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**Datasheet for the decision
of 27 July 2010**

Case Number: T 0244/10 - 3.3.08

Application Number: 01964687.6

Publication Number: 1268846

IPC: C12Q 1/02

Language of the proceedings: EN

Title of invention:
Diagnosis of autoimmune disease

Applicant:
DIAGNOSTIC HYBRIDS, INC.

Opponent:
-

Headword:
Diagnosis autoimmune/DIAGNOSTIC HYBRIDS

Relevant legal provisions:
EPC Art. 123(2)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Main request - added subject-matter (no)"
"Remittal to examining division (yes)"

Decisions cited:
-

Catchword:
-



Case Number: T 0244/10 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 27 July 2010

Appellant:

DIAGNOSTIC HYBRIDS, INC.
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Athens
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Representative:

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Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 7 September 2009
refusing European application No. 01964687.6
pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: T. J. H. Mennessier
Members: P. Julià
D. S. Rogers

Summary of Facts and Submissions

I. European patent application no. 01 964 687.6, published as International patent application WO 01/75146 (referred to in this communication as "*the application as filed*"), was refused by the examining division under Article 97(2) EPC because the main request and the first and second auxiliary requests all filed on 12 June 2009 were considered not to fulfil the requirements of Article 123(2) EPC.

II. Claim 1 of the main request refused by the examining division read as follows:

- "1. A method for detecting the presence of thyroid-stimulating autoantibodies in a test sample, comprising:
- a) providing:
 - i) CHO-Rluc cells,
 - ii) a starvation medium consisting of salts and glucose in solution,
 - iii) a test sample suspected of containing thyroid-stimulating autoantibodies,
 - iv) a stimulation medium comprising a salt solution and sucrose;
 - b) exposing said cells to said starvation medium overnight, wherein starved cells are produced,
 - c) exposing said starved cells with said stimulation medium and with said test sample, and
 - d) detecting the presence of thyroid-stimulating autoantibodies using

said starved cells exposed to said stimulation medium."

III. Claims 1 of the first auxiliary request and of the second auxiliary request refused by the examining division read as claim 1 of the main request except for the starvation medium of step ii) and the stimulation medium of step iv), which were defined in the first auxiliary request as being:

- ii) a starvation medium comprising standard Hank's Balanced Salt Solution (HBSS),
- iv) a stimulation medium comprising an HBSS - NaCl buffer and sucrose at a concentration selected from the group consisting of 111 mM and 222 mM;

and in the second auxiliary request:

- ii) a starvation medium selected from the group consisting of standard Hank's Balanced Salt Solution (HBSS) and HBSS + 20 mM sucrose,
- iv) a stimulation medium comprising an HBSS - NaCl buffer, sucrose at a concentration selected from the group consisting of 111 mM and 222 mM and polyethylene glycol.

IV. According to the examining division, there was no general disclosure in the application as filed of a stimulation medium without polyethylene glycol (PEG). Although Examples 2 and 5 disclosed methods for detecting the presence of thyroid-stimulating autoantibodies in a test sample not using PEG in the stimulation buffer, these examples did not refer to the starvation medium of claim 1 and they failed to

disclose the composition of the stimulation used (Example 2) or they disclosed only a specific stimulation medium that could not form a basis for the broader formulation used in claim 1. The main request and the first auxiliary request were refused for these reasons. According to the examining division, Example 6 was the basis for claim 1 of the second auxiliary request. However, there was no basis in that example or in any other section of the application as filed for a stimulation medium comprising HBSS without NaCl and being supplemented with 222 mM sucrose and PEG. Thus, the second auxiliary request was also considered not to fulfil the requirements of Article 123(2) EPC.

V. The applicant (appellant) filed a notice of appeal and a statement setting out the grounds of appeal. The main request and the first and the second auxiliary requests filed on 12 June 2009 before the first instance were filed again with the appellant's grounds of appeal and maintained in the appeal proceedings, together with a third auxiliary request.

VI. Claim 1 of the third auxiliary request filed with the appellant's grounds of appeal read as claim 1 of the second auxiliary request except for the stimulation medium of step iv), which was defined as being:

iv) a stimulation medium comprising HBSS - NaCl buffer, 111 mM sucrose and polyethylene glycol;

VII. On 26 May 2010, the board summoned the appellant to attend oral proceedings. A communication pursuant to Article 15(1) of the Rules of Procedure of the Boards

of Appeal (RPBA), annexed to the summons, informed the appellant of the preliminary, non-binding opinion of the board on the issues of the appeal proceedings. In particular, the board did not see any reason to deviate from the conclusions of the examining division regarding appellant's main, first auxiliary and second auxiliary requests. Example 6 of the application as filed was considered a valid basis for claim 1 of the appellant's third auxiliary request.

VIII. In a letter on 9 July 2010, the appellant withdrew its main, first auxiliary and second auxiliary requests and informed the board that its third auxiliary request was henceforth its new main request. A clean copy of the new main request (and a copy with amendments) was also attached to that letter. The appellant submitted that the claims of that request fulfilled the requirements of Article 123(2) EPC and requested the board to remit the case to the examining division for further prosecution.

IX. In a brief communication dated 13 July 2010 and sent by telefax, the board informed the appellant that the main request filed on 9 July 2010 was considered to fulfil the requirements of Article 123(2) EPC. Nevertheless, the concentration of sucrose in claim 2 had to be brought into line with that indicated in claim 1 (111 mM, 38 g/L). If a main request with that correction were filed, the oral proceedings could be cancelled and the appellant's request for remittal be granted.

X. On 19 July 2010, the appellant filed an amended new main request with the correction in claim 2.

- XI. By fax of 20 July 2010, the board informed the appellant that the oral proceedings were cancelled and that the decision in writing would follow.
- XII. The appellant (applicant) requested that the decision under appeal be set aside and that the case be remitted to the first instance for further prosecution on the basis of the main request filed on 19 July 2010.

Reasons for the Decision

Main request

Article 123(2) EPC

1. The appellant's main request is substantially identical to the second auxiliary request before the examining division. For that request, the examining division raised a single objection under Article 123(2) EPC against claim 1 (cf. page 7, point 5.3 of the decision under appeal), which following the deletion of the sucrose concentration 222 mM in the stimulation medium of claim 1 in the appellant's main request is no longer of relevance (cf. points III, IV and VI *supra*). No other objections were raised in the decision under appeal against claim 1 of the second auxiliary request before the examining division.
2. Indeed, the board is also satisfied that claim 1 of the appellant's main request fulfils the requirements of Article 123(2) EPC. Example 6 in the application as filed provides an adequate basis for the subject-matter of that claim. All the essential technical features of

the method for detecting the presence of thyroid-stimulating antibodies disclosed in the application as filed are recited in claim 1, *inter alia* the use of CHO-Rluc cells, the starvation medium with standard Hank's Balanced Salt Solution (HBSS) or HBSS + 20 mM sucrose and the stimulation medium comprising an HBSS - NaCl buffer, 111 mM sucrose and polyethylene glycol (PEG) (cf. Example 6, pages 37 to 39 of the application as filed).

3. Although in the decision under appeal, no objections were raised under Article 123(2) EPC other than for the subject-matter of claim 1, the board notes that in a communication of the examining division dated 4 June 2008, objections were raised against the subject-matter of several dependent claims. However, after amendments were introduced into the dependent claims - amendments which are now in the appellant's main request - and, in view of the arguments presented by the applicant in its letter dated 30 September 2008, the examining division did not raise these objections in its communication of 21 April 2009 annexed to a summons to oral proceedings nor did it further mention them in the decision under appeal. The board does not see any reason to question the allowability under Article 123(2) EPC of the dependent claims. Formal basis for these claims is to be found in the application as filed, in particular, in Example 6.

4. Example 6 refers to a stimulation medium comprising HBSS - NaCl, 111 mM sucrose and PEG-8000. The specific composition of that medium - expressed in g/L of its components - is explicitly disclosed in the general description of the invention (cf. page 8, lines 16 to

22). Although it is only given for a concentration of sucrose of 222 mM (76 g/L), the amount of sucrose (g/L) required to achieve the sucrose concentration used in the stimulation medium of Example 6 (111 mM) can be derived directly from that information (38 g/L). Thus, the subject-matter of claim 2, which relates to the composition of the stimulation medium of claim 1, has also a formal basis in the application as filed.

5. Thus, the board considers that the main request fulfils the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution on the basis of the main request filed on 19 July 2010.

The Registrar:

The Chairman:

A. Wolinski

T. Mennessier