

CAVELIER
ABOGADOS

WEB SITE: www.caveller.com
E-MAIL: caveller@caveller.com

EDIFICIO SISKI
CARRERA 4 No. 72 - 35
BOGOTÁ 8, COLOMBIA

TELEFONO: (57) (1) 347-3611
TELEFAX: (57) (1) 217-9211 (57) (1) 310-4995

Señora Jefe de la
DIVISION DE NUEVAS CREACIONES
Superintendencia de Industria y Comercio
E. S. D.

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SUPERINDUSTRIA Y COMERCIO
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Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

Trámite : 011
Evento : 379
Actuación: 329

Referencia : Expediente No. 02.089.194

Solicitante : **SANKYO COMPANY, LIMITED AND
GEORGETOWN UNIVERSITY**

Asunto : Solicitud de patente para: **ISOFORMAS DE
ESFINGOSINA CINASA TIPO 2 DE MAMÍFERO,
CLONACIÓN EXPRESIÓN Y MÉTODOS DE USO
DE LAS MISMAS.**

Fecha de presentación: 3 de octubre de 2002

Yo, Emilio FERRERO obrando como apoderado de solicitante en el asunto antes identificado, atentamente presento el reporte del examen preliminar de la solicitud de patente internacional No. PCT/US01/09664, correspondiente a la solicitud de Fase Nacional de la referencia.

Bogotá, - 6 JUN 2003
Señora Jefe,

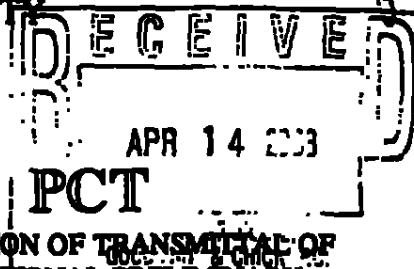

EMILIO FERRERO
T.P.A. No. 31.929

COLO 13473-841-001-5
MRE/MRM/
ID-000010/WPC13473

PATENT COÖPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
RICHARD S. BARTH
FRISHAUF, HOLTZ, GOODMAN, LANGER &
CHICK, P.C.
767 THIRD AVENUE
NEW YORK, NY 10017-2023



NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing
(day/month/year)

10 APR 2003

Applicant's or agent's file reference

00170PCT/HG

IMPORTANT NOTIFICATION

International application No.

PCT/US01/09664

International filing date (day/month/year)

26 March 2001 (26.03.2001)

Priority date (day/month/year)

03 April 2000 (03.04.2000)

Applicant

SANKYO COMPANY, LIMITED

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231
Facsimile No. (703)305-3230
Form PCT/IPEA/416 (July 1992)

Authorized officer

David J. Steadman

Telephone No. (703) 308-0196

David J. Steadman

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 00170PCT/EG	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US01/09664	International filing date (day/month/year) 26 March 2001 (26.03.2001)	Priority date (day/month/year) 03 April 2000 (03.04.2000)
International Patent Classification (IPC) or national classification and IPC IPC(7): C07H 21/04; C12N 9/12, 15/63, 5/00, 5/04, 5/06, 1/20, 1/16; C12P 21/06; C12Q 1/48; G01N 33/53; A61K and US CL: 536/23.2; 433/194, 320.1, 325, 419, 252.3, 254.11, 69.1, 15, 7.1, 6; 424/94.5, 139.1; 514/44		
Applicant SANKYO COMPANY, LIMITED		
1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of <u>8</u> sheets, including this cover sheet. ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of <u> </u> sheets. 3. This report contains indications relating to the following items: I ☒ Basis of the report II ☐ Priority III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability IV ☒ Lack of unity of invention V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI ☐ Certain documents cited VII ☐ Certain defects in the international application VIII ☒ Certain observations on the international application		
Date of submission of the demand 27 August 2001 (27.08.2001)	Date of completion of this report 23 MARCH 2003	
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20531 Facsimile No. (703)305-3230	Authorized officer David J. Stoddman Telephone No. (703) 308-0196	

Form PCT/IPEA/409 (cover sheet)(July 1998)

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-48 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____
- ☒ the claims:
pages 74-80 as originally filed
pages NONE as amended (together with any statement) under Article 19
pages NONE filed with the demand
pages NONE filed with the letter of _____
- ☒ the drawings:
pages 1-11 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____
- ☒ the sequence listing part of the description:
pages 49-71 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in printed form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under Item 1 and annexed to this report.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
☒ paid additional fees.
☐ paid additional fees under protest.
☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
☐ the parts relating to claims Nos. ____

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V. Reasoned statement under Rule 66.2(a)(II) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)

Claims 1-50 YES

Claims NONE NO

Inventive Step (IS)

Claims 1-50 YES

Claims NONE NO

Industrial Applicability (IA)

Claims 1-50 YES

Claims NONE NO

2. CITATIONS AND EXPLANATIONS

Claims 1-50 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the sphingosine kinase type 2 (SPHK2) polypeptide of claims 1-28, 31-38, 43, and 46, agents that modulate SPHK2 of claims 29, 30, and 47, methods of treatment by administering an SPHK2 antibody of claims 39-44, method for detecting SPHK2 of claim 48, and a kit for detecting SPHK2 of claims 49 and 50.

NEW CITATIONS

NONE

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:

Please See Continuation Sheet

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Certain Documents Cited

1. Certain published documents (Rule 70.10)

Application No

Publication Date

Filing Date

Priority date (valid clai

Patent No.

(day/month/year)

(day/month/year)

(day/month/year)

None

None

None

None

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure

Date of written disclosure referring
non-written disclosure

(day/month/year)

(day/month/year)

None

None

None

263 265

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

VIII. The following observations on the clarity of the claims, description, and drawings or on the questions, are made:

Claims 1-7 and 11-50 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because practice of the claimed invention is not adequately described in writing, as required under PCT Rule 5.1(a)(iii), for the reasons set forth in the following paragraph.

Claims 1-5 and 11-28 are drawn to nucleic acids encoding a sphingosine kinase type 2 (SPHK2) polypeptide, vectors comprising said nucleic acids, host cells comprising said vectors, methods of producing polypeptides using said host cells, and methods of detecting an agent or a drug that modulates SPHK2 activity. Claims 6, 7, 31-38, and 45-47 are drawn to SPHK2 polypeptides, compositions comprising SPHK2 polypeptides, and methods of use thereof for regulating a biological process, treating a disease, and screening agents. Claims 39-44 are drawn to methods for treating a disease using an antibody to an SPHK2 polypeptide. Claim 48 is drawn to a method of detecting an SPHK2 polypeptide using an antibody. Claim 49 is drawn to a method for detecting SPHK2 in a sample by PCR. Claim 50 is drawn to a diagnostic kit for detecting SPHK2 RNA or cDNA. The description provides only a single representative species of a murine SPHK2, i.e., SEQ ID NO:12, encoded by SEQ ID NO:11. The description provides only a single representative species of a human SPHK2, i.e., SEQ ID NO:14, encoded by SEQ ID NO:13. No description has been provided of other SPHK2 polypeptides or encoding nucleic acids which would indicate that applicants had possession of the claimed subject matter. No description has been provided of agents that modulate SPHK2 activity which would indicate applicants had possession of the claimed subject matter.

Claims 1-7 and 11-50 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because practice of the claimed invention is not enabled as required under PCT Rule 5.1(a) for the reasons set forth in the following paragraph.

Claims 1-7 and 11-50 while being enabling for the polynucleotides of SEQ ID NO:11, encoding SEQ ID NO:14 and the polynucleotide of SEQ ID NO:13 encoding SEQ ID NO:14, does not reasonably enable all nucleic acids encoding mammalian, murine, or human SPHK2 polypeptides, polypeptides encoded thereby, antibodies thereto, and methods of use. Furthermore, the description provides no enablement for an agent that modulates SPHK2 activity. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of SPHK2 polypeptides and methods of use thereof, encoding nucleic acids and methods of use thereof, methods of using antibodies thereto, and agents that modulate SPHK2 activity.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Thus, applicants have not provided sufficient guidance to enable one to make and use the claimed invention in a manner reasonably correlated with the scope of the claims.

Claims 1-3, 10, and 31 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 1-3, 10, and 31 are indefinite for the following reason(s):

* claims 1-3 are indefinite in the recitation of "mammalian sphingosine kinase", "mouse sphingosine kinase" and "human sphingosine kinase". The claims are indefinite because, without identifying characteristics, such as an amino acid sequence, it is unclear as to how one distinguishes the recited kinases from other kinases.

* claim 10 is indefinite in the recitation of "Genbank Accession No. x12325785" and "Genbank Accession No. bank1325732". GenBank Accession Numbers can be modified and revised. As such identification of a DNA by reference to a GenBank Accession Number renders the claim indefinite.

* claim 31 is indefinite in the recitation of "biological process". It is unclear from the claims and the specification as to the scope of biological processes that are meant to be included in the claim.