

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 091504	FOR FURTHER ACTION		See item 4 below
International application No. PCT/JP2010/052374	International filing date (<i>day/month/year</i>) 17 February 2010 (17.02.2010)	Priority date (<i>day/month/year</i>) 18 February 2009 (18.02.2009)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant TAKEDA PHARMACEUTICAL COMPANY LIMITED			

<p>1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.</p>																								
<p>3. This report contains indications relating to the following items:</p> <table> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> <p>4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).</p>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input checked="" type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
<input checked="" type="checkbox"/>	Box No. I	Basis of the report																						
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<input type="checkbox"/>	Box No. VII	Certain defects in the international application																						
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application																						

<p align="center">The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 338 82 70</p>	<p>Date of issuance of this report 13 September 2011 (13.09.2011)</p>
	<p>Authorized officer</p> <p align="center">Masashi Honda</p> <p>e-mail: pt08.pct@wipo.int</p>

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing (day/month/year) **16.03.2010**

Applicant's or agent's file reference
091504

FOR FURTHER ACTION
See paragraph 2 below

International application No. PCT/JP2010/052374	International filing date (day/month/year) 17.02.2010	Priority date (day/month/year) 18.02.2009
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International Patent Classification (IPC) or both national classification and IPC
see supplemental Box

Applicant
TAKEDA PHARMACEUTICAL COMPANY LIMITED

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/JP	Date of completion of this opinion	Authorized officer
Facsimile No.		Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

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Box No. I	Basis of this opinion
1.	<p>With regard to the language, this opinion has been established on the basis of:</p> <p><input checked="" type="checkbox"/> the international application in the language in which it was filed</p> <p><input type="checkbox"/> 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)).</p>
2.	<p><input type="checkbox"/> 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))</p>
3.	<p>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 filed or furnished:</p> <p>a. (means)</p> <p><input type="checkbox"/> on paper</p> <p><input checked="" type="checkbox"/> in electronic form</p> <p>b. (time)</p> <p><input checked="" type="checkbox"/> in the international application as filed</p> <p><input type="checkbox"/> together with the international application in electronic form</p> <p><input type="checkbox"/> subsequently to this Authority for the purposes of search</p>
4.	<p><input type="checkbox"/> 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 in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.</p>
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. 22, 23

because:

the said international application, or the said claims Nos. 22, 23 relate to the following subject matter which does not require an international search (*specify*):

Claims 22 and 23 include "a method for treatment of the human or animal body by surgery or therapy".

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

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. 22, 23

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 Rule 13ter.1(a) or (b).

See Supplemental Box for further details.

**WRITTEN OPINION OF THE
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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)	Claims <u>1-21, 24-45</u>	YES
		Claims _____	NO
	Inventive step (IS)	Claims <u>1-21, 24-45</u>	YES
		Claims _____	NO
	Industrial applicability (IA)	Claims <u>1-21, 24-45</u>	YES
		Claims _____	NO
<p>2. Citations and explanations:</p> <p style="margin-left: 40px;">Document 1: WO 2008/137436 A1 (BRISTOL-MYERS SQUIBB CO.), 13 November 2008</p> <p style="margin-left: 40px;">Document 2: WO 2006/083491 A2 (ARENA PHARMACEUTICALS, INC.), 10 August 2006</p> <p style="margin-left: 40px;">Document 3: WO 2005/121121 A2 (ARENA PHARMACEUTICALS, INC.), 22 December 2005</p> <p style="margin-left: 40px;">Document 4: WO 2005/007647 A1 (ARENA PHARMACEUTICALS, INC.), 27 January 2005</p> <p style="margin-left: 80px;">The abovementioned documents 1 to 4 are cited in the ISR.</p> <p style="margin-left: 40px;">• The invention as in claims 1 to 21 and 24 to 25 is novel and involves an inventive step in relation to documents 1 to 4.</p> <p style="margin-left: 80px;">None of documents 1 to 4 describes or suggests the compound represented by the chemical structural formula in claim 1 of the present application, the compounds described in claims 10 to 12 of the present application, and the compound represented by the chemical structural formula in claim 13 of the present application.</p>			

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International application No.
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Box No. VI	Certain documents cited			
1. Certain published documents (Rule 43bis.1 and 70.10)				
	Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
	WO 2009/141238 A1 [E, X]	26.11.2009	11.05.2009	19.05.2008
	WO 2009/051119 A1 [E, A]	23.04.2009	15.10.2008	16.10.2007
2. Non-written disclosures (Rule 43bis.1 and 70.9)				
	Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)	

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: International Patent Classification (IPC)

C07D401/14 (2006.01) i, A61K31/454 (2006.01) i,
A61K31/506 (2006.01) i, A61K31/519 (2006.01) i,
A61K31/5377 (2006.01) i, A61K31/55 (2006.01) i,
A61P1/00 (2006.01) i, A61P1/02 (2006.01) i,
A61P1/04 (2006.01) i, A61P1/08 (2006.01) i,
A61P1/12 (2006.01) i, A61P1/16 (2006.01) i,
A61P1/18 (2006.01) i, A61P3/04 (2006.01) i,
A61P3/06 (2006.01) i, A61P3/10 (2006.01) i,
A61P7/00 (2006.01) i, A61P9/00 (2006.01) i,
A61P9/04 (2006.01) i, A61P9/10 (2006.01) i,
A61P9/12 (2006.01) i, A61P11/00 (2006.01) i,
A61P13/10 (2006.01) i, A61P13/12 (2006.01) i,
A61P15/00 (2006.01) i, A61P17/02 (2006.01) i,
A61P17/06 (2006.01) i, A61P19/02 (2006.01) i,
A61P19/06 (2006.01) i, A61P19/10 (2006.01) i,
A61P21/04 (2006.01) i, A61P25/00 (2006.01) i,
A61P25/02 (2006.01) i, A61P25/28 (2006.01) i,
A61P27/02 (2006.01) i, A61P27/12 (2006.01) i,
A61P27/16 (2006.01) i, A61P29/00 (2006.01) i,
A61P31/00 (2006.01) i, A61P35/00 (2006.01) i,
A61P35/02 (2006.01) i, A61P43/00 (2006.01) i,
C07D405/14 (2006.01) i, C07D413/14 (2006.01) i,
C07D487/04 (2006.01) i