Title: HERV-K ANTIGENS, ANTIBODIES, AND METHODS

Abstract: Methods and compositions for cancer diagnostics and therapy are provided. More particular, methods and compositions for detecting, preventing, and treating HERV-K+ cancers are provided. One example of a method may involve a method for preventing or inhibiting cancer cell proliferation by administering to a subject a cancer cell proliferation blocking or reducing amount of a HERV-K env protein binding antibody.
### INTERNATIONAL SEARCH REPORT

**International application No**

**PCT/JUS 07/69497**

#### A CLASSIFICATION OF SUBJECT MATTER

<table>
<thead>
<tr>
<th>IPC(B)</th>
<th>USPC</th>
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<tr>
<td>A61 K 39/1 2. C12P 21/06 (2008 01)</td>
<td>424/186 1, 435/69 1</td>
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</table>

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)

| USPC | 435/91 1 | 424/186 1 | 424/204 1 | 435/69 1 | 435/91 33. 530/300 |

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 practicable, search terms used)

WEST (PCT/SA/2) (second sheet) (April 2007)

**USPC**

**B** 424/186

**L** 424/204

**F** 435/69

**P** 435/91

**A** 530/300

**C DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No</th>
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<tr>
<td>X</td>
<td>WO 03/060258 A1 (GARCIA et al ) 19 Jun 2003 (19 06 2003), pg 1 ln 25-32, pg 13, in 11-17</td>
<td>1-3, 5-8, 10, 32 and 34</td>
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<td>pg 16, in 21-28, pg 18, in 5, 8-9 30-31, pg 19, in 4-10, 25-26</td>
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<td>Y</td>
<td>US 6,656 480 B2 (RETTER et al ) 2 Dec 2003 (02 12 2003), abstract, col 16, in 23. col 17, in 60</td>
<td>4 and 9</td>
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<td>A</td>
<td>WANG-JOMANNING et al Quantitation of HERV-K [inv gene expression and splicing in human breast cancer Oncogene 2003 Vol 22, pages 1528-1535</td>
<td>1-10, 32 and 34</td>
</tr>
</tbody>
</table>

Further documents are listed in the continuation of Box C

- Special categories of cited documents
  - A document defining the general state of the art which is not considered to be of particular relevance
  - E' carrel application or patent but published on or after the international filing date
  - L' document which may throw doubts on novelty claim(s) or which is considered 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

#### Date of the actual completion of the international search

17 January 2008 (17 01 2008)

#### Date of mailing of the international search report

16 APR 2008

#### Name and mailing address of the ISA/US

Mail Slop PCT Attn ISA/US, Commissioner for Patents
P O Box 1450, Alexandria, Virginia 22313-1450
Facsimile No 571-273-3201

Lee W Young

#### Authorized officer

PCT Handshake 571 273-4300
PCT CDP 571 272 7774
**INTERNATIONAL SEARCH REPORT**

**Box No. II**  
**Observations** where certain claims were found unsearchable (Continuation of item Z or first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(i) 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 64(a)

**Box No HI**  
**Observations** where unity of invention is lacking (Continuation of item 3 of first sheet)

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

- **Group I** claims 1-10, 32 and 34 are directed to an antibody that binds to HERV-K env protein
- **Group H** claims 11-16 and 33 are directed to an oligonucleotide that binds to a polynucleotide encoding HERV-K env protein
- **Group III** claims 17-18 and 22 are directed to a method for preventing or inhibiting cancer cell proliferation by administering an antibody that binds to HERV-K env protein
- **Group IV** claims 19 and 20 are directed to a method of monitoring or diagnosing cancer by determining the level of HERV-K env protein

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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 additional fees, this Authority did not invite payment of additional fees**
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**

  Claims 1-10, 32 and 34

**Remark on Protest**

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation
- No protest accompanied the payment of additional search fees

Form PCT/ISA/2 10 (continuation of first sheet (2)) (Ap n 1 2007)
Group V: claim 21 is directed to a method for screening a compound that inhibits or prevents HERV-K+ cancer cell proliferation.

Group VI: claims 23-30 are directed to a method for providing a target for T cells or B cells comprising providing a HERV-K env protein.

Group VII: claim 31 is directed to a method for stimulating PBMCs by providing autologous DC pulsed with MERV-K target for T cells or B cells comprising providing a KERV-K env protein.

The Inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding technical features for the following reasons:

The technical feature of Groups I and II resides in an antibody that binds to HERV-K env protein.

The technical feature of Group III resides in an oligonucleotide that binds to a polynucleotide encoding HERV-K env protein.

The technical feature of Group IV resides in utilizing an antibody that binds to HERV-K env protein for preventing or inhibiting cancer cell proliferation.

The technical feature of Group V resides in utilizing an antibody that binds to HERV-K env protein for determining the level of HERV-K env protein.

The Inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature is a contribution over the prior art. However, said shared same or corresponding technical feature is not an improvement over the prior art of US 2003/012263 A1 (Dupuis) 26 Aug 2003 (28.08.2003) because Dupuis teaches the ENV protein of the human endogenous retrovirus HERV-K18 and antibodies which specifically bind to HERV-K18 ENV thereby inhibiting its activity (Abstract and claims 14-19). Thus, the shared technical feature cannot function as a novel (special) technical feature to maintain unity of invention. Groups I-VIII thus lack unity of invention because they do not share a same or corresponding special technical feature.