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**Datasheet for the decision
of 15 January 2008**

Case Number: T 1057/07 - 3.3.08

Application Number: 99925541.7

Publication Number: 1057000

IPC: G01N 33/53

Language of the proceedings: EN

Title of invention:

Methods for predicting pregnancy outcome in a subject by hCG assay

Applicants:

The Trustees of Columbia University in the City of New York

Headword:

hCG assay/COLUMBIA

Relevant legal provisions:

EPC Art. 123(2)
EPC R. 31

Relevant legal provisions (EPC 1973):

EPC R. 28

Keyword:

"Added matter (yes)"

Decisions cited:

G 0010/93

Catchword:

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Case Number: T 1057/07 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 15 January 2008

Appellants: The Trustees of Columbia University in the
City of New York
Broadway and West 116th Street
New York, NY 10027-6699 (US)

Representative: Lawrence, John
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 8 February 2007
refusing European application No. 99925541.7
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: L. Galligani
Members: T. J. H. Mennessier
C. Heath

Summary of Facts and Submissions

- I. The applicants (appellants) lodged an appeal against the decision of the examining division of 8 February 2007 refusing the European patent application No. 99 925 541.7 with publication number 1 057 000. The application entitled "Methods for Predicting Pregnancy Outcome in a Subject by hCG Assay" originated from an international patent application published as WO 99/41584 (referred to in the present decision as the "application as filed").
- II. The decision was based on the request filed on 8 November 2006 which was refused for reason of added matter (Article 123(2) EPC) and lack of clarity (Article 84 EPC).
- III. On 8 June 2007, the appellants filed a statement setting out the grounds of appeal which was accompanied by a new request (claims 1 to 28) to replace the request of 8 November 2006.

Claims 1 and 6 to 8 of the request read:

"1. A method for predicting pregnancy outcome in a subject by determining the amount of EPMI-hCG in a sample from the subject comprising the steps of:

- (a) (1) contacting a first portion of the sample from the subject with B152 antibody produced by the hybridoma cell line deposited with the American Type Culture Collection under Designation No. HB-12467;
- (2) contacting the sample resulting from (a) (1) with a second, labeled antibody which binds

to the complex formed by B152 antibody and EPMI-hCG;

- (3) measuring the amount of any bound second antibody in the sample, so as to thereby determine the amount of EPMI-hCG in the sample;
- (b) (1) contacting a second portion of the sample from the subject with a third antibody which binds to intact, non-nicked hCG;
- (2) contacting the sample resulting from (b)(1) with a fourth, labeled antibody which binds to intact non-nicked hCG simultaneously with the third antibody;
- (3) measuring the amount of bound fourth antibody in the sample, so as to thereby determine the amount of intact hCG in the sample; and
- (c) comparing the amount of EPMI-hCG in the sample determined in step (a)(3) with either the amount of EPMI-hCG determined in a sample from a temporally matched, normal pregnant subject or the amount of EPMI-hCG determined in a sample from a non-pregnant subject,

wherein an amount of EPMI-hCG in the subject's sample similar to the amount of EPMI-hCG in the sample from the temporally matched, normal pregnant subject indicates a positive outcome of the pregnancy and an amount of EPMI-hCG in the subject's sample similar to the amount of EPMI-hCG in the sample from the non-pregnant subject indicates a negative outcome of the pregnancy."

"6. The method of claim 1, wherein the second antibody is designated B207, produced by the hybridoma cell line **deposited with the American Type Culture Collection under Designation No. PTA-1626.**"

(emphasis added by the Board)

"7. The method of claim 1, wherein the third antibody is designated B109, produced by the hybridoma cell line **deposited with the American Type Culture Collection under Designation No. PTA-1624.**"

(emphasis added by the Board)

"8. The method of claim 1, wherein the fourth antibody is designated B108, produced by the hybridoma cell line **deposited with the American Type Culture Collection under Designation No. PTA-1625.**"

(emphasis added by the Board)

IV. The examining division did not rectify its decision and referred the appeal to the Board of Appeal (Article 109 EPC).

V. A communication under Article 11(1) (now Rule 15(1) - see OJ EPO 2007, 543) of the Rules of Procedure of the Boards of Appeal presenting some preliminary and non-binding views of the Board was sent to the appellants. In point 10 thereof, the remark was made that none of the ATCC deposit accession numbers PTA-1624 (with respect to antibody B109), PTA-1625 (with respect to antibody B108) and PTA-1626 (with respect to antibody B207) indicated in the claims of

8 June 2007, in particular claims 6 to 8, appeared to have been referred to in the application as filed, and that, therefore, their introduction in the claims had resulted in the presence of added matter. In point 16 of the same communication, the further remark was made that in the patent US-B2-6,927,034, which was an American counterpart of the present application, it was stated that the three corresponding hybridoma cell lines were deposited on 4 April 2000.

- VI. On 18 December 2007, in reply to the Board's communication the appellants filed a letter in which they informed the Board that they were not intending to attend the summoned oral proceedings. The appellants did not comment on the remarks, as outlined at section V (see supra), made by the Board in its communication.
- VII. The oral proceedings, which took place as scheduled on 15 January 2008, were not attended by the appellants.
- VIII. The appellants requested in writing that the decision of the examining division be set aside and a patent be granted on the basis of the request of 8 June 2007.

Reasons for the decision

- 1. According to decision G 10/93 (OJ EPO, 1995, 172), in an appeal from a decision of an examining division in which an application was refused, the Board has the power to examine whether a requirement of the EPC, which the examining division did not take into consideration in the examination proceedings, is met.

2. Therefore, the Board is entitled to examine whether the presence in the claims on file of certain accession numbers of deposited biological materials is in agreement with Article 123(2) EPC.

3. The biological materials concerned are hybridoma cell lines producing antibodies B108, B109 and B207 which were deposited with the American Type Culture Collection (ATCC). The corresponding accession numbers are referred to in particular in present claims 6 to 8. These are accession numbers PTA-1626 (allocated to a deposit of the hybridoma cell line producing antibody B207), PTA-1624 (allocated to a deposit of the hybridoma cell line producing antibody B109), and PTA-1625 (allocated to a deposit of the hybridoma cell line producing antibody B108).

4. In its statement of grounds of appeal the appellant has referred to page 15 in the application as filed as a support for the subject-matter of claims 6 to 8. However, while this page mentions antibodies B108, B109 and B207, it is totally silent in respect of the hybridoma cell lines secreting the same, let alone their deposits with a recognised depositary institution. A review of the rest of the application as filed has shown that none of the three accession numbers PTA-1624, PTA-1625 and PTA-1626 are stated therein. Nor is the depositary institution referred to. Moreover, an inspection of the file has revealed that the relevant information as referred to in Rule 31(1)(c) EPC (former Rule 28(1)(c) EPC) has not been submitted.

5. As stated in the patent US-B2-6,927,034 (expert opinion), the hybridoma cell lines in question were indeed deposited with the ATCC on 4 April 2000 (see column 7, lines 18 to 28), i.e. at a date later than the date of filing of the present application. This means that the deposits were not valid for the purpose of the examination proceedings before the EPO and explains why the relevant information referred to in Rule 31(1)(c) EPC is not found in the present application.

6. In view of the above remarks, it is concluded that the introduction of the accession numbers PTA-1624, PTA-1625 and PTA-1626 in the claims during the examination proceedings and their keeping in the present claims have resulted in the application being amended in such a way that it contains subject-matter which extends beyond the content of the application as filed.

7. Thus, the request on file does not meet the requirements of Article 123(2) EPC and, as such, cannot form a basis for the grant of a patent.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

A. Wolinski

L. Galligani