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Datasheet for the decision of 1 June 2010

Case Number: T 0495/09 - 3.3.04

Application Number: 00928991.9

Publication Number: 1176981

IPC: A61K 39/395

Language of the proceedings: EN

Title of invention:
Treatment of autoimmune diseases with antagonists which bind to B cell surface markers

Patentee:
Genentech, Inc., et al

Opponents:
01 Trubion Pharmaceuticals, Inc.
02 MEDIMMUNE, INC.
03 Elend, Almut Susanne
04 CENTOCOR, INC.
05 GLAXO GROUP LIMITED
06 Merck Serono SA
07 Genmab A/S
08 Wyeth

Headword:
Treatment of autoimmune diseases/GENENTECH

Relevant legal provisions:
EPC Art. 111(1), 123(2)
RPBA Art. 12(2), 13

Relevant legal provisions (EPC 1973):
-

Keyword:
"Admissibility auxiliary request - yes"
"Added matter - no"
"Remittal - yes"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0495/09 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 1 June 2010

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 16 December 2008 revoking European patent No. 1176981 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman: C. Rennie-Smith
Members: B. Claes
M. Wieser

Summary of Facts and Submissions

I. The appeal was lodged by the patent proprietors (appellants) against the decision of the opposition division, whereby the European patent No. 1 176 981 with the title "*Treatment of autoimmune diseases with antagonists which bind to B cell surface markers*" and published as WO 00/67796 was revoked.

The patent had been opposed by eight parties (opponents 01 to 08) under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC) and under Articles 100(b) and 100(c) EPC.

II. The decision of the opposition division was based on a main request and an auxiliary request, each consisting of two claims. Claims 1 and 2 of the main request before the opposition division read:

"1. Use of an anti-CD20 antibody in the manufacture of a medicament for treatment of rheumatoid arthritis in a mammal, wherein the medicament is for administration with methotrexate to the mammal.

2. Use according to claim 1 wherein the antibody comprises rituximab."

The claims of the auxiliary request read:

"1. Use of an anti-CD20 antibody in the manufacture of a medicament for treatment of rheumatoid arthritis in a mammal by administration with methotrexate.

2. Use according to claim 1 wherein the antibody comprises rituximab."

The opposition division decided that claim 1 of both requests infringed the requirements of Article 123(2) EPC. In its decision it did not deal with any of the grounds for opposition raised by the opponents, other than that under Article 100(c) EPC.

III. With the statement of grounds of appeal filed on 24 April 2009 the appellants requested that the decision under appeal be set aside, that the main request filed with the grounds of appeal be found to comply with Article 123(2) EPC, and that the case then be remitted to the opposition division for consideration of other issues raised in the oppositions. It was further stated:
"In the event that the Board does not find the Main Request to be allowable, we request the opportunity to make further amendments where such amendments address any concerns the Board has."

IV. By letters dated and faxed on respectively 26 March 2010 and 9 April 2010 respondent III (opponent 01) and the appellants, to enable them to prepare for the oral proceedings, asked the board whether it intended to deal solely with the ground of opposition resulting in the revocation, namely Article 100(c) EPC, or to deal with all the grounds of opposition. The appellants also submitted that such an indication would enable them to prepare final written submissions due on 30 April 2010.

V. The board replied in a communication dated 15 April 2010 that if at the oral proceedings it found a request

to comply with the requirements of Articles 100(c) and 123(2) EPC, the parties would then also be required to express their opinions on whether or not the case should be remitted to the first instance for further prosecution. While the board understood the wish of some parties to learn in advance what other issues (if any) might be discussed at the oral proceedings, it could not decide this before the issue of remittal had been decided. Taking into consideration all relevant factors including the scope of the written submissions, in which none of the parties had filed arguments on any other issue than Article 123(2) EPC, the board's provisional view was that remittal would be appropriate. Regarding the appellants' reference to final written submissions, the board said it did not expect any further written submissions which, in any event, would only be admissible in its discretion under Article 13 RPBA.

VI. In a letter dated and filed on 30 April 2010, the appellants made further written submissions in response to the board's communication and the written submissions of respondents I, II, III, VI and VIII (opponents 05, 07, 01, 03 and 08, respectively). In addition to repeating their requests in the statement of grounds of appeal (see section III, above) and presenting arguments in favour of remittal and against the respondents' submissions, they also filed an auxiliary request and supplied reasons why they considered this to comply with Article 123(2) EPC. The sole claim of this auxiliary request read:

"1. Use of rituximab in the manufacture of a medicament for treatment of rheumatoid arthritis in a mammal,

wherein the medicament is for administration with methotrexate to the mammal."

VII. Oral proceedings were held on 1 June 2010 in the absence of respondents IV, VII, V and VIII (opponents 02, 06, 04 and 08, respectively) who all had informed the board that they would not be represented at the oral proceedings.

VIII. The appellants' arguments, as far as they are relevant for the present decision, can be summarised as follows:

Admissibility of the auxiliary request filed on 30 April 2010

– This request contained only one claim which was effectively claim 2 of the main request before the opposition division. Thus, the claim inherently had already been present in the proceedings then and the respondents could not have been surprised by the request. It could therefore not be considered as being late filed.

– When asked by the board at the oral proceedings why the auxiliary request had not been filed with the statement of grounds of appeal, the appellants submitted that they had been surprised not to have received a preliminary opinion from the board on their main request which would have allowed them to decide whether an auxiliary request was necessary. Accordingly the auxiliary request had been filed to overcome any objections under Article 123(2) EPC which the board might have to the main request. It represented a fall-back

position which the respondents could expect if the main request should fail.

Article 123(2) EPC

– The claim was based on claims 1, 4, 9 and 20 and on example 1 on page 25 of the original application and met the requirements of Article 123(2) EPC.

Remittal

– As the opposition division had not dealt with any other issue besides Article 123(2) EPC, the case had to be remitted for further prosecution (Article 111(1) EPC).

IX. The respondents' arguments, as far as they are relevant for the present decision, can be summarised as follows:

Admissibility of the auxiliary request flied on 30 April 2010

– None of the respondents presented any arguments as to the admissibility of the appellants' auxiliary request. Respondent III (opponent 01) was prepared to abide by the board's exercise of its discretion. The other respondents present at the oral proceedings made no observations.

Article 123(2) EPC

– The claims as originally filed contained a long list of pharmacologically active compounds and a

long list of diseases. They did not disclose the combination of rituximab and rheumatoid arthritis (RA).

– Example 1 referred to the treatment of RA with rituximab. It contained a long list of agents employed for treating RA, including methotraxate, to be used in addition to rituximab. However, the patients preferably were treated with rituximab only. The example was a specific embodiment of the claimed invention and disclosed the route of administration and the exact dosage regime of rituximab to be used for the treatment of RA. It was not in agreement with the requirements of Article 123(2) EPC to select, by way of "cherry-picking", only one specific feature of the treatment of example 1, namely methotraxate, and neglecting all others (such as the route of administration or the dosage regimen).

Remittal

– Respondent III (opponent 01) explicitly argued that in case the board should decide that appellants' request meets the requirements of Article 123(2) EPC, the case should be remitted to the opposition Division for further prosecution.

X. The appellants requested that the decision under appeal be set aside and the case be remitted to the opposition division for further prosecution based on the auxiliary request filed on 30 April 2010.

All respondents (opponents 01 to 08), either only in writing or at the oral proceedings requested that the appeal be dismissed. Respondent III (Opponent 01) requested, as auxiliary request that the case be remitted to the opposition division for further prosecution based on the auxiliary request filed on 30 April 2010.

Reasons for the Decision

1. The appeal is admissible.

Admissibility of the auxiliary request flied on 30 April 2010

2. The appellants' auxiliary request, having been filed both after their statement of grounds of appeal and after oral proceedings had been arranged, had to be considered in the light of Article 13 RPBA. Since the request was simply claim 2 of the main request, neither complexity nor procedural economy nor the provision in Article 13(3) RPBA suggested non-admissibility, but the current state of the proceedings was more pertinent. It appears from their notice of appeal (see section III, above) that the appellants originally intended to file an auxiliary request, but then filed only a main request with their statement of grounds of appeal and made a purported request for an "opportunity to make further amendments where such amendments address any concerns the Board has" (*ibid*). Their subsequent argument - that the auxiliary request was not filed with the grounds of appeal because the board did not give them a preliminary opinion on their main request which would have allowed them to decide whether an

auxiliary request was necessary - is wholly implausible because it was always possible that, as happened, the board would not give such an opinion.

3. If the appellants wished the board to consider two attempts to overcome the decision under appeal, they should have set out both in their statement of grounds of appeal and, by not doing so, they failed to meet the complete case requirement of Article 12(2) RPBA. That was unfair on the respondents who did not know until a month before the oral proceedings of the appellants' "fall-back position". Even if, as the appellants also argued, the respondents could have expected such a fall-back position, that possibility cannot justify non-compliance with the rules of procedure - patent proceedings are not guessing games. Fortunately for the appellants, the absence of objection by the respondents allowed the board to exercise its discretion, on balance in a borderline case, in favour of admissibility of the auxiliary request.

Article 123(2) EPC

4. Claim 1 of the auxiliary request refers to the treatment of rheumatoid arthritis (RA) by combined administration of rituximab and methotraxate. The application as published mentions methotraxate only five times. Three times on page 9, in a long list of "chemotherapeutic agents", once on page 15, line 1 in a shorter list of "cytotoxic agents", and once in example 1 on page 25, line 15.

5. Example 1, on page 25, lines 9 to 10, discloses the treatment of patients with clinical diagnosis of RA

with rituximab (RITUXAN^{R}). In lines 10 to 16 it contains a list of possible agents to be administered to the patients together with rituximab. This list includes methotraxate (page 25, line 15). Immediately thereafter it is stated that preferably rituximab is used as the only active agent and the route of administration (i.e. intravenously (IV)) and an exact dosage regimen for rituximab are given (page 25, lines 17 to 23). These specific features (IV administration and dosage regimen) are part of a treatment of an RA patient with rituximab alone. No such restrictions are given in example 1 for a combined treatment with rituximab and methotraxate which are described in a generic way only.

6. The respondents' argument, that the appellants had "cherry-picked" one feature from the disclosure in example 1 and neglected all others is therefore without merit.

7. The board arrives therefore at the decision that claim 1 of the auxiliary request filed on 30 April 2010 has a basis in example 1 (see exactly page 25, lines 9 to 16) of the application as published.

Remittal

8. Pursuant to Article 111(1) EPC the board of appeal may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution.

9. Although Article 111(1) EPC does not guarantee an absolute right to have all the issues in the case

considered by two instances, it is well recognised that parties should preferably be given the opportunity to have two instances consider the important elements of their case. The essential function of appeal proceedings is to consider whether the decision which has been issued by the first instance department is correct. Hence, a case is normally remitted if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

10. In particular, remittal is taken into consideration by the boards in cases where a first instance department issues a decision solely upon one particular issue which is decisive for the case against one party and leaves other essential issues outstanding. If, following appeal proceedings, this party's appeal on the particular issue is allowed, the case is normally remitted to the first instance department for consideration of the undecided issues.

12. The opposition division in the decision under appeal has only dealt with the question of amendments in relation to Article 100(c) EPC, without touching upon any other substantive requirements of the EPC. Therefore the board exercises its discretion under Article 111(1) EPC to remit the case to the opposition division for further prosecution.

Order

For these reasons it is decided:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition Division for further prosecution on the basis of the auxiliary request filed on 30 April 2010.

Registrar: Chairman:

P. Cremona C. Rennie-Smith