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# Datasheet for the decision of 27 November 2007

**Case Number:** T 0328/04 - 3.3.04

**Application Number:** 94926660.5

**Publication Number:** 0742721

**IPC:** A61K 39/395

**Language of the proceedings:** EN

**Title of invention:**
Methods of prolonged suppression of humoral immunity

**Patentee:**
Trustees of Dartmouth College

**Opponent:**
BIOGEN IDEC MA INC.

**Headword:**
Humoral immunity/DARTMOUTH COLLEGE

**Relevant legal provisions (EPC 1973):**
EPC Art. 83
EPC R. 28
PCT Art. 27(4)
PCT R. 13bis.3 and 4
RPBA Art. 10b(1)

**Keyword:**
"Sufficiency of disclosure (no)"

**Decisions cited:**
G 0002/93

**Catchword:**
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

**Case Number:** T 0328/04 - 3.3.04

# D E C I S I O N
**of the Technical Board of Appeal 3.3.04**
**of 27 November 2007**

**Appellant:** (Patent Proprietor)
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**Decision under appeal:**
**Decision of the Opposition Division of the European Patent Office posted 17 November 2003 revoking European patent No. 0742721 pursuant to Article 102(1) EPC.**

**Composition of the Board:**

**Chair:** U. Kinkeldey
**Members:** B. Claes
R. Moufang

## Summary of Facts and Submissions

I. International patent application PCT/US94/09872 was filed on 2 September 1994 and published on 9 March 1995 as WO 95/06480 with the title "Methods of prolonged suppression of humoral immunity". It claims priority from US08/115,990 filed on 2 September 1993, and US08/232,929 filed on 25 April 1994.

On page 23, lines 14 to 18, the international application as published stated:

"The 89-76 and 24-31 hybridomas, producing the 89-76 and 24-31 antibodies, respectively, were deposited under the provisions of the Budapest Treaty with the American Type Culture Collection, Parklawn Drive, Rockville, Md., on September 2, 1994. The 89-76 hybridoma was assigned ATCC Accession Number ____ and the 24-31 hybridoma was assigned ATCC Accession Number ____."

Similarly, the international application as published referred in claims 11, 21 and 31 to "monoclonal antibody 24-31 (ATCC Accession No.____)" and in claims 12, 22 and 32 to "monoclonal antibody 89-76 (ATCC Accession No.____)".

II. On 23 November 1995, the EPO completed the International Preliminary Examination Report (IPER) for the international application. Basis of the report was the international application as originally filed (see point I.1. of the IPER). Furthermore, point VII.1. of the IPER stated:

"*The lack of deposit accession numbers in claims 11, 12, 21, 22, 31 and 32 and on page 23, lines 14 - 18 means that the application does not meet the requirements of Rule 13$^{bis}$.3(a)(iii) PCT. Furthermore, the time limit for furnishing the relevant information has expired (see Rule 13$^{bis}$.4 PCT).*"

III. On 2 April 1996 the international patent application entered into the regional phase before the EPO as elected Office as European patent application No. 94926660.5. On form 1200 the applicant declared in item 6.2:

"Proceedings before the EPO as elected Office (PCT II) are to be based on the following documents: the documents on which the international preliminary examination report is based, including any annexes enclosed in triplicate unless replaced by the amendments enclosed in triplicate."

Enclosed the applicant submitted replacement page 23 and amended claims 1 to 27. On page 23, lines 14 to 18 of the replacement page it stated:

"The 89-76 and 24-31 hybridomas, producing the 89-76 and 24-31 antibodies, respectively, were deposited under the provisions of the Budapest Treaty with the American Type Culture Collection, Parklawn Drive, Rockville, Md., on September 2, 1994. The 89-76 hybridoma was assigned ATCC Accession Number **HB 11713** and the 24-31 hybridoma was assigned ATCC Accession Number **HB 11712**." (emphasis added by the board)

Amended claim 22 referred to "monoclonal antibody 24-31 (ATCC No. **HB11712**) or monoclonal antibody 89-76 (ATCC No. **HB11713**)." (emphasis added by the board)

The applicant declared further on form 1200 in item 8.:

"The invention relates to one or more micro-organism(s) deposited with a recognised depository institution under Rule 28(1)(a) EPC. The particulars referred to in Rule 28(1)(c) EPC are given in the international publication or in the translation submitted under Section 7 on p. 23, l. 14-18, p. 23, l. 30, to p. 24, l. 1-2. The receipt(s) of deposit issued by the depository institution will be filed at a later date."

IV. The relevant deposit receipt was filed with letter dated 23 September 1996 stating that the deposits were received by the depositary institution on 2 September 1994.

V. The communication under Rule 51(4) EPC dated 13 May 1998 stated that the examining division intended to grant a European patent with a description on the basis of pages 3 to 22 and 24 to 27 as published, page 23 as received on 2 April 1996, page 1 as received on 1 July 1997 and pages 2, 2a and 2b as received on 1 April 1998.

VI. The mention of the grant of the patent (European patent No. 0 742 721) was published on 6 May 1999. Claims 1 and 19 to 21 of the patent read:

"1. A pharmaceutical composition comprising a thus-dependent (*sic*) (TD) antigen and a gp39 antagonist."

"19. The composition or use of any of claims 1 to 18 wherein the antagonist is an anti-gp39 antibody."

"20. The composition or use of claim 19, wherein the anti-gp39 antibody is a monoclonal antibody."

"21. The composition or use of claim 20, wherein the anti-gp39 antibody is monoclonal antibody 24-31 (ATCC No. **HB11712**) or 89-76 (ATCC No. **HB11713**)". (emphasis added by the board)

Point (43) on the cover sheet of the published patent states: "Date of publication of application: 20.11.1996 Bulletin 1996/47".

VII. The patent was opposed invoking the grounds of opposition under Article 100(a) EPC, in particular lack of novelty and inventive step, and Articles 100(b) and 100(c) EPC.

VIII. The appeal was lodged by the patent proprietor (appellant) against the decision of the opposition division to revoke the patent pursuant to Article 102(1) EPC. With the statement of the grounds for appeal the appellant filed a main request and two auxiliary requests.

IX. Oral proceedings were held on 27 November 2007 in the absence of the respondent (opponent) who had informed the board with letter dated 26 October 2007 that he would not be represented at the oral proceedings. During the oral proceedings, the appellant filed a new main request, replacing the previous requests.

Claim 1 of the new main request read:

"1. A pharmaceutical composition comprising a gp39 antagonist and a thymus-dependent (TD) antigen selected from a proteinaceous antigen or an allergen, **wherein the gp39 antagonist is an anti-gp39 antibody selected from mAb 89-76 or 24-31, or a humanised or chimaeric form thereof**." (emphasis added by the board).

X. The submissions by the appellant, as far as they are relevant for the present decision, may be summarised as follows:

– In the present case, Rule 28 EPC was more favorable to the applicant in respect of the time limits for furnishing the indications relating to deposited biological material than those of Rule $13^{bis}$.3 PCT as in force from 1 July 1992. Accordingly, the provisions of Article 27(4) PCT applied.

– Rule 28(2)(a) EPC provided that the time limit for submission of information referred to in Rule 28(1)(c) EPC, i.e. the depositary institution and the accession number of the deposited biological material, is deemed to have been met if the information is communicated before completion of the technical preparations for publication of the European patent application.

– Since the cover sheet of the published patent states in point (43) that "the date of the publication of application" is 20 November 1996 (see section VI above), this should be taken as

the relevant date for the purpose of Rule 28(2)(a) EPC. The information as filed upon entry into the regional phase before the EPO as designated Office, i.e. on 2 April 1996, was thus well before completion of the technical preparations for publication of the European patent application as required by Rule 28(2)(a) EPC. Claim 1 of the main request therefore complied with the requirements of Article 83 EPC.

XI. The respondent has submitted the following arguments during the opposition proceedings which are relevant for the present decision:

– The applicant had only indicated the ATCC accession numbers for both monoclonal antibodies 24-31 and 89-76 on 2 April 1996, i.e. upon entry of the international application into the regional phase before the EPO. This date was beyond the time limit set by Rule 28(2)(a) EPC for submitting such indications.

– The skilled person was unable to reproduce the identical antibodies as deposited at the ATCC. Accordingly any subject-matter referring to the deposited monoclonal antibodies was not sufficiently disclosed.

XII. The appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request filed at the oral proceedings.

The respondent had requested in writing to dismiss the appeal.

## Reasons for the Decision

*Admission of the main request into the proceedings*

1. Independent claims 1, 3 and 7 of the **new** main request differ from the independent claims 1, 3 and 7 of the main request previously before the board *inter alia* in that the claims now define the gp39 antagonist as being "an anti-39 antibody selected from mAb 89-76 or 24-31, or a humanised or chimaeric form thereof".

2. The board considers that since the subject-matter of the independent claims of the main request has been restricted to particular monoclonal antibodies (mAb) as gp39 antagonists as compared to the previous request on file, there is a *prima facie* presumption that these claims attend to the patentability issues arising in relation to the subject-matter of the previous main request, i.e. as filed with the statement of the grounds for appeal. Furthermore, the patent as granted, in claim 21 (see section VI above) already referred to these particular monoclonal antibodies (mAb) as preferred embodiments for the gp39 antagonist.

3. For the above reasons the board exercises its discretion provided for in Article 10b(1) of the Rules of procedure of the Boards of Appeal and admits the new main request into the proceedings.

*Sufficiency of disclosure*

4. Claim 1 of the new main request defines the gp39 antagonist comprised in the pharmaceutical composition as being "an anti-39 antibody selected from mAb 89-76 or 24-31, or a humanised or chimaeric form thereof" (see section IX.). It can be taken from paragraph [0076] of the patent in suit (the text of which is identical to the text on page 23, lines 14 to 18 of the replacement page to the application filed by the applicant upon entry into the regional phase before the EPO as elected Office (see section III)) that these mAbs are produced by the 89-76 and 24-31 hybridomas respectively, which were deposited under the provisions of the Budapest Treaty with the American Type Culture Collection on September 2, 1994, whereby the 89-76 hybridoma was assigned ATCC Accession Number **HB 11713** and the 24-31 hybridoma was assigned ATCC Accession Number **HB 11712**.

5. The board considers, and the contrary has not been argued by the appellant during the oral proceedings, that the subject-matter of claim 1, for the purpose of satisfying the requirement of sufficiency of disclosure under Article 83 EPC, must be read in conjunction with the deposit information for the hybridomas contained in the patent. The claimed invention is therefore a microbiological invention concerning deposited biological material which was not available to the public and which could not be described in such a manner as to enable the invention to be carried out by a person skilled in the art.

6. The patent application underlying the patent in suit has been filed as an international patent application on 2 September 1994, claims priority from a first US

patent application filed on 2 September 1993 and was published on 9 March 1995 (see section I above). Accordingly, Rule 13$^{bis}$ PCT entitled "Microbiological Inventions" of the Patent Cooperation Treaty (PCT) as in force at the relevant period, i.e. from the date of filing of the application (2 September 1994) to its publication date (9 March 1995), applies to the present case.

7. Rule 13$^{bis}$.3 PCT applicable at the relevant period stipulated in paragraph (a) that a reference to a deposited microorganism shall indicate *inter alia* (iii) the accession number given to the deposit by the depositary institution with which the deposit was made, and provided in paragraph (b) that failure to include a reference to a deposited microorganism or failure to include, in a reference to a deposited microorganism, an indication in accordance with paragraph (a) shall have no consequence in any designated State whose national law did not require such reference or such indication in a national application.

8. The board notes that, since the EPC provides in Rule 28(1) that if an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in the European patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, the invention shall only be regarded as being disclosed as prescribed in Article 83 EPC if *inter alia* (c) the depositary institution and the accession number of the deposited biological material are stated in the application, the provision of Rule 13$^{bis}$.3(b) PCT does not apply.

9. Rule 13$^{bis}$ PCT applicable at the relevant period dealt with the time limit for the furnishing of the information required by Rule 13$^{bis}$.3(a) PCT. Rule 13$^{bis}$.4, first sentence, provided that if any of the indications referred to in Rule 13$^{bis}$.3(a) PCT was not included in a reference to deposited biological material in the international application as filed but was furnished by the applicant to the International Bureau within 16 months after the priority date, the indication should be considered by any designated Office to have been furnished in time unless its national law required the indication to be furnished at an earlier time in the case of a national application and the International Bureau (IB) had been notified of such agreement pursuant to Rule 13$^{bis}$.7(a)(ii) PCT, provided that the IB had published such requirement in the Gazette in accordance with Rule 13$^{bis}$.7(c) PCT at least two months before the filing of the international application.

In the last two sentences, Rule 13$^{bis}$.4 PCT provided that, irrespective of whether the applicable time limit under the preceding sentences has been observed, the IB should notify the applicant and the designated Offices of the date on which it had received any indication not included in the international application as filed, whereby the IB should indicate the date in the international publication of the international application if the indication has been furnished before the completion of the technical preparations for international publication.

10. The board notes that the international publication pamphlet of the international application, dated

9 March 1995, i.e. more than 18 months after the earliest priority date, neither contains the accession number given to the relevant deposits by the depositary institution with which the deposit was made as required by Rule 13$^{bis}$.3(a)(iii) PCT nor contains an indication to the effect that such indications have been made by the applicant.

11. The earliest reference to a document containing the deposit details as required by Rule 13$^{bis}$.3(a)(iii) PCT in the EPO dossier pertaining to the case was on 2 April 1996, i.e. 31 months after the earliest priority date and 19 months after the filing date, when the International patent application entered into the regional phase before the EPO as elected Office and replacement page 23 and amended claims 1 to 27 were submitted (see section III above).

In view of the above the board concludes that the indications referred to in Rule 13$^{bis}$.3(a) PCT as in force at the relevant period were not furnished by the applicant to the International Bureau within any of the time limits provided for by Rule 13$^{bis}$.4 of the same version of the PCT.

12. Article 27(4) PCT stipulates that where the national law provides, in respect of the form or contents of national applications, for requirements which, from the viewpoint of applicants, are more favorable than the requirements provided for by the Treaty and its Regulations in respect of international applications, the national Office, the courts and any other competent organs of or acting for the designated State may apply the former requirements, instead of the latter

requirements, to international applications, except where the applicant insists that the requirements provided for by the Treaty and the Regulations be applied to his international application.

13. The appellant has argued that in the present case Rule 28 EPC was more favorable to the applicant since the time limit for furnishing indications relating to deposited biological material was deemed to have been met if the information was communicated before completion of the technical preparations for publication of the European patent application. Therefore, Article 27(4) PCT should apply.

14. The board notes however, that the wording of Rule 28(2)(a) EPC applicable to the relevant period (see 7th and 8th edition of the EPC published in 1993 and 1995 respectively) read "within a period of sixteen months after the date of filing of the application or, if priority is claimed, after the priority date" and thus did not contain a reference to the completion of the technical preparations for publication of the European patent application. The appellant’s argument must therefore already fail for this reason alone. However, even if present Rule 28 EPC had to be applied, the information would have been filed beyond the time limits set in it:

Article 158(1) EPC provides that publication under Article 21 PCT of an international application for which the EPO is a designated Office shall, subject to paragraph (3), take the place of the publication of a European patent application and shall be mentioned in the European Patent Bulletin.

It is true, as pointed out by the appellant, that the published patent in point (43) on the cover sheet states: "Date of publication of application: 20.11.1996 Bulletin 1996/47". However, this statement merely reflects the implementation of the above provision of Article 158(1) EPC without thereby establishing a "new" publication date for the European patent application. Accordingly, for the purposes of Rule 28 EPC, the relevant publication date in the present case is 9 March 1995, i.e. the date of publication of the international application. The additional deposit information filed upon entry into the regional phase before the EPO as designated Office, i.e. on 2 April 1996, was therefore filed beyond the time limits as set by Rule 28 EPC.

15. For the above reasons, which are in line with decision G 2/93 of the Enlarged Board of Appeal (OJ EPO 1995, 275) ruling that the information concerning the file number of a culture deposit according to Rule 28(1)(c) EPC may not be submitted after expiry of the time limit set out in Rule 28(2)(a) EPC, neither the requirements of Rule 13$^{bis}$ PCT nor those of Rule 28 EPC, both as in force at the relevant period, have been satisfied.

Accordingly, the board concludes that the subject-matter to which claim 1 of the new main request refers is not sufficiently disclosed (Article 100(b) EPC).

## Order

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar | The Chair

P. Cremona | U. Kinkeldey