



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁶ : C12N 15/12, C07K 14/47, 14/82, 14/15, C12Q 1/68, G01N 33/53, A61K 38/17, 39/00</p>	A3	<p>(11) International Publication Number: WO 97/25426</p> <p>(43) International Publication Date: 17 July 1997 (17.07.97)</p>
<p>(21) International Application Number: PCT/US97/00485</p> <p>(22) International Filing Date: 10 January 1997 (10.01.97)</p> <p>(30) Priority Data: 08/585,392 10 January 1996 (10.01.96) US 08/700,014 20 August 1996 (20.08.96) US</p> <p>(71) Applicant: CORIXA CORPORATION [US/US]; Suite 464, 1124 Columbia Street, Seattle, WA 98104 (US).</p> <p>(72) Inventors: FRUDAKIS, Tony, N.; Magnolia Station, 3211 West McGraw, P.O. Box 99232, Seattle, WA 98232-0232 (US). SMITH, John, M.; 208 - 116th Place S.E., Everett, WA 98208 (US). REED, Steven, G.; 2843 - 122nd Place N.E., Bellevue, WA 98005 (US).</p> <p>(74) Agents: MAKI, David, J. et al.; Seed and Berry L.L.P., 6300 Columbia Center, 701 Fifth Avenue, Seattle, WA 98104- 7092 (US).</p>		<p>(81) Designated States: AL, AM, AT, AU, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p> <p>(88) Date of publication of the international search report: 30 October 1997 (30.10.97)</p>
<p>(54) Title: COMPOSITIONS AND METHODS FOR THE TREATMENT AND DIAGNOSIS OF BREAST CANCER</p>		
<p style="text-align: center;"><u>GENOMIC CLONE MAP</u></p> <p>The diagram shows a horizontal line representing a genomic region with six vertical lines indicating XbaI sites. Between these sites are boxes labeled with clone numbers: 11-22, 14, B18Ag-1, 13, 12, 10, 3, 11-29, and 6. Below the line, horizontal brackets indicate the sizes of clones: Clone 5 is approximately 6kb (spanning from the second to the fourth XbaI site), Clone 2 is approximately 2.5kb (spanning from the fourth to the fifth XbaI site), Clone 4 is approximately 3.5kb (spanning from the fifth to the sixth XbaI site), Clone 3 is approximately 6kb (spanning from the third to the sixth XbaI site), and Clone 9 is approximately 12-18kb (spanning from the first to the sixth XbaI site).</p>		
<p>(57) Abstract</p> <p>Compositions and methods for the detection and therapy of breast cancer are disclosed. The compounds provided include nucleotide sequences that are preferentially expressed in breast tumor tissue, as well as polypeptides encoded by such nucleotide sequences. Vaccines and pharmaceutical compositions comprising such compounds are also provided and may be used, for example, for the prevention and treatment of breast cancer. The polypeptides may also be used for the production of antibodies, which are useful for diagnosing and monitoring the progression of breast cancer in a patient.</p>		

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/00485

A. CLASSIFICATION OF SUBJECT MATTER IPC 6 C12N15/12 C07K14/47 C07K14/82 C07K14/15 C12Q1/68 G01N33/53 A61K38/17 A61K39/00				
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 6 C07K C12Q				
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)				
C. DOCUMENTS CONSIDERED TO BE RELEVANT				
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
Y	WERNER T ET AL: "S71 is a phylogenetically distinct human endogenous retroviral element with structural and sequence homology to simian sarcoma virus (SSV)." VIROLOGY, JAN 1990, 174 (1) P225-38, UNITED STATES, XP000670325 see the whole document	1-10,15, 20,22, 28,31, 37,40,42		
Y	--- HALTMEIER M ET AL: "Identification of S71-related human endogenous retroviral sequences with full-length pol genes." VIROLOGY, JUN 1 1995, 209 (2) P550-60, UNITED STATES, XP002031074 see the whole document ---	1-9		
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<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C.				
<input checked="" type="checkbox"/> Patent family members are listed in annex.				
* Special categories of cited documents :				
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none; vertical-align: top;"> *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed </td> <td style="width: 50%; border: none; vertical-align: top;"> *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *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 </td> </tr> </table>			*A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *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
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Date of the actual completion of the international search <p style="text-align: center; font-size: 1.2em;">27 May 1997</p>	Date of mailing of the international search report <p style="text-align: center; font-size: 1.2em;">17.09.97</p>			
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Authorized officer <p style="text-align: center; font-size: 1.2em;">Gurdjian, D</p>			

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/00485

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 95 32311 A (CALYPTE INC) 30 November 1995 see abstract; claims 1,15,23,28,32,34,38 ---	10,20, 22,31,37
Y	LEIBMOSCH C ET AL: "EVOLUTION AND BIOLOGICAL SIGNIFICANCE OF HUMAN RETROELEMENTS" VIRUS GENES, 1995, 11, 133-145, XP000673508	15,28, 40,42
A	see the whole document ---	10,20, 22,31,37
A	GB 2 273 099 A (ASTA MEDICA AG) 8 June 1994 see claims 1,4 ---	10,20, 22,31,37
A	WO 95 19369 A (VANDERBILT UNIVERSITY) 20 July 1995 see page 6, paragraph 2; claims 25-40; examples 1-6 ---	10,20, 22,31, 33,37
A	WO 91 02062 A (TRITON BIOSCIENCES INC) 21 February 1991 see page 9, paragraph 2 - paragraph 3 see page 23, paragraph 2; claims 1-64; example 5 ---	10,20, 22,31, 33,37
A	WATSON M A ET AL: "ISOLATION OF DIFFERENTIALLY EXPRESSED SEQUENCE TAGS FROM HUMAN BREAST CANCER" CANCER RESEARCH, vol. 54, no. 17, 1 September 1994, pages 4598-4602, XP000576043 see the whole document ---	15,28, 40,42
A	ZEHAN CHEN ET AL: "DIFFERENTIAL EXPRESSION OF HUMAN TISSUE FACTOR IN NORMAL MAMMARY EPITHELIAL CELLS AND IN CARCINOMAS" MOLECULAR MEDICINE, vol. 1, no. 2, January 1995, pages 153-160, XP000607858 see the whole document ---	10,20, 22,31, 33,37
A	BYRNE J A ET AL: "A SCREENING METHOD TO IDENTIFY GENE COMMONLY OVEREXPRESSED IN CARCINOMAS AND THE IDENTIFICATION OF A NOVEL COMPLEMENTARY DNA SEQUENCE" CANCER RESEARCH, vol. 55, no. 13, 1 July 1995, pages 2896-2903, XP002025781 see the whole document -----	15,28, 40,42

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 97/ 00485

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see continuation-sheet

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Invention 1 (see continuation-sheet)

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US 97/ 00485

FURTHER INFORMATION CONTINUED FROM PCT/ISA/210

Invention 1 :

Claim 3, claims 1,2,4-10,12,13,15,17-20,22,24,25,27-29,31,33-35,37,39, 40,42 (partially) :
nucleic acids of human endogenous retroviral element encoding breast tumor specific polypeptides with sequences 1,3-10,103,126-140,141 , polypeptide with amino acids sequence 2 ,corresponding polypeptides , antibodies , epitopes , pharmaceutical composition , vaccines ,their use for determining the presence , or monitoring the progresssion of breast cancer and diagnostic kit .

Inventions 2-142 :

Claims 1,2,4-10,11,13,15,17-20,22,24,25,27-29,31,33-35,37,39, 40,42 (partially) :
nucleic acids encoding breast tumor specific polypeptides with sequence 11 ,corresponding polypeptides ,antibodies , epitopes , pharmaceutical composition , vaccines ,their use for determining the presence , or monitoring the progresssion of breast cancer and diagnostic kit .

...ibidem for each of sequences 12-77, 142,143,146-152,154-166,168-176, 178-192,194-198,200-204,206, 207,209-214,216,218,219,221-227 separately

Inventions 143-163 :

Claims 11,14,16,17,19,21,23,24,26,27,30,32,36,38,39,41,43 (partially) :
breast tumor specif c polypeptides with sequence 78 ,corresponding , antibodies , epitoras , pharmaceutical composition and vaccines against breast cancer ,their use for determining the presence , or monitoring the progresssion of breast cancer and diagnostic kit .

...ibidem for each of sequences 79-86,144,145,153,167,177,193,199,205, 208,215,217,220 separately

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 97/00485

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9532311 A	30-11-95	AU 2690995 A CA 2191099 A EP 0763137 A	18-12-95 30-11-95 19-03-97

GB 2273099 A	08-06-94	WO 9411514 A	26-05-94

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