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Señores

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
Rad: 08-0963/8- -00002-0000
Rec: 2007-01-30 17:23:04 Dep. 2007 NUEVAS CREACIONES
Ita. 11 PATENTE/IIU
Evo: 3/0 FASE NACIONAL
Act 444 RESOLUCION/IIU Folio: 1/

E. _____ S. _____

Expediente No. 06-096.376

Solicitud de Patente de Invención titulada: "COMPOSICIONES FARMACEUTICAS
SECADAS POR ATOMIZACION"

Solicitante: SMITHKLINE BEECHAM CORPORATION

RESPUESTA AL OFICIO N°. 13882 NOTIFICADO
POR FIJACION EN LISTA No. 425 DE FECHA 1 DE DICIEMBRE DE 2006.
(EXAMEN DE FORMA)

J. IAN RAISBECK, mayor de edad y vecino de Bogotá, identificado tal como aparece al pie de mi firma, en mi carácter de apoderado de la sociedad solicitante, me permito manifestar lo siguiente ante el auto emanado de ese Despacho, dentro del plazo legal previsto en el artículo 39 de la Decisión 486, en los siguientes términos:

1. En respuesta a la primera observación del Examinador, me permito aclarar al Despacho que la presente solicitud entra en Fase Nacional Capítulo I y no Capítulo II como inicialmente se presentó. Para tal efecto, adjunto copia del Reporte Preliminar Internacional de Patentabilidad, el cual, valga aclarar, no contiene anexos.
2. En respuesta a la segunda observación del Examinador, me permito aportar, junto al presente memorial, el documento de cesión debidamente legalizado, junto con su correspondiente traducción, según lo previsto en el Art. 26- k de la Decisión 486.

Atentamente,



J. IAN RAISBECK
C. C. N° 79.376.996 de Bogotá
T.P. 135.799 CSJ

Anexo: Reporte Preliminar Internacional de Patentabilidad
Documento de Cesión

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 P860811	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2005/010350	International filing date (<i>day/month/year</i>) 28 March 2005 (28.03.2005)	Priority date (<i>day/month/year</i>) 30 March 2004 (30.03.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant: SMITHKLINE BEECHAM CORPORATION		

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).
2. This RIPOUT consists of a total of 6 sheets, including this cover sheet.

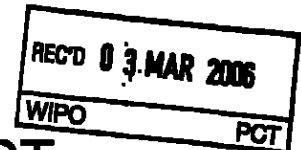
In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.
3. This report contains indications relating to the following items:

☒ Box No. I	Basis of the report
☐ 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 Article 35(2) 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
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).

	Date of issuance of this report 04 October 2006 (04.10.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Philippe Becamel e-mail: pt12@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY



From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

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

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/US2005/010350

International filing date (day/month/year)
28.03.2005

Priority date (day/month/year)
30.03.2004

International Patent Classification (IPC) or both national classification and IPC
A61K9/16, A61K31/47

Applicant
SMITHKLINE BEECHAM CORPORATION

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 usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, 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 three 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:



European Patent Office - P.B. 5818 Patentzen 2
NL-2280 HV Rijswijk - Pays Bas
Tel: +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Authorized Officer

Martin, E

Telephone No. +31 70 340-2982



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/010350

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Box No. 1 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, unless otherwise indicated under this item.
☐ 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 Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, 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:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table 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:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/010350

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

1. Statement

Novelty (N)	Yes: Claims	1-32
	No: Claims	
Inventive step (IS)	Yes: Claims	1-32
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-32
	No: Claims	

2. Citations and explanations

see separate sheet

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:

see separate sheet

Re Item V.

- 1 Reference is made to the following document (for relevant passages see search report):**

**D1 : WO 02/094187 A (SMITHKLINE BEECHAM CORPORATION; HAY,
DOUGLAS, WILLIAM, PIERRE; SANGER,) 28 November 2002 (2002-11-28)**

- 2 Document D1, which is considered to represent the most relevant state of the art, discloses talnetant particles having a size of 2 to 10 micrometer.**

From this, the subject-matter of independent claim 1 differs in that: the particles are spray-dried and comprise at least one ionic surfactant and one or more soluble carriers.

- 2.1 The subject-matter of claim 1 is therefore novel (Article 33(2) PCT)
The problem to be solved by the present invention may be regarded as: the provision of spray dried talnetant particles which have the same size as the freshly-milled particles, when dispersed in aqueous medium.**
- 2.2 The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons: D1 is not concerned with spray-drying micronised talnetant and does not disclose the problem of the poor recovery of particle size.**
- 2.3 Claims 2-18 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.**
- 2.4 The same applies *mutatis mutandis* to independent claims 19 and 30, and dependent claims 20-29 and 31-32.**

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2005/010350

Re Item VIII.

- 1 The application does not meet the requirements of Article 6 PCT, because claims 1 and 19 are not clear.

The term D₉₀ used in claims 1 and 19 is vague and unclear and leaves the reader in doubt as to the meaning of the technical features to which it refers, thereby rendering the definition of the subject-matter of said claims unclear, Article 6 PCT.

AP STILLA

(Convención de la Haya del 5 de Octubre de 1961)

1. País: Estados Unidos de América
El presente documento público
2. Ha sido firmado por: **ARLENE ELIZABETH CANNON**
3. Actuando en su calidad de Notario Público
4. Aparece el sello **ARLENE ELIZABETH CANNON, NOTARIO PUBLICO, CONDADO DE MONTGOMERY, COMUNIDAD DE NACIONES DE PENNSYLVANIA.**
Se certifico
5. En Harrisburg, Pennsylvania
6. El 04 de agosto de 2006
7. Por Pedro A. Cortés, Secretario de la Comunidad de Naciones de Pennsylvania.
8. Bajo el Número **200630911**
9. Lleva el Sello del Secretario de la Comunidad de Naciones de Pennsylvania.
10. Firmado por Pedro A. Cortés.

A
X

CERTIFICACIÓN NOTARIAL

Yo, Arlene Elizabeth Cannon, una Notaria Pública comisionada para la comunidad de Naciones de Pennsylvania, condado de Montgomery, por medio de la presente certifico que el documento anexo constituye una fiel copia de la cesión correspondiente a **60/557,571** presentada el **30 de marzo de 2004**, y la **Solicitud Internacional PCT/US2005/010350** presentada el **28 de marzo de 2005** Titulada: **"COMPOSICIONES FARMACEUTICAS SECADAS POR ATOMIZACION"**

Fecha: 3 de agosto de 2006

(FDO) ARLENE ELIZABETH CANNON

UPPER MERION, Twp., Condado Montgomery, cuya comisión vence el 21 de mayo de 2009.

Comunidad de Naciones de Pennsylvania

(SELLO)

CESION

CONSIDERANDO QUE **Vlaslos ANDRONIS**, de c/o 709 Swedeland Road, del Reino de Prussia, PA 19406, U.S.A, un ciudadano de Grecia; **Rennan PAN** de 709 Swedeland Road, del Reino de Prussia, PA 19406, U.S.A, un ciudadano de China; y **Kamlesh Rameshchandra PATEL** de 709 Swedeland Road, del Reino de Prussia, PA 19406, U.S.A, un ciudadano de Estados Unidos de America; respectivamente han realizado un invento, o han descubierto ciertas mejoras en: **"COMPOSICIONES FARMACEUTICAS DE SECADO CON SPRAY"** en adelante llamado la Invención y mejora para dicha solicitud de Prioridad 60/557,571 fue presentada el 30 de marzo de 2004 en la Oficina de Marcas y Patentes de los Estados Unidos de América y cuya Solicitud Internacional PCT fue presentada designada en Los Estados Unidos de América y llamado Inventor el cedente, y solo en los Estados Unidos inventor de la solicitud.

(PCT/US2005/010350 presentada 28 de marzo 2005)

y CONSIDERANDO QUE, **SMITHKLINE BEECHAM CORPORATION** una compañía constituida en La Comunidad de Naciones de Pennsylvania de One Franklin Plaza, PO Box 7929, Filadelfia, PA 19101 USA, desea adquirir la totalidad de los derechos, títulos e interés del CEDENTE sobre dicho Invento y mejoras, y cualquier solicitud de dicha Invención y mejoras y cualquier Patente que por consiguiente sea obtenida, en todos los países incluyendo los Estados Unidos, en sus posesiones territoriales;

POR CONSIGUIENTE, a quien pueda Interesar: Sépase que **Vlasios ANDRONIS, Rennan PAN y Kamlesh Rameshchandra PATEL** por contraprestación onerosa nuestra cuyo recibo reconozco, por el presente, hemos vendido cedido y transferido y por el medio del presente, venden, ceden, y transfieren a favor del Cesionario, la totalidad y exclusividad de su derecho, título e Intereses en el mencionado Invento, y mejoras a la mencionada **SMITHKLINE BEECHAM CORPORATION** en todos los Estados Unidos de América y en sus posesiones territoriales, en y para la mencionada solicitud, o de cualquier continuación, continuación parcial, división, renovación, sustitución, conversión o re-expedición que se haga al respecto, y en y para cualquier y todas las patente de los Estados Unidos de América;

Y, todos nuestro derechos títulos e intereses en y para dicha Invención y mejoras a **SMITHKLINE BEECHAM CORPORATION** en todos los otros países a través del mundo, y en y para cualesquiera solicitudes en los otros países mencionados, y continuaciones parciales, adiciones de patentes, validaciones de patentes, patentes de Importación, registros y cualquier renovación, extensiones y divisiones de la misma, y en y para cualquier y todas las patentes de todos los países mencionados en donde pueda ser otorgada dicha Invención y mejoras Incluyendo cualquier derecho de prioridad bajo la Convención Internacional.

Y, Yo/Nosotros por el presente autorizamos y solicitamos a la autoridad de expedición para que expida todas y cualesquiera patentes relacionadas con la solicitud mencionada, a favor de **SMITHKLINE BEECHAM CORPORATION**, en calidad de cesionaria de la totalidad de todos los derechos, título e intereses y así como la venta y uso de la misma en nombre de los cesionarios, sus

sucesores y cesionarios, así como sus Intereses tal como aparece en el presente;

Y, Yo/Nosotros garantizamos que no hemos informado nuestro conocimiento a otros en ninguno de nuestros derechos, mejoras, en las solicitudes o patentes ó ninguna licencia de uso de dicha invención, y así como la venta y uso de la misma, o uso de dicha invención y mejora y que tenemos todo el derecho de ceder el mismo a **SMITHKLINE BEECHAM CORPORATION**; Y nosotros los firmantes **Vlasios ANDRONIS, Rennan PAN y Kamlesh Rameshchandra PATEL**, en consideración mencionada, por medio de la presente acordamos que nuestros ejecutores o representantes legales, suministrarar toda la información, ejecutar y entregar cualesquiera y todos los otros instrumentos por escrito, y todos los hechos adicionales, solicitudes por escrito, declaraciones juramentadas, documentos de cesiones y otros documentos que sean necesarios o requeridos para obtener más efectiva la protección de la mencionada en dicha **SMITHKLINE BEECHAM CORPORATION**, sus sucesores y cesionarios, todos los derechos título e intereses en y para el mencionado invento y mejoras, solicitudes, patentes, derechos, títulos e Intereses vendidos en la presente, cedido y traspasado, o que se trata de hacer. *Esta cesión debe hacerse efectiva a partir del 30 de marzo de 2004.*

EN FE DE LO CUAL, firmo y estampo mi sello en la fecha indicada a continuación.

(FDO) **Vlasios ANDRONIS**

Inventor: **Vlasios ANDRONIS**

Fecha: 25 de abril de 2005

EN FE DE LO CUAL, firmo y estampo mi sello en la fecha indicada a continuación.

(FDO) **Rennan PAN**

Inventor: **Rennan PAN**

Fecha: 28 de abril de 2005

Handwritten signature and initials in the top right corner.

EN FE DE LO CUAL, firmo y estampo mi sello en la fecha indicada a continuación.

(FDO) Kamlesh Rameshchandra PATEL

Inventor: **Kamlesh Rameshchandra PATEL** Fecha: 28 de abril de 2005

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APOSTILLE

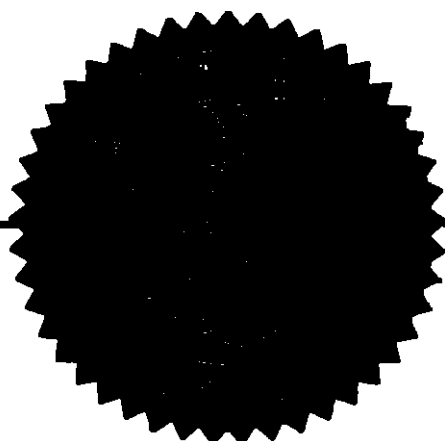
(Convention de La Haye du 5 octobre 1961)

1. Country : United States Of America
2. This public document has been signed by **ARLENE ELIZABETH CANNON**
3. acting in the capacity of **NOTARY PUBLIC**
4. bears the seal/stamp **ARLENE ELIZABETH CANNON, NOTARY PUBLIC, MONTGOMERY COUNTY, COMMONWEALTH OF PENNSYLVANIA**
5. at Harrisburg, Pennsylvania
6. The 4th day of August, 2008
7. by **Pedro A. Cortés, Secretary of the Commonwealth of Pennsylvania**
8. No : 200830911
9. Seal/Stamp
10. Signature

Certified

Pedro A. Cortés

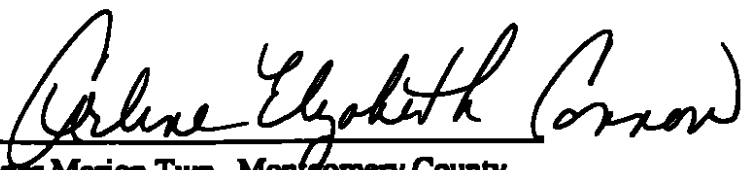
Pedro A. Cortés

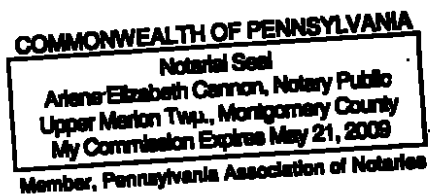


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*70***NOTARIAL CERTIFICATION**

I, Arlene Elizabeth Cannon, a Notary Public commissioned in the Commonwealth of Pennsylvania, County of Montgomery, do hereby certify that annexed hereto is a true and correct copy of the executed assignment pursuant to 60/557,571 filed 30 March 2004 and International Application No. PCT/US2005/010350 filed 28 March 2005, entitled "Spray Dried Pharmaceutical Compositions."

Date: 3 August 2006


Upper Merion Twp., Montgomery County
My Commission Expires May 21, 2009



Assignment

WHEREAS, I/we Vlasios ANDRONIS, of c/o 709 Swedeland Road, King of Prussia, PA 19406 USA, a citizen of Greece; Rennan PAN of 709 Swedeland Road, King of Prussia, PA 19406 USA, a citizen of China; and Kamlesh Rameshchandra PATEL of 709 Swedeland Road, King of Prussia, PA 19406 USA, a citizen of United States of America; respectively has/have invented or discovered certain improvements in Spray Dried Pharmaceutical Compositions hereinafter referred to as said invention and improvements for which a priority application 60/557,571 was filed on 30 March 2004 in the United States Patent and Trademark Office and for which a PCT international application is now being filed designating the United States of America and naming assignor as inventor, and in the United States only applicant/inventor.

(PCT/US2005/010350 filed 28 March 2005)

WHEREAS, SMITHKLINE BEECHAM CORPORATION., a company incorporated in the Commonwealth of Pennsylvania, in the United States of America, whose registered office is at One Franklin Plaza, PO Box 7929, Philadelphia, Pennsylvania 19101, is desirous of acquiring the whole right, title and interest in and to said invention and improvements, and in and to any applications for said invention and improvements and any Letters Patent to be obtained therefor, in all countries, including the United States, its territories and possessions;

NOW, THEREFORE, to all whom it may concern, be it known that I/we, Vlasios ANDRONIS, Rennan PAN and Kamlesh Rameshchandra PATEL for good and valuable consideration unto me/us moving, the receipt whereof is hereby acknowledged, have sold, assigned and transferred, and by these presents do sell, assign and transfer my/our whole right, title and interest in and to said invention and improvements to said SMITHKLINE BEECHAM CORPORATION, throughout the United States of America, its territories and possessions, and in and to said application and any extensions, reissues, continuations, continuations-in-part, and any divisions thereof, and in and to any and all Letters Patent of the United States of America;

AND, my/our whole right, title and interest in and to said invention and improvements to SMITHKLINE BEECHAM CORPORATION, in all other countries throughout the world, and in and to any applications in said other countries, and continuations-in-part, patents of addition, revalidation patents, patents of importation, registrations, and any renewals, extensions and divisions thereof, and in and to any and all Letters Patent of said all other countries which may be granted on said invention and improvements including any priority rights under the International Convention.

AND, I/we do hereby authorize and request the issue of any Letters Patent in the respective areas referred to, to said SMITHKLINE BEECHAM CORPORATION, as assignees of my/our whole right, title and interest in and to the same for the sole use and behalf of the said assignees, their successors and assigns as their interests appear herein;

AND, I/we warrant that I/we have not knowingly conveyed to others any right in said invention, improvements, applications or patents or any license to use the same or to make, use or sell anything embodying or utilizing said invention and improvements and that I/we have good right to assign the same to SMITHKLINE BEECHAM CORPORATION;

AND, I/we the undersigned Vlasios ANDRONIS, Rennan PAN and Kamlesh Rameshchandra PATEL for the consideration aforesaid, do hereby agree that I/we or my/our executors or legal representatives, will provide information and make, execute and deliver any and all other instruments in writing, and any and all further acts, application papers, affidavits, assignments and other documents which may be necessary or desirable to more effectually secure to and vest in said SMITHKLINE BEECHAM CORPORATION, their successors and assigns, the whole right, title and interest in and to the said invention and improvements, applications, Letters Patent, rights, title and interest hereby sold, assigned and conveyed, or intended so to be. *This assignment should be deemed effective as of 30 March 2004.*

IN WITNESS WHEREOF, I/we have hereunto set my/our hand(s) and affixed my/our seal(s) on the date(s) indicated below.

V G Andronis 4/25/05
Inventor: Vlasios ANDRONIS Date

IN WITNESS WHEREOF, I/we have hereunto set my/our hand(s) and affixed my/our seal(s) on the date(s) indicated below.

Rennan PAN 28 Apr 2005
Inventor: Rennan PAN Date

IN WITNESS WHEREOF, I/we have hereunto set my/our hand(s) and affixed my/our seal(s) on the date(s) indicated below.

Kamlesh Rameshchandra PATEL 28 Apr 2005
Inventor: Kamlesh Rameshchandra PATEL Date