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Datasheet for the decision of 16 January 2007

Case Number: T 1189/06 - 3.3.08

Application Number: 97905808.8

Publication Number: 0879290

IPC: C12N 15/57

Language of the proceedings: EN

Title of invention:
Prostate specific antigen peptides and uses thereof

Applicant:
ABBOTT LABORATORIES

Opponent:
-

Headword:
Prostate-specific antigens/ABBOTT

Relevant legal provisions:
EPC Art. 123(2), 84, 54

Keyword:
"Sole request on file - added subject-matter - no"
"Clarity - yes"
"Novelty - no"

Decisions cited:
-

Catchword:
-

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Case Number: T 1189/06 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 16 January 2007

Appellant: ABBOTT LABORATORIES
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 11 April 2006 refusing European application No. 97905808.8 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: L. Galligani
Members: F. Davison-Brunel
C. Heath

Summary of Facts and Submissions

I. European patent application No. 97 905 808.8 published as International application No. WO 97/29199 with the title "Prostate specific antigen peptides and uses thereof" was refused by the examining division. The decision of refusal focused on the second auxiliary request, the main and first auxiliary requests not having been admitted into the proceedings under Rule 86(3) EPC.

The second auxiliary request then on file comprised 12 claims. Claims 1, 4, 7, 9 and 11 read as follows:

"1. An antibody specific for free PSA produced in response to immunization by a peptide selected from the group consisting of ABT6 (SEQ.ID.NO:6) and ABT1 (SEQ.ID.NO:1).

4. A method for detecting PSA in a test sample suspected of containing PSA comprising the steps of:

a) contacting the test sample with an antibody or fragment thereof which specifically binds to at least one site on a peptide or antigen for a time and under conditions sufficient to allow for the formation of antigen/antibody complexes

wherein said peptide or antigen is selected from the group consisting of ABT6 (SEQ.ID.NO:6) and ABT1 (SEQ.ID.NO:1) and said antibody or fragment thereof has been produced in response to said peptide or antigen;

b) adding a probe antibody to said resulting antigen/antibody complexes for a time and under conditions sufficient to allow said probe to bind to bound antigen, wherein said probe binds to a second site on said peptide or antigen; and

c) determining the amount of bound probe and thus the amount of PSA in said test sample.

7. The method of claim 6 wherein one antibody is specific for free PSA and the other antibody is specific for total PSA, or both antibodies are specific for total PSA.

9. The method of claim 8 wherein if free PSA is to be detected, said antibody of step (a) binds specifically to free PSA, and if total PSA is to be detected, said antibody of step (a) binds to total PSA.

11. A kit for determining the presence of PSA in a test sample comprising:

a) an antibody or fragment thereof which specifically binds to at least one site on PSA

wherein said antibody or fragment thereof is produced in response to immunization by a peptide comprising an amino acid sequence of approximately 10-20 residues wherein said sequence is identical to the amino acid sequence of a region of PSA and comprises one or more amino acids nonidentical to the amino acid sequence of hK2, and wherein said peptide is selected from the group consisting of ABT6 (SEQ.ID.NO:6) and ABT1 (SEQ.ID.NO:1);

b) a probe antibody wherein said probe binds to a second site on said PSA."

Dependent claims 2 and 3, 5 and 6 respectively related to further features of the subject-matter of claims 1 and 4. Claim 8 was directed to a further method for detecting PSA making use of an antibody which specifically binds to ABT6 or ABT1. Claim 10 related to a kit comprising an antibody produced in response to immunization by ABT6 or ABT1. Claim 12 related to a further kit for determining the presence of PSA in a sample comprising, in particular, an antibody raised against ABT6.

II. The examining division gave no consent to the introduction of the main and first auxiliary requests under Rule 86(3) EPC for a number of reasons, in particular, because they had not been filed within the time limit set by Rule 71a EPC. Claim 1 of the second auxiliary request was found to lack novelty over the teachings in document (4) (see infra) of the monoclonal antibody (mAb) 2E9. MAb 2E9 recognized both free PSA and complexed PSA. As the instant application did not provide any experimental evidence that the claimed anti-ABT6 or anti-ABT1 antibodies only bound free PSA and not complexed PSA, the possibility that they recognized both antigens could not be discarded. Accordingly, the teachings of document (4) destroyed the novelty of the subject-matter of claim 1.

III. The appellant (applicant) filed a notice of appeal against this decision, paid the appeal fee and submitted a statement of grounds of appeal requesting

the grant of a patent on the basis of the second auxiliary request refused by the examining division.

IV. The appealed decision was not rectified by the examining division and the case was remitted to the board of appeal (Article 109(2) EPC).

V. Oral proceedings were summoned for 16 January 2007. The summons were sent together with a communication pursuant to Article 11(1) of the Rules of Procedure of the Boards of Appeal (RPBA), stating the board's preliminary non-binding opinion.

VI. With letter dated 7 November 2006, the appellant informed the board of its intention not to attend oral proceedings and requested that the oral proceedings be cancelled and the case be decided on the basis of the written submissions. Further submissions were made as regards novelty and inventive step which were accompanied by an amended "main" request to replace the request on file. Claims 1 to 6, 8 and 10 of this request were identical to the corresponding claims in the second auxiliary request refused by the examining division. Claims 7, 9 and 11 read as follows:

"7. The method of claim 4 wherein one antibody is specific for free PSA and the other antibody is specific for total PSA.

9. The method of claim 8 wherein free PSA is to be detected and wherein said antibody of step (a) binds specifically to free PSA.

11. A kit for determining the presence of PSA in a test sample comprising:

a) an antibody or fragment thereof which specifically binds to at least one site on PSA

wherein said antibody or fragment thereof is produced in response to immunization by a peptide selected from the group consisting of ABT6 (SEQ.ID.NO:6) and ABT1 (SEQ.ID.NO:1);

b) a probe antibody wherein said probe binds to a second site on said PSA."

The same amendment was made in claim 12 as in claim 11 as regard step a), the antibody being defined as produced in response to immunisation by ABT6.

VII. In conformity with the appellant's request, oral proceedings were cancelled on 15 December 2006.

VIII. The following document is referred to in this decision:

(4): Pettersson, K. et al., Clin.Chem., Vol.41, No.10, pages 1480 to 1488, 1995;

IX. The appellant's arguments in writing insofar as relevant to the present decision may be summarized as follows:

The disclosure of mAb 2E9 in document (4) was not detrimental to the novelty of present claim 1. In Table 1 of this document, 2E9 was shown to bind not only to free PSA but also to PSA-ACT. In contrast,

claim 1 was directed to antibodies specific for free PSA. 2E9, thus, did not fall within the scope of the claim.

Monoclonal antibodies 5A10 or 9B10 which were disclosed in document (4) as specific for free PSA and, in the instant application (page 24), as recognizing ABT6 also did not destroy the novelty of present claim 1. Indeed, it was not because mAbs 5A10 or 9B10 and the claimed antibodies bound ABT6 that they were the same antibodies. The fact that 5A10 or 9B10 were raised against full length PSA rather than against ABT6 was a proof, albeit indirect, that they had to be different. This difference would be reflected in that 5A10 or 9B10 would have a lower quantitative affinity to ABT6 than the claimed antibodies which were raised directly against ABT6.

X. The appellant requested that a patent be granted on the basis of the amended main request filed with submissions dated 7 November 2006.

Reasons for the decision

Articles 123(2) and 84 EPC

1. Claims 7, 9, 11 and 12 of the sole request on file are amended versions of claims 7, 9, 11 and 12 of the second auxiliary request refused by the examining division (see Sections I and VI, supra). The amendments - by deletion - are meant to take into account the board's remarks in its communication pursuant to Article 11(1) RPBA that the earlier claims were

internally inconsistent insofar as they defined the "detecting antibodies" not only as binding to total PSA or as being raised against a peptide comprising 10 to 20 amino acid residues but also, at the same time, as being specific for free PSA or as being raised against either one of two, respectively 13- and 17- amino acid long, specific peptides.
The amendments do not introduce added subject-matter and eliminate previous ambiguities. The requirements of Articles 123(2) and 84 EPC are, thus, fulfilled.

Article 54 EPC; novelty of the subject-matter of claim 1

2. Document (4) discloses, in particular, the monoclonal antibody 9B10 as being **specific for free PSA** (Table 1, page 1483). In the present application, 9B10 is described on page 24 as binding **specifically to ABT6**. These are the two features to be expected from the group of antibodies claimed in claim 1. This situation led the board in its communication pursuant to Article 11(1) RPBA to express the concern that 9B10 fell within the scope of the claim. Further information was, thus, requested from the appellant as regards the possibility that 9B10 which had been raised against an antigen different from ABT6, ie a mixture of different forms of PSA, would have a specific structure due to its process of isolation which would distinguish it from antibodies raised against ABT6.

3. In answer, the appellant provided two kinds of arguments, firstly that all monoclonal antibodies were different irrespective of whether or not they bound to the same antigen - implying that, although 9B10 bound to ABT6, it would be different from an antibody

belonging to the group now claimed - and, secondly, that the way 9B10 was isolated implied that it would have less quantitative affinity for ABT6 than anti-ABT6 antibodies.

4. The board agrees that monoclonal antibodies all have different chemical structures even if they bind the same antigen but does not consider this known fact as being relevant in the present context. Indeed, the question is not whether 9B10 is identical to a specific (as yet unidentified) antibody falling within the scope of the claim but rather whether 9B10 is at all distinguishable from an antibody which belongs to the group of antibodies which is now claimed. In this respect, insofar as the chemical structure of the antibody is not a characteristic which "tells" the way in which the antibody was isolated, it must be concluded that the process of isolation of mAb 9B10 does not impart said antibody with specific and unique structural characteristics which would make it irrelevant to novelty.

5. As for the fact that 9B10, although having the same qualitative properties as the claimed antibodies, would be expected to be different on a quantitative basis, namely to have a lower level of affinity for ABT6 than **all** anti-ABT6 antibodies, it is a mere assumption which does not amount to a distinguishing feature because not all anti-ABT6 antibodies will necessarily have high binding affinity for ABT6.

6. For these reasons, it is concluded that the disclosure of eg. mAb 9B10 in document (4) destroys the novelty of the subject-matter of claim 1. The sole request on file

fails to fulfil the requirements of Article 54 EPC and is, therefore, rejected.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar The Chairman

A. Wolinski L. Galligani