

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)**

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2016/049709

International filing date (day/month/year)
31.08.2016

Priority date (day/month/year)
31.08.2015

International Patent Classification (IPC) or both national classification and IPC
INV. A61K39/12 A61P31/00

Applicant
BOEHRINGER INGELHEIM VETMEDICA GMBH

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:



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Date of completion of this opinion

see form PCT/ISA/210

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - the international application in the language in which it was filed.
 - a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. forming part of the international application as filed:
 - in the form of an Annex C/ST.25 text file.
 - on paper or in the form of an image file.
 - b. furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. furnished subsequent to the international filing date for the purposes of international search only:
 - in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).
 - on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).
4. In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

Box No. II Priority

1. The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-23</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	<u>1-23</u>
	No: Claims	
Industrial applicability (IA)	Yes: Claims	<u>1-23</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- D1 ANNE-LIE BLOMSTR?M ET AL: "Astrovirus as a possible cause of congenital tremor type All in piglets?",
ACTA VETERINARIA SCANDINAVICA, BIOMED CENTRAL LTD, LO,
vol. 56, no. 1, 16 December 2014 (2014-12-16), page 82, XP021207657,
ISSN: 1751-0147, DOI: 10.1186/S13028-014-0082-Y
- D2 BAILEY L. ARRUDA ET AL: "Identification of a Divergent Lineage Porcine Pestivirus in Nursing Piglets with Congenital Tremors and Reproduction of Disease following Experimental Inoculation",
PLOS ONE,
vol. 11, no. 2, 24 February 2016 (2016-02-24), page e0150104,
XP055319736,
DOI: 10.1371/journal.pone.0150104
- D3 DATABASE EMBL [Online] 2 February 2016 (2016-02-02),
"Porcine pestivirus 1 isolate ISDVDL2014016573 polyprotein gene, complete cds.",
retrieved from EBI accession no. EM_STD:KU194229
Database accession no. KU194229
- D4 DATABASE UniProt [Online] 13 April 2016 (2016-04-13),
"RecName: Full=Genome polyprotein {ECO:0000256|SAAS:SAAS00058068};",
retrieved from EBI accession no. UNIPROT:A0A120H3X4
Database accession no. A0A120H3X4
- D5 BEN. M. HAUSE ET AL: "Discovery of a novel putative atypical porcine pestivirus in pigs in the USA",
JOURNAL OF GENERAL VIROLOGY.,
vol. 96, no. 10, 24 July 2015 (2015-07-24), pages 2994-2998,
XP055230950,
GB
ISSN: 0022-1317, DOI: 10.1099/jgv.0.000251

D6 DATABASE EMBL [Online] 7 August 2015 (2015-08-07),
"Porcine pestivirus 1 strain 000515 polyprotein mRNA, complete cds.",
retrieved from EBI accession no. EM_STD:KR011347
Database accession no. KR011347

Claims 1, 2,8,9, 15,16, are directed to compositions comprising inactivated or attenuated pestivirus having at least 95% sequence identity to SEQ ID NOs: 1 and 2 or to a composition comprising a vector having nucleic acid or protein fragments of SEQ ID NOs: 1 and 2.

D5 and the corresponding Genbank deposit (KR011347) has less than 90% sequence identity with SEQ ID NO: 1. The query sequence SEQ ID NO:1 has 88 % identity (88 % similarity) over 11270 positions in a common overlap (range (q:s): 257-11526:3-11270) with subject EM_STD:KR011347 (D6) (length: 11276).

These sequences in the claims are new and the closest hits which were published before the priority date have less than 95% identity with SEQ ID NOs 1 and 2. This applies also to the fragments of SEQ ID NOs: 1 and 2 as defined in claims 15 and 16.

Therefore the subject-matter of claims 1-23 is novel (Article 33(2) PCT).

The applicants show that this newly discovered lineage of porcine pestivirus is linked to the disease of congenital tremor in piglets and it is rendered plausible that a vaccine against this virus can protect piglets against congenital tremor.

D1 (abstract) aims at finding a possible cause of congenital tremor. However D1 points at an astrovirus as the cause and does not give any hint or indication that the specifically claimed pestivirus could be the cause. Therefore the subject-matter of claims 1-23 involves an inventive step (Article 33(3) PCT).

Claims 18-23 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) / 67.1(iv) PCT. Patentability, in particular novelty and inventive step, of said claims has been assessed on the basis of a purpose-limited product claim taking into account the alleged effects of the compound/composition. The patentability can be dependent upon the formulation of the claims. The EPO, for example, does not recognise as patentable claims to the use of a compound in medical treatment, but may allow claims to a product, in particular substances or compositions for use in a first or further medical treatment.

Re Item VI

Certain documents cited

It appears that document D2, which was published between the claimed priority date and the filing date of the present application the inventor disclose the data of the present application. As the priority document was not available to the examiner at the time point of establishing the present Written Opinion and the priority was considered as being validly claimed, the document D2 is not considered to form part of the prior art.

The corresponding sequences were also published after the priority date as can be seen in the database entry below.

The query sequence SEQ ID NO:1 has 99.9 % identity (99.9 % similarity) over 11525 positions in a common overlap (range (q:s): 20-11544:12-11536) with subject EM_STD:KU194229 (D3) (length: 11545).

The query sequence SEQ ID NO:2 has 99.9 % identity (99.9 % similarity) over 3635 positions in a common overlap (range (q:s): 1-3635:1-3635) with subject UNIPROT:A0A120H3X4 (D4) (length: 3635).