

**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 p2004289343	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. PCT/JP2005/003872	International filing date ( <i>day/month/year</i> ) 07 March 2005 (07.03.2005)	Priority date ( <i>day/month/year</i> ) 30 September 2004 (30.09.2004)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant KOBAYASHI PHARMACEUTICAL CO., LTD.			

<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 6 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 border="0"> <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 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 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 checked="" 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 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 type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application
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<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application																						

	Date of issuance of this report 03 April 2007 (03.04.2007)
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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)

Applicant's or agent's file reference <b>p2004289343</b>		<b>FOR FURTHER ACTION</b> See paragraph 2 below	
International application No. <b>PCT/JP2005/003872</b>	International filing date (day/month/year) <b>07.03.2005</b>	Priority date (day/month/year) <b>30.09.2004</b>	
International Patent Classification (IPC) or both national classification and IPC			
Applicant <b>KOBAYASHI PHARMACEUTICAL CO., LTD.</b>			

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	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.	With regard to the <b>language</b> , this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
<input type="checkbox"/>	This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2.	With regard to any <b>nucleotide and/or amino acid sequence</b> disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
a.	type of material
<input type="checkbox"/>	a sequence listing
<input type="checkbox"/>	table(s) related to the sequence listing
b.	format of material
<input type="checkbox"/>	in written format
<input type="checkbox"/>	in computer readable form
c.	time of filing/furnishing
<input type="checkbox"/>	contained in the international application as filed.
<input type="checkbox"/>	filed together with the international application in computer readable form.
<input type="checkbox"/>	furnished subsequently to this Authority for the purposes of search.
3.	<input type="checkbox"/> 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.
4.	Additional comments:

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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 _____ Claims 1-9 _____	YES NO
	Inventive step (IS)	Claims _____ Claims 1-9 _____	YES NO
	Industrial applicability (IA)	Claims 1-9 _____ Claims _____	YES NO
2.	Citations and explanations:		
	<p>Document 1: JP 2004-231516 A (Daiya Seiyaku Kabushiki Kaisha), 19 August 2004  Document 2: JP 2004-57430 A (Daiya Seiyaku Kabushiki Kaisha), 26 February 2004  Document 3: JP 2003-70898 A (Raifukea Giken Kabushiki Kaisha), 11 March 2003</p> <p>(i) The inventions of claims 1-9 do not appear to possess novelty or involve an inventive step based on document 1 cited in the ISR.</p> <p>Document 1 describes a pad material formed by a heat release-promoting part having an external gel composition of which water content is 30 to 95 wt.%, wherein heat is released by making a larger contact area with external air on the front surface or the back surface (Claims 1 and 9). Also, the following matters are described: (A) the heat release-promoting part is a concave shape or a ditch shape (claim 11, Figs. 27-31); (B) a support material can be provided on the front surface or the back surface (claim 24); (C) the external gel composition can contain aroma oil or pharmacologically active substances (claim 25); and (D) carrageenan is used as a water-soluble high molecule forming the gel composition and 1-menthol is used as a pharmacologically active substance (paragraphs 0026, 0039).</p> <p>(ii) The inventions of claims 1-4 and 6-9 do not appear to possess novelty or involve an inventive step based on document 2 cited in the ISR.</p> <p>Document 2 describes, in a pad material comprising a gel composition which is turned into gel by containing water-soluble high molecule and water, a pad material provided with a heat release-promoting part wherein heat is released by making a larger contact area with external air is described (claim 1). Also, the following matters are described: (A) the heat release-promoting part, which is in a concave or ditch shape for heat release, is provided on a surface opposite to a sticking surface (claim 3, Figs. 8-12), (B) the gel composition may contain aroma oil or pharmacologically active substances (claim 6), and (C) carrageenan can be given as an example of a water-soluble high molecule and 1-menthol can be given as an example of a pharmacologically active substance used for the gel composition (paragraphs 0014, 0023).</p>		

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

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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 question whether the claims are fully supported by the description, are made:

Claim 8 describes “menthol and derivative thereof”, and “salicyl acid and substance similar thereto”, but to what extent of compounds do “derivative thereof” and “substance similar thereto” encompass is unclear.

Supplemental Box

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

Continuation of: Box V

(iii) The invention of claim 5 does not appear to involve an inventive step based on documents 2 and 3 cited in the ISR.

Document 3 describes a sticking agent wherein a support body is provided on one surface and a gel layer of water-soluble high molecule material of which water content is 90 wt.% or more is layered on the other surface (claim 1), and describes that the sticking agent evaporates its water content by sticking and exhibits high cooling effect (paragraph 0030).

Therefore, in the invention described in document 2, in order to exhibit a cooling effect, employing a constitution wherein the water content of the gel layer is 90 wt.% or more could easily be conceived by a person skilled in the art, and no outstanding effect due to this matter can be found.