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**Datasheet for the decision
of 11 January 2011**

Case Number: T 0433/07 - 3.3.04

Application Number: 00110373.8

Publication Number: 1033135

IPC: A61K 39/085

Language of the proceedings: EN

Title of invention:

Broadly reactive opsonic antibodies that react with common staphylococcal antigens

Applicant:

HENRY M. JACKSON FOUNDATION FOR THE ADVANCEMENT OF MILITARY MEDICINE

Headword:

Opsonic antibodies/HENRY M. JACKSON FOUNDATION

Relevant legal provisions:

EPC Art. 83

Keyword:

"Sufficiency of disclosure - (no)"

Decisions cited:

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Catchword:

-



Case Number: T 0433/07 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 11 January 2011

Appellant:

HENRY M. JACKSON FOUNDATION FOR THE
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Representative:

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Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 23 October 2006
refusing European patent application
No. 00110373.8 pursuant to Article 97(1) EPC
1973.

Composition of the Board:

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

Summary of Facts and Submissions

I. The appeal was lodged by the Applicant (Appellant) against the decision of the Examining Division to refuse under Article 97(1) EPC 1973 the patent application EP 00 110 373.8, having the title: "Broadly reactive opsonic antibodies that react with common staphylococcal antigens." The application had been filed as a divisional application of the earlier application EP 93907460.5 (published as WO 93/19373) in accordance with Article 76 EPC.

II. The Examining Division decided that the only request before it, claims 1 to 12 of the main request dated 2 November 2005, did not meet the requirements of Articles 54, 56, 83 and 84 EPC.

III. The Board expressed its preliminary opinion in a communication dated 26 July 2010.

Oral proceedings were held on 11 January 2011 in the absence of the Appellant which had informed the Board by a letter dated 7 January 2011 that it would not attend the oral proceedings and that it wished to rely on its written submissions.

IV. The Appellant requested that the decision under appeal be set aside and a patent be granted on the basis of claims 1 to 4 of its main request submitted with its letter dated 11 November 2010.

V. Claim 1 of the Appellant's request reads as follows:

"A method of producing broadly reactive opsonic monoclonal immunoglobulin, comprising:

(a) obtaining an antigen preparation capable of inducing an antibody that reacts with *Staphylococcus epidermis* strain Hay ATCC 55133;

(b) contacting a sample of immunoglobulin with the antigen preparation; and

(c) isolating immunoglobulin that binds to an antigen preparation from *Staphylococcus epidermis* strain Hay ATCC 55133,

wherein the immunoglobulin specifically reacts in an assay with *Staphylococcus epidermis* of at least two serotypes selected from Serotypes I, II and III and exhibits opsonic activity."

VI. The submissions made by the Appellant in writing, as far as they are relevant to the present decision, may be summarised as follows:

The application provided adequate teaching as how to screen for monoclonal antibodies that were useful in the invention. The skilled person was told to screen them for reactivity against HAY and then screen them for cross reactivity against more than one *Staphylococcus epidermis* serotype. Such a process might be laborious, but it could not be considered to be unduly burdensome and would provide monoclonal antibodies having the desired properties. If, as the

Examining Division mentioned in its decision, there were more than one antigen involved in providing the cross reactivity, this would make the screening process even easier, since more antibodies (raised against any of the different antigens) would be likely to satisfy the screening criteria. It would not be necessary to identify each and every antigen that was cross reactive. The invention provided the skilled person with the knowledge that cross reactivity was possible and with that information it was a relatively easy task lying well within the skilled person's ability to produce by conventional means a single monoclonal antibody which would react simultaneously with different serotypes.

Reasons for the decision

1. The application discloses neither any serotype cross reactive monoclonal antibody nor the isolation of an antigen associated with the serotype cross protective response required by claim 1. None of examples 1 to 13 of the application is concerned with the production of monoclonal antibodies.

The application, published as EP-A-1 033 135, refers in paragraphs [0041] to [0044] to the general techniques for making monoclonal antibodies.

2. The Board agrees with the Examining Division (point 2.2 of the decision under appeal) that the crucial step in the preparation of monoclonal antibodies having desired binding characteristics is the immunisation step. The Appellant's argument that the preparation of such antibodies merely involves standard techniques which

- are described in the screening process of the application does not mirror reality. The method of claim 1 can only be put into practice with success if the immunisation is carried out with a structural motif common to *Staphylococcus epidermis* serotypes I, II and III.
3. A European patent application containing a claim referring to a method of production has to provide the skilled person with the **means** to produce the desired **product** (here with a **common epitope** to produce a **serotype cross reactive monoclonal antibody**). If this is not the case, this shortcoming cannot be overcome by telling him/her exactly how the desired product has to look and which screening criteria have to be applied to find it.
 4. As long as the application does not contain any information concerning one such common epitope, theoretical considerations whether or not a complex antigenic mixture ("an antigen preparation capable of inducing an antibody that reacts with *Staphylococcus epidermis* strain Hay ATCC 55133") might probably contain even more of these common epitopes, are irrelevant for the examination of the requirements of Article 83 EPC.
 5. Contrary to the requirements of Article 83 EPC the application does not disclose "a method for producing broadly opsonic monoclonal immunoglobulin" according to claim 1 in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

P. Cremona

C. Rennie-Smith