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D E C I S I O N
of 3 December 2004

Case Number: T 0964/01 - 3.3.4
Application Number: 91917891.3
Publication Number: 0504363
IPC: C07K 16/06, C12P 21/08
Language of the proceedings: EN

Title of invention:
Purified IgG antibodies

Patentee:
THE WELLCOME FOUNDATION LIMITED

Opponents:
Lonza AG
Chugai Seiyaku Kabushiki Kaisha
F. Hoffmann-LaRoche AG

Headword:
IgG antibodies/THE WELLCOME FOUNDATION LIMITED

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

Keyword:
"Added subject-matter - new main request and auxiliary request
- (no)"
"Remittal to first instance department - (yes)"

Decisions cited:
-

Catchword:
-



Case Number: T 0964/01 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 3 December 2004

Appellant: THE WELLCOME FOUNDATION LIMITED
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted 18 June 2001
revoking European patent No. 0504363 pursuant
to Article 102(1) EPC.**

Composition of the Board:

Chairman: R. Moufang
Members: A. L. L. Marie
R. E. Gramaglia

Summary of Facts and Submissions

I. The appeal lies from the decision of the opposition division dated 18 June 2001 to revoke the European patent No. 0 504 363 pursuant to Article 102(1) EPC on the ground that the subject-matter of claim 1 of the then main request of the appellant (patentee) contravened the requirements of Article 123(2) EPC. The opposition division did not decide on the further grounds of opposition under Article 100(a) and (b).

II. With letter of 9 August 2004 the respondent III (intervener = opponent 3) informed the board that the infringement proceedings instituted against it by the appellant before the Landgericht Düsseldorf were no longer pending.

III. With letter of 7 September 2004 the appellant submitted a new main request consisting of claims 1 to 23.

Claim 1 read:

"A process for obtaining a purified preparation of an anti-CDw52 IgG antibody prepared using a recombinant expression system, which process comprises:

(a) applying an aqueous solution of the antibody to a Protein A or Protein G column so as to absorb the antibody onto the column and then eluting the antibody with an acidic solution of a pH from 3.0 to 3.5;

(b) applying the acidic eluate to an ion-exchange column of charged particles so as to absorb the antibody onto the column and then eluting the antibody with an aqueous solution of counter-charged ions; and

(c) applying the aqueous eluate to a size exclusion column of porous particles so as to retain non-antibody

molecules in the porous particles and to obtain the desired antibody in selected fractions eluted from the column which contain less than 2% of antibody aggregate as measured on size exclusion chromatography."

- IV. In a communication dated 17 September 2004 the Board indicated its provisional view that the subject-matter of the claims of the new main request met the requirements of Article 123(2) EPC and that the case should be remitted to the first instance. Furthermore the Board drew attention to a typographical error in claim 13 of the new main request.

- V. With letter of 12 October 2004 the appellant submitted a retyped version of the sets of claims of the new main request including a corrected claim 13.

- VI. The respondents did not put forward any objection under Article 123(2) EPC against the claims of the main request.

- VII. The appellant requested that the decision of the opposition division be set aside and the patent be maintained on the basis of the claims of the new main request filed with the letter of 12 October 2004 or, as an auxiliary request, on the basis of the claims of the auxiliary request filed with the statement of grounds of appeal. The appellant further requested that the case be remitted to the first instance for consideration of the further issues raised by the opponents.

- VIII. The respondents I, II and III (opponent 1, 2 and 3) requested that the appeal be dismissed.

IX. Respondent I did not request oral proceedings. The appellant and respondents II and III withdrew their requests for oral proceedings on condition that the Board finds that the main request meets the requirements of Article 123(2) EPC and remits the case to the opposition division for further prosecution.

Reasons for the decision

1. The appeal satisfies the requirements of Articles 106 to 108 and Rule 64 EPC and is therefore admissible.
2. Respondent III became party to the opposition proceedings due to its intervention pursuant to Article 105 EPC before the first instance. The party status is not negatively affected by the fact that the infringement proceedings instituted against it by the appellant before the Landgericht Düsseldorf are no longer pending. Although the institution of infringement proceedings (or proceedings for declaration of non-infringement) is a prerequisite for an admissible intervention, Article 105 EPC does not make the party status of an intervener dependent on future developments of these proceedings.

Article 123(2) EPC

3. The subject-matter of the claims of the new main request is restricted to a process for obtaining a purified preparation of an anti-CD_w52 antibody, the preparation itself, a formulation containing such preparation and uses thereof in the manufacture of a

medicament. It thus corresponds to the introductory statement in the application as filed (page 1, first sentence) according to which "*(t)he present invention relates to a purified preparation of monoclonal antibodies against the antigen CD_w52, to their use in therapy and to processes for their production.*"

In general, claims 1, 13, 15 and 19 to 23 of the new main request are based on claim 8, claim 1, claim 14 and claim 16 respectively. The specific technical features mentioned in the claims of the new main request can be found in the application as filed, as shown by the following survey:

- the reference to Protein A and Protein G (claims 1 and 4), the pH of the acidic solution of from 3.0 to 3.5 (claim 1) and the amount of less than 2% (claim 1) or less than 0.5% (claim 14) of antibody aggregate corresponds to the disclosure on page 7 (lines 21 and 26) and page 5 (three last lines);
- the filtration and/or concentration by ultrafiltration (claim 2) are mentioned in the sentence bridging pages 6 and 7;
- the use of tris- or phosphate-buffered saline at a pH around 7.0 and the elution at pH of from 3.0 to 3.5 (claim 3) are disclosed in the last paragraph of page 7;
- the elution with citric acid (claim 5) can be found on page 7, lines 22 to 27;

- the use of a cation-exchange column in step (b) of the process of claim 1 (claim 6) is described on page 8, first paragraph;
- the ultrafiltration to which the antibody obtained is subjected (claim 7) is described on page 9, second paragraph;
- the recombinant expression system (claim 1), the use of CHO cells (claim 8) and of the glutamine synthetase amplification system (claim 9) are disclosed in Example 1C and on page 6 (first two paragraphs);
- reference to the use of a chimaeric antibody (claim 10), a CDR-grafted antibody (claim 11) or a human antibody (claim 12) is made on page 10, second paragraph;
- a purified preparation as disclosed in claims 13 and 14 is described on page 6 (first paragraph), on page 5 (last paragraph) and in the paragraph bridging pages 9 and 10;
- a formulation as described in claims 15 to 17 is found in the paragraph bridging pages 11 and 12;
- a purified preparation for use in immunotherapy as in claim 18 or its use in the manufacture of a medicament as in claims 19 to 23 can be found on page 11 (first two paragraphs).

Therefore, in the Board's view, the claims of the new main request do not contain any subject-matter which goes beyond the application as filed, so that the requirements of Article 123(2) EPC are fulfilled.

Remittal to the first instance

4. In accordance with Article 111(1) EPC, it is within the discretion of the Board to either exercise any power within the competence of the first instance or to remit the case to the first instance for further prosecution. The decision under appeal revoked the patent on the sole ground that the main request before the opposition division did not comply with the requirements of Article 123(2) EPC. Thus the first instance did not decide on the further grounds of opposition under Article 100(a) and (b) EPC and expressed no view as to whether the claimed subject-matter fulfilled the requirements of Article 54, 56 and 83 EPC. Under these circumstances the Board considers it appropriate to allow the subject-matter of the claims of the new main request to be considered by two instances. Moreover, in view of the fact that the infringement proceedings against respondent III are no longer pending, the Board sees no particular need for acceleration through the exercise of the powers of the first instance with respect to the further grounds of opposition. Consequently the Board uses its discretion under Article 111(1) EPC by remitting the case to the opposition division for further prosecution.

Conditional requests for oral proceedings

5. Respondent I has not requested oral proceedings. The appellant and respondents II and III have withdrawn their requests for oral proceedings on condition that the Board finds that the main request meets the requirements of Article 123(2) EPC and remits the case to the opposition division for further prosecution. The Board can therefore reach its decision without oral proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division for further prosecution.

The Registrar:

The Chairman:

P. Cremona

R. Moufang