Title: PCV2 IMMUNOGENIC COMPOSITIONS AND METHODS OF PRODUCING SUCH COMPOSITIONS

Abstract: An improved method for recovering the protein expressed by open reading frame (2) from porcine circovirus type (2) is provided. The method generally involves the steps of transfecting recombinant virus containing open reading frame (2) coding sequences into cells contained in growth media, causing the virus to express open reading frame (2), and recovering the expressed protein in the supernate. This recovery should take place beginning approximately (5) days after infection of the cells in order to permit sufficient quantities of recombinant protein to be expressed and secreted from the cell into the growth media. Such methods avoid costly and time consuming extraction procedures required to separate and recover the recombinant protein from within the cells.
1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, the international search was carried out on the basis of:
   a. type of material
      ☒ a sequence listing
      ☐ table(s) related to the sequence listing

   b. format of material
      ☒ on paper
      ☐ in electronic form

   c. time of filing/furnishing
      ☒ contained in the international application as filed
      ☐ filed together with the international application in electronic form
      ☐ furnished subsequently to this Authority for the purposes of search

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:
### INTERNATIONAL SEARCH REPORT

**Box No. II**  Observations where certain claims were found unsearchable (Continuation of item 2 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. [ ] Claim Nos.:
   because they relate to subject matter not required to be searched by this Authority, namely:

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

**Box No. III**  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:

Please 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 additional fees, this Authority did not invite payment of any 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. 1-35 and 38-48.

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.:

**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.
# INTERNATIONAL SEARCH REPORT

**International application No.**
PCT/US05/47596

## A. CLASSIFICATION OF SUBJECT MATTER
IPC: C12Q 1/68 (2006.01)

USPC: 435/6
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)
U.S.: 435/6

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)

Please See Continuation Sheet

## 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>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>NAWAGITGUL et al. Modified Indirect Porcine Circovirus (PCV) Type 2-Based and</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Recombinant Capsid Protein (ORF2)-Based Enzyme-Linked Immunosorbent Assays for</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Detection of Antibodies to PCV. CLINICAL AND DIAGNOSTIC LABORATORY IMMUNOLOGY.</td>
<td></td>
</tr>
</tbody>
</table>

| Y        | NA WAGITGUL et al. Open reading frame 2 of porcine circovirus type 2 encodes a   |
|          | pages 2281-2287, see the entire document.                                       | 1-35, 38-48           |

| Y        | BLANCHARD et al. Protection of swine against post-weaning multisystemic wasting  |
|          | syndrome (PMWS) by porcine circovirus type 2 (PCV2) proteins. Vaccine. November|
|          | 2003, Vol. 21, pages 4565-4575, see the abstract.                             | 1-35, 38-48           |

**X** Further documents are listed in the continuation of Box C. **See patent family annex.**

**•** Special categories of cited documents:

• "A" document defining the general state of the art which is not considered to be of 
  particular relevance

• "E" earlier application or patent 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

**"X"** 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

**"E"** document member of the same patent family

**Date of the actual completion of the international search**
08 September 2006 (08.09.2006)

**Date of mailing of the international search report**
02 October 2006

**Name and mailing address of the ISA/US**
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Facsimile No. (571) 273-3201

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<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>
</tr>
</thead>
</table>
BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-15, drawn to method of recovering recombinant protein expressed by ORF2 of PCV2.

Group II, claim(s) 16-30, drawn to method of preparing a composition for invoking an immune response against PCV2.

Group III, claim(s) 31, 32, drawn to method of recovering recombinant protein expressed by ORF2 of PCV2.

Group IV, claim(s) 33-35, drawn to composition of matter and the use.

Group V, claim(s) 36, 37, drawn to method of producing a diagnostic kit for detection of PCV2.

Group VI, claim(s) 38, 39, drawn to an immunogenic composition effective for lessening symptoms associated with PCV2.

Group VII, claim(s) 40-51, drawn to a container comprising at least one dose of immunogenic composition of PCV2 ORF2.

Group VIII, claim(s) 52-53, drawn to a kit comprising a container and instruction manual.

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 special technical features for the following reasons: The invention of Group I is known in the prior art as evidence by either Nawagit et al (CLINICAL AND DIAGNOSTIC LABORATORY IMMUNOLOGY, Jan. 2002, Vol. 9, No. 1, pages 33-40) wherein the reference teaches method of inserting ORF2 of PCV2 into a expression vector and its recovered protein to be utilized in a diagnostic assay (see the abstract, and page 34, left column) or Blanchard et al (VACCINE, 2003, Vol. 21, pages 4565-4575) wherein cloning of PCV2 ORF2 and its use is taught (see page 4566, 3rd and 4th full paragraph). The cited evidence prove that the technical feature of Group I does not make a contribution over the prior art. Thus, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2
Continuation of B. FIELDS SEARCHED Item 3:
MEDLINE, CAPLUS, DERWENT, JPA, EPA, WEST, NPL

search terms: Circovirus type 2, ORF2, PCV2, PMWS, vector, vaccine, porcine