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SUPERINTENDENCIA DE INDUSTRIA Y C
DIVISION DE NUEVAS CREACIONES
E. S. D.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
Rad: 06-034940-00001-0000
Fec: 2006-05-22 15:15:39 Dep: 2020 NUECREACIONES
Tm: 11 PATENTE
Eve: 378 FASE NACIONAL
Act: 329 OTOMFORMACION Fclon: 11

REF: Expediente No. 06 034.940 - Solicitud de Patente Entrada en Fase Nacional Corresp. a la Solicitud Internacional PCT/GB2004/003923 a favor de **ASTRAZENECA AB**
Titulada: DERIVADOS DE QUINAZOLINA COMO INHIBIDORES DE TIROSINA CINASA

JUAN PABLO CADENA SARMIENTO, vecino de Bogotá, portador de la tarjeta profesional No. 57492, obrando como apoderado de la sociedad **ASTRAZENECA AB**, según lo acredita el documento de poder presentado en esa División, me permito allegar.

1. Reporte de Examen Preliminar Internacional (formas PCT/IB326, PCT/IB/373 y PCT/ISA/237).

De la señora jefe atentamente,


JUAN PABLO CADENA SARMIENTO
C.C. No. 80.410.337 de Usaquén
Cra 7 No. 16-56 Piso 9

Bogotá, 29 de mayo de 2006
CHP/MEV/hsr.

PATENT COOPERATION TREATY

PCT/GB2004/003923

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)

(PCT Rule 44bis.1(c))

To:

ASTRAZENECA
Global Intellectual Property
S-151 85 Sodertälje
SUÈDE

CODE	DATE	NTD

ANKOM 31 MAR 2006 GIPS

DATA
ENTERED

FINAL

CHECK

IMPORTANT NOTICE

Date of mailing (day/month/year)
23 March 2006 (23.03.2006)Applicant's or agent's file reference
101211-1 WOInternational application No.
PCT/GB2004/003923International filing date (day/month/year)
13 September 2004 (13.09.2004)Priority date (day/month/year)
16 September 2003 (16.09.2003)

Applicant

ASTRAZENECA AB et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

- 4 APR 2006

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Dorothee Mülhausen

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

293 9478

CODE	DATE	NTD
ANKOM 31 MAR 2006 GIPS		
DATA ENTERED		
FINAL CHECK		

Applicant's or agent's file reference 101211-1 WO	FOR FURTHER ACTION See item 4 below	
International application No. PCT/GB2004/003923	International filing date (day/month/year) 13 September 2004 (13.09.2004)	Priority date (day/month/year) 16 September 2003 (16.09.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ASTRAZENECA AB		

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 REPORT consists of a total of 9 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).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35	Date of issuance of this report 16 March 2006 (16.03.2006)
	Authorized officer Dorothee Mülhausen Telephone No. +41 22 338 87 40

Form PCT/IB/373 (January 2004)



PATENT COOPERATION TREATY

24/3

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 14 JAN 2005

PCT/PO PCT

To:

see form PCT/ISA220

CODE	DATE	NTD
ANKOM	31 MAR 2006	GIPS
DATA		
ENTERED		
FINAL		
CHECK		

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)Date of mailing
(day/month/year) see form PCT/ISA210 (second sheet)Applicant's or agent's file reference
see form PCT/ISA220FOR FURTHER ACTION
See paragraph 2 belowInternational application No.
PCT/GB2004/003923International filing date (day/month/year)
13.09.2004Priority date (day/month/year)
16.09.2003International Patent Classification (IPC) or both national classification and IPC
C07D401/12, C07D405/14, C07D401/14, A61K31/517, A61P35/00Applicant
ASTRAZENECA AB

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/ISA220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA220.

3. For further details, see notes to Form PCT/ISA220.

Name and mailing address of the ISA:



European Patent Office
D-80288 Munich
Tel. +49 89 2399-0 Tx: 523658 epmu d
Fax: +49 89 2399-4465

Authorized Officer

Kyriakakou, G
Telephone No. +49 89 2399-7835



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

245 246 P
International application No.
PCT/GB2004/003923

Box No. I 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**

296 297 \$
International application No.
PCT/GB2004/003923

Box No. || Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. ☐ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

4. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

297 298 P
International application No.
PCT/GB2004/003923

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. 30-33 in respect of industrial applicability

because:

- ☒ the said international application, or the said claims Nos. 30-33 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

- ☐ 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.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- the written form ☐ has not been furnished
☐ does not comply with the standard
- the computer readable form ☐ has not been furnished
☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

298 204 8
International application No.
PCT/GB2004/003923

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

1. Statement

Novelty (N)	Yes: Claims	1-35
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-35
Industrial applicability (IA)	Yes: Claims	1-29,,34,35
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 30-33 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1 (iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: WO-A-03040109

D2: WO-A-02092578

D3: WO-A-0194341

D4: WO-A-0132651

D5: WO-A-0031048

D6: WO-A-0055141

D7: Bioorg. Med. Chem. Lett. 13(2003), 637

D8: J. Med. Chem. 2002, 45(6), 1300

D9: J. Med. Chem. 2001, 44(17), 2719

D10: J. Med. Chem. 2000, 43(7), 1380

2. Novelty (Art. 33(2) PCT)

The present application and the prior art documents relate to substituted 4-phenylaminoquinazolines. The main structural difference resides in the nature or the position of the 5, 6 and 7 substituents at the quinazoline ring.

The subject matter of the present claims 1-35 can therefore be considered to be novel.

3. Inventive step

3.1 The object of the present invention is to provide compounds useful in the prevention or treatment of solid tumour disease.

3.2 In the light of the pharmacological tests comprised in the Description (pages 80-84) it is considered as credible that a limited number of the claimed compounds have the alleged activity.

3.3 The prior art documents D2, D4 D5 and D8 which disclose structurally similar 4-phenylaminoquinazoline derivatives with the same pharmacological activity, are considered to represent the closest state of the art. With respect to the said prior art

documents the main structural difference lies in the nature of the 7-substituent of the quinazoline moiety. Furthermore the prior art Document D1, D3, D6, D7 D9 and D10 disclose phenylaminoquinazoline derivatives with a variety of substituents and the same pharmacological activity. Taking the above into account it is evident for the person skilled in the art that the 4-phenylaminoquinazoline group is fundamental for the antiproliferative activity and further modification of the substituents results to more or less potent agents while the pharmacological activity is maintained. The claimed compounds are therefore considered to be prima facie obvious and before an inventive step could be acknowledged, it will be necessary for the Applicant to demonstrate that the present compounds display an unexpected property or a particularly advantageous effect compared to the compounds of the closest state of the art. It has to be stressed that an inventive step could only be based on quantitative data. It should also be taken into consideration that only the structural closest prior art compounds are useful for a meaningful comparison.

3.4 It could be expected that the compounds claimed would actually solve the problem underlying the invention. In this connection it has to be stressed that an inventive step could only be acknowledged on the basis of relevant quantitative data. It has to be taken into account that a limited number of the claimed compounds is used for the pharmacological tests comprised in the Description. These test results do not therefore support the pharmacological activity of all the compounds. It has also to be taken into consideration that a technical effect which justifies the selection of the claimed compounds must be one which can be fairly assumed to be produced by substantially all the selected compounds. In the present case if some of the claimed compounds are indeed potent antitumour agents, it cannot be regarded as sufficient evidence, that all the claimed compounds possess an excellent activity. In view of the above considerations an inventive step could be acknowledged only for those of the claimed compounds which display a better activity and their obvious equivalents. The Applicant is therefore requested to submit a representative range of relevant comparative tests, otherwise the corresponding claims must be amended so as to exclude non inventive subject matter.

Re Item VI

Certain documents cited

301 *[Handwritten signature]*

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

International application No.

PCT/GB2004/003923

Certain published documents

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO-A-0382290	09. 10.2003	25. 03.2003	30.03.2002
			13.07.2002
WO-A-03082831	09. 10.2003	26.03.2003	28. 03.2002
			24. 12.2002
			28.01.2003

302

REPUBLICA DE COLOMBIA
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

Folio 303

2020
Bogotá D.C.,

Doctor(a)
CADENA SARMIENTO JUAN PABLO
Apoderado(a) y/o Representante de
ASTRAZENECA AB

REFERENCIA	Radicación No.	6 34940
	Solicitud internacional	GB2004/003923
	Fecha inicio fase nacional	16/04/2006
	Trámite	11
	Evento	378
	Actuación	416
	Oficio No.	1076
	Folios	1

Teniendo en cuenta que la solicitud de privilegio de patente que se tramita bajo el expediente indicado en la referencia, reúne los requisitos de forma establecidos en la Decisión 486 de la Comisión de la Comunidad Andina, el Tratado de Cooperación en Materia de Patentes (PCT), el Reglamento y la Circular Única de la Superintendencia de Industria y Comercio, se envía el extracto de la solicitud a la Oficina de Comunicaciones para efecto de su publicación en la Gaceta de Propiedad Industrial.

Cúmplase
Dado en Bogotá DC, 14 AGO. 2006

ALIX CARMENZA CESPEDES DE VERGEL
Jefe de la división de Nuevas Creaciones

adpal

DIVISION DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 06-034940

EL EXTRACTO DE LA PRESENTE SOLICITUD DE PATENTE DE INVENCION

PCT FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No 569

DE FECHA 31 DE OCTUBRE DEL 2006, EL TERMINO HABIL SEÑALADO POR

LA LEY EXPIRA EL 01 DE FEBRERO DEL 2007

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicación en la gaceta de Propiedad Industrial, deberá solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, de acuerdo con lo establecido en el Artículo 44 de la Decisión 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI ☐ ☐

NO ☒ ☐ ☐

Bogotá D.C., Mayo de 2007

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

304

RADICACIÓN: 6-34940

EDICTO No. 9917

**LA SECRETARÍA GENERAL AD-HOC
HACE SABER:**

Que esta Superintendencia profirió Resolución No. 14764 de 25-MAY-2007. Que el contenido de la parte resolutive es como sigue: El Superintendente de Industria y Comercio.

RESUELVE

ARTICULO PRIMERO: Declarar abandonada la solicitud de privilegio de patente de invención que entró en fase nacional en virtud del Tratado de Cooperación en Materia de Patentes (PCT), de acuerdo con las razones expuestas en la parte considerativa de la presente resolución.

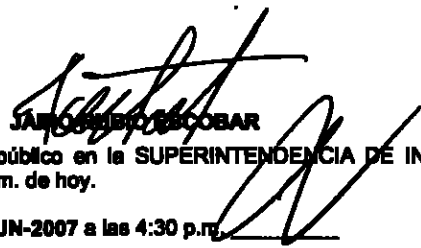
ARTICULO SEGUNDO: Notificar personalmente el contenido de la presente resolución al

doctor Juan Pablo Cadena Samiento, o a quien haga sus veces, en su calidad de apoderado de AstraZeneca Ab., entregándole copia de la misma, advirtiéndole que contra ella procede el recurso de reposición interpuesto ante el Superintendente de Industria y Comercio, al momento de la notificación o dentro de los 5 días hábiles siguientes a ella.

NOTIFÍQUESE Y CUMPLASE

Dada en Bogotá, D.C., a los 25 MAYO 2007

EL SUPERINTENDENTE DE INDUSTRIA Y COMERCIO,


JAIME GÓMEZ ESCOBAR

Para notificar a los interesados, se fija el presente EDICTO en lugar visible al público en la SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO, por el término de (10) diez días hábiles contados a partir de las 8:00 a.m. de hoy.

Secretaría General Ad-Hoc 12-JUN-2007 Este edicto se desflja hoy 26-JUN-2007 a las 4:30 p.m.
Secretaría General Ad-Hoc
EDICTO No. 9917