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(54) Title: REAGENTS AND METHODS USEFUL FOR DETECTING DISEASES OF THE BREAST

(57) Abstract: Multimeric polypeptides antigens comprising polypeptides designated as BS106 and transcribed from breast tissue is described. These sequences are useful for the detecting, diagnosing, staging, monitoring prognosticating or determining the predisposition of an individual to diseases and conditions of the breast such as breast cancer. Also provided are antibodies which specifically bind to BS106-encoded polypeptide or protein.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/06516

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07K14/47 C07K16/30 C07K19/00 C12N5/10 G01N33/574

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07K G01N C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

SEQUENCE SEARCH, EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 18945 A (ABBOTT LABORATORIES) 7 May 1998 (1998-05-07) cited in the application the entire document, particularly page 25, line 1 - line 6; example 14, SEQ ID NOs 16 to 20	1-13, 15-24
X	WO 99 23230 A (ABBOTT LABORATORIES) 14 May 1999 (1999-05-14) cited in the application the entire document, particularly page 14, line 16 - line 22; page 18, line 20 - line 22; examples 10 and 14; SEQ ID NOs 16 to 20	1-13, 15-24
A	WO 98 21331 A (INCYTE PHARMACEUTICALS, INC.) 22 May 1998 (1998-05-22) page 2, line 8 - line 30	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

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- *Y* document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- * & * document member of the same patent family

Date of the actual completion of the international search

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11/02/2002

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INTERNATIONAL SEARCH REPORT

International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>BECKER RM ET AL.: "Identification of Mammaglobin B, a Novel Member of the Uteroglobin Gene Family" GENOMICS, vol. 54, 1998, pages 70-78, XP000892829 page 70</p> <p style="text-align: center;">-----</p>	

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 14 (completely) and 1-19,24 (partially)

Present claims 1-19 and 24 relate to multimeric polypeptide antigens (MPA) and methods thereof defined by reference to a desirable characteristic or property, namely MPAs comprising at least one BS106 polypeptide fused to at least one other polypeptide.

The claims cover all multimeric polypeptide antigens having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and disclosure within the meaning of Article 5 PCT for only a very limited number of such MPAs (see example 16). In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible.

Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the other polypeptide linked to a BS106 peptide only by its molecular weight and the suggestion that "multiple proteins present in both aqueous and fatty fractions of milk contain amino acids sequence identical to or strongly related to that of BS106 peptide (SEQ ID NO 26)" (see page 108, line 3 - line 5). Such a statement is completely unclear in the sense of Article 6 PCT as a 23-mer peptide (SEQ ID NO 26) cannot be used to sufficiently identify a protein of 120 or 200 kDa.

Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible.

In addition, the cell line 106C1 of claim 14 lacks any technical feature allowing a search for said cell line (Article 6 PCT).

Consequently, the search has been carried out for the concept underlying the present application, namely fusion proteins of BS106 and for those parts of the claims which appear to be clear, supported and disclosed, namely the methods of claims 20 to 23.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internal Application No

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Patent document cited in search report	A	Publication date		Patent family member(s)	Publication date
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