request would necessitate the board and the other party dealing with subject-matter which had not previously been the subject of the appeal proceedings. Thus, neither the board nor the other party in fact could prepare adequately and the admittance of the request would necessitate adjourning the oral proceedings. Accordingly, also these considerations relating to the complexity of the amendments made and of procedural economy speak against admitting the claim request.
9. In view of the above considerations, the board decided not to admit the main request into the appeal proceedings (Article 13 RPBA 2007).
10. Thus, no allowable claim request is in these appeal proceedings and the appeal of appellant I must be dismissed. As a consequence, and in line with appellant II's request, the appealed decision must be set aside and the patent must be revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chair:



I. Aperribay

B. Claes

Decision electronically authenticated