

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
SUANNE NAKAJIMA
ELMORE PATENT LAW GROUP, P.C.
209 MAIN STREET
N. CHELMSFORD, MA 01863

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **19 AUG 2008**

Applicant's or agent's file reference
4056.1108 WO

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US07/75146

International filing date (day/month/year)
03 August 2007 (03.08.2007)

Priority date (day/month/year)
04 August 2006 (04.08.2006)

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

IPC: **A61K 38/12(2006.01);C07K 5/12(2006.01)**
USPC: 514/10,11;530/317

Applicant

ENANTA PHARMACEUTICALS, INC.

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 or 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 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.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (571) 273-3201

Date of completion of this opinion
14 July 2008 (14.07.2008)

Authorized officer
Andrew D. Kosar

Telephone No. (571)272-1600

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Box No. I Basis of this 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 43bis.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. 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.
4. In addition, in the case that more than one version or copy of a sequence listing and/or table(s) 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.
5. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- the entire international application
- claims Nos. 4 and 12

because:

- the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international search (*specify*):

- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 4 and 12 are so unclear that no meaningful opinion could be formed (*specify*):

Claim 4 and 12 reference the specification for elements of the claims, and thus are incomplete, therefore no meaningful search or opinion can be formed.

- the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

- no international search report has been established for said claims Nos. _____

- a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

- furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

- pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

- a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

- the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

- See Supplemental Box for further details.

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

1. Statement

Novelty (N)	Claims <u>1-3,5-11 and 13-16</u>	YES
	Claims <u>none</u>	NO
Inventive step (IS)	Claims <u>1-3,5-11 and 13-16</u>	YES
	Claims <u>none</u>	NO
Industrial applicability (IA)	Claims <u>1-3,5-11 and 13-16</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-3, 5-11 and 13-16 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the compounds of formula (I) as claimed, where G is $\text{NHS}(\text{O})_2\text{-R}^3$ or $\text{NHS}(\text{O})_2\text{NR}^4\text{R}^5$ and R^3 is neither phenylmethyl or phenylethyl.

Claims 1-3, 5-11 and 13-16 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 3 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: The claim should not refer to example #, but rather refer to the compounds as 'compound #'. Additionally, the claims should not include a 'table', but rather a list of compounds embraced by the claims. Further, the last two species should be separated by 'and' and the claim should end with a period.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 1, 2, 5-11 and 13-16 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because the claims are not fully supported by the description. The application, as originally filed, did not describe: esters or prodrugs of the compounds as claimed. The specification provides no specific examples of either esters or prodrugs contemplated. Prodrugs are not necessarily structurally related compounds, as for example, glucose and hypoxanthine are prodrug forms of hydrogen peroxide, and they are greatly divergent in their structures. Here, there is no description of prodrugs contemplated or the esters, and it is noted that the embodied compounds of the instant claims lack esterifying groups, e.g. claim 3 compounds have no free hydroxyl or carboxylic acid, and the specification provides no description of any specific esters contemplated.

Claim 3 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim 3 is indefinite for the following reason(s): Claim 3 ends with a period after the statement: ...table 1. However, the claim appears to continue further having formula (III) and the species recited in tabular form.