

06-120228

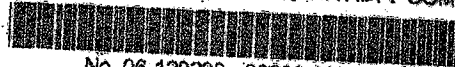
SEÑORES

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

DIVISION DE NUEVAS CREACIONES

E. S.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 06-120228-00003-0000

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Act. 444 RESPUESTA REQUE Folios: 26

Ref.: Expediente N°. 06-120.228

Solicitud de Patente de Invención Titulada: "TRATAMIENTO DE LA HEMORRAGIA DE DISRUPCION EN REGIMENES ANTICONCEPTIVOS EXTENDIDOS".

Solicitantes: SCHERING AKTIENGESELLSCHAFT.

RESPUESTA AL OFICIO N°. 14707 NOTIFICADO
POR FIJACION EN LISTA No. 457, DE FECHA 22 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 en referencia, me permito dar respuesta al auto proferido por ese Despacho, dentro del término legal previsto en mi memorial de prórroga solicitado el 14 de febrero de 2007, en los siguientes términos:

1. En respuesta a la primera observación del Examinador, me permito adjuntar copia del Examen Preliminar Internacional de la presente solicitud, junto con su correspondiente traducción.

2. En respuesta a la segunda observación del Examinador, me permito adjuntar a la solicitud 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. No. 79.376.996 de Bogotá
T.P. 135.799 CSI

Anexos: Examen Preliminar Internacional
Documento de Cesión

TRATADO DE COOPERACIÓN INTERNACIONAL EN MATERIA DE PATENTES

Remitente: EL ORGANISMO DE EXAMEN
PRELIMINAR INTERNACIONAL

PCT

SCHERING AKTIENGESELLSCHAFT
13342
Berlin
Alemania

NOTIFICACIÓN DE ENVÍO DEL INFORME DEL
EXAMEN PRELIMINAR INTERNACIONAL
SOBRE PATENTABILIDAD

(regla PCT Nº 71.1)

Referencia del Solicitante o Agente 53213AWO		Fecha de envío (día/mes/año) 02.11.2006
NOTIFICACIÓN IMPORTANTE		
Referencia Internacional PCT/EP 2005/004777	Fecha de Presentación Internacional (día/mes/año) 29.04.2005	Fecha de Prioridad (día/mes/año) 30.04.2004
Solicitante SCHERING AKTIENGESELLSCHAFT		

1. Se notifica al solicitante que el organismo encargado del Examen Preliminar Internacional envía, mediante la presente, el Informe de Examen Preliminar Internacional elaborado para esta Solicitud Internacional, eventualmente, con los anexos correspondientes.
2. Una copia del Informe - eventualmente, con los anexos correspondientes - es enviada a la Oficina Internacional para su derivación a todos los organismos seleccionados.
3. A petición de un organismo seleccionado, la Oficina Internacional traducirá el Informe (pero no sus anexos) al inglés y lo enviará a tal organismo.
4. **RECORDATORIO**

Para el ingreso en la fase nacional, el solicitante debe proceder, dentro de los 30 meses de la fecha de prioridad (o más tarde en otros organismos), a llevar a cabo ciertos trámites (presentación de traducciones y pago de tasas nacionales) (artículo 39 (1)) (ver también la información brindada por la Oficina Internacional por medio del formulario PCT/B/301).

Cuando se debe enviar a un organismo seleccionado una traducción de la solicitud internacional, esta traducción debe contener también las traducciones de todos los anexos del Informe del Examen Preliminar Internacional. Es responsabilidad del solicitante elaborar tales traducciones y enviarlas directamente al organismo correspondiente seleccionado.

Otros detalles de los plazos y requisitos normativos de los organismos seleccionados se pueden tomar del Manual PCT para solicitantes.

El solicitante es advertido acerca del artículo 33 (5) en el cual se aclara que los criterios de novedad, actividad inventiva y aplicabilidad industrial descritos en el artículo 33 (2) a (4) solo tienen significado para el Examen Preliminar Internacional, y que "cada estado adherido (...) pueda disponer atributos adicionales o modificatorios en tal estado para la determinación de la patentabilidad de la invención reivindicada" (ver también artículo 27 (5)). Tales atributos adicionales se pueden referir, por ejemplo, a excepciones de patentabilidad, a requisitos para la revelación de la invención, así como a claridad y apoyo de los reivindicaciones.

nombre y dirección postal del organismo encargado del
examen preliminar internacional
European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Holanda
Tel. (+31-70) 340-2040; Tx: 31.691.epo.nl
Fax: (+31-70) 340-3016

Funcionario Apoderado
LAFFITTE DE JONG, S
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**INFORME PRELIMINAR INTERNACIONAL
SOBRE PATENTABILIDAD**

Referencia Internacional
PCT/EP 2005/004777

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Campo N° | Fundamento del Informe

1. Con respecto al idioma, el Informe está basado sobre
- ☒ la solicitud internacional en el idioma en que fue presentada
 - ☐ una traducción del idioma original al siguiente idioma, el que se trata del idioma de la traducción suministrada a los siguientes efectos:
 - ☐ búsqueda internacional (según reglas 12.3 y 23.1 b))
 - ☐ publicación de la solicitud internacional (según regla 12.4(a))
 - ☐ examen preliminar internacional (según regla 55.2 y 55.3)

2. Con respecto a los elementos* de la Solicitud Internacional, el informe se basa en (las hojas de reemplazo que fueron presentadas al organismo como invitación según el artículo 14 son válidas como "presentadas originalmente" en el marco de este informe y no se adjuntan).

Descripción, páginas

1-12 en la versión presentada originalmente

Reivindicaciones, N°

1-71 en la versión presentada originalmente

3. ☐ Como consecuencia de las modificaciones caducaron los siguientes documentos:
- ☐ Descripción: páginas
 - ☐ Reivindicaciones N°
 - ☐ Ilustraciones: hoja/figura
 - ☐ Listado de secuencias (especificar):
 - ☐ Eventual(es) tabla(s) perteneciente(s) al listado de secuencias (especificar):
4. ☐ Este informe fue elaborado sin tomar en consideración (algunas de) las modificaciones adjuntas a este informe, dado que se considera que las mismas exceden el contenido revelado en el texto presentado originalmente (regla 70.2(c)), tal como se indica en el campo suplementario.
- ☐ Descripción: páginas
 - ☐ Reivindicaciones N°
 - ☐ Ilustraciones: hojas/figuras
 - ☐ Listado de secuencias (especificar):
 - ☐ Eventual(es) tabla(s) perteneciente(s) al listado de secuencias (especificar):

* Cuando corresponde el punto 4, algunas o todas estas hojas pueden estar provistas de la observación "reemplazada".

**INFORME PRELIMINAR INTERNACIONAL
SOBRE PATENTABILIDAD**

Referencia Internacional
PCT/EP 2005/004777

Campo N° III

No realización de ningún dictamen sobre novedad, actividad inventiva y aplicabilidad industrial

Las cuestiones acerca de si la invención reivindicada parece ser novedosa, descansa en actividad inventiva (no obvio) o es aplicable industrialmente no ha sido examinada con respecto a:

- ☐ La solicitud internacional completa
- ☒ Reivindicaciones N° 1-7, 9-16, 19-49, 53, 56-60, 62-69 (todas parcialmente, 1-4, 6, 7, 9-16, 19-49, 53 (con respecto a la aplicabilidad industrial), 17, 18, 50, 51, 54, 55, 58, 59, 61, 67-71
porque:
 - ☒ La solicitud internacional completa o las reivindicaciones N° 1-7, 9-16, 19-49, 53 (con respecto a la aplicabilidad industrial) mencionadas anteriormente se refieren al objeto siguiente, para el cual no es necesario efectuar un Examen Preliminar Internacional (especificar):
ver hoja adjunta
 - ☒ la descripción, las reivindicaciones o las ilustraciones (se ruega especificar detalladamente) o las reivindicaciones N° 1-7, 9-16, 19-49, 53, 56-60, 62-69, todas parcialmente mencionadas anteriormente son tan poco claras que no se pudo realizar ningún dictamen coherente (especificar):
ver hoja adjunta
 - ☐ las reivindicaciones o las reivindicaciones N° mencionadas anteriormente están tan inadecuadamente apoyadas por la descripción que no se pudo realizar ningún dictamen coherente (especificar):
 - ☒ no se realizó ningún Informe de Búsqueda Internacional para tales reivindicaciones N° 17, 18, 50, 51, 54, 55, 58, 59, 61, 70-71
 - ☐ no se pudo confeccionar un informe coherente sin el listado de secuencias; el solicitante, en el plazo prescrito:
 - ☐ no suministró sobre papel un listado de secuencias que cumpla con el estándar provisto para ello en el Anexo C de las Instrucciones Administrativas, y tal listado no estaba disponible para el Organismo de Búsqueda Internacional en un formulario y manera aceptable.
 - ☐ no suministró en forma electrónica un listado de secuencias que cumpla con el estándar provisto para ello en el Anexo C de las Instrucciones Administrativas, y tal listado no estaba disponible para el Organismo de Búsqueda Internacional en un formulario y manera aceptable.
 - ☐ no pagó la tasa requerida por la presentación tardía de un listado de secuencias en respuesta a una invitación según las reglas 13ter.1(a) o (b).
 - ☐ no se pudo confeccionar un informe coherente sin las tablas relacionadas con el listado de secuencias; el solicitante no suministró en el plazo prescrito tales tablas en forma electrónica para cumplir con los requisitos técnicos provistos para ello en el Anexo C de las Instrucciones Administrativas, y tal listado no estaba disponible para el Organismo de Búsqueda Internacional en un formulario y manera aceptable.
 - ☐ las tablas relacionadas con el listado de secuencias de nucleótidos y/o aminoácidos, si están sólo en forma legible por computadora, no cumplen con los requerimientos técnicos provistos por el Anexo C-bis de las Instrucciones Administrativas.
 - ☐ Para otras indicaciones, ver hoja adjunta

PATENT COOPERATION TREATY

L12
10/12

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

SCHERING AKTIENGESELLSCHAFT
13342
Berlin
ALLEMAGNE

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(PCT Rule 71.1)

Date of mailing
(day/month/year)

02.11.2006

Applicant's or agent's file reference
53213AWO

IMPORTANT NOTIFICATION

International application No.
PCT/EP2005/004777

International filing date (day/month/year)
29.04.2005

Priority date (day/month/year)
30.04.2004

Applicant

SCHERING AKTIENGESELLSCHAFT

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability 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/01).

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 report on patentability. 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.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international
preliminary examining authority:



European Patent Office - P.O. Box 5516 Patentplan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Fax: 31 651 epo nl
Fax +31 70 340 - 3016

Authorized Officer

LAFITTE-DE JONG, S

Tel. +31 70 340-4827



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 53213AWO		FOR FURTHER ACTION		See Form PCT/PEA/418
International application No. PCT/EP2005/004777		International filing date (day/month/year) 29.04.2005	Priority date (day/month/year) 30.04.2004	
International Patent Classification (IPC) or national classification and IPC INV. A61K31/565				
Applicant SCHERING AKTIENGESELLSCHAFT				
1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 11 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. ☐ sent to the applicant and to the International Bureau a total of sheets, as follows: ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).				
4. 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				
Date of submission of the demand 26.02.2006		Date of completion of this report 02.11.2006		
Name and mailing address of the international preliminary examining authority:  European Patent Office • P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk • Pays Bas Tel. +31 70 340 • 2040 Tlx 31 651 epo nl Fax: +31 70 340 • 8916		Authorized officer Leherle, Chantal Telephone No. +31 70 340-		

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2005/004777

Box No. 1 Basis of the report

1. With regard to the language, this report is based on

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 56.3(a))

2. With regard to the elements* of the international application, this report is based on (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).

Description, Pages

1-12 as originally filed

Claims, Numbers

1-71 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

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

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (specify):
- ☐ any table(s) related to sequence listing (specify):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below 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(e)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (specify):
- ☐ any table(s) related to sequence listing (specify):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2005/004777

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. 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. 1-7, 9-16, 19-49, 53, 56-60, 62-69 (all partially), 1-4, 6, 7, 9-16, 19-49, 53 (with regard to industrial applicability), 17, 18, 50, 51, 54, 55, 58, 59, 61, 67-71

because:

- ☒ the said international application, or the said claims Nos. 1-7, 9-16, 19-49, 53 (with regard to industrial applicability) 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. 1-7, 9-16, 19-49, 53, 56-60, 62-69 (all partially) are so unclear that no meaningful opinion could be formed (specify):

see separate sheet

- ☐ 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 the said claims Nos. 17, 18, 50, 51, 54, 55, 58, 59, 61, 70-71

- ☐ 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 Preliminary Examining 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 Preliminary Examining 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 Rules 13ter.1(a) or (b) and 13ter.2.

- ☒ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic 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

INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY

1/6
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International application No.
POT/EP2005/004777

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees, the applicant has, within the applicable time limit:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☒ paid additional fees under protest and, where applicable, the protest fee.
 - ☐ paid additional fees under protest but the applicable protest fee was not paid.
 - ☐ neither restricted the claims 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 in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☐ complied with.
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-7, 9-16, 19-47, 53, 56-60, 62-69 (all partially), 48, 49.

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	62-67
	No: Claims	1-7, 9-16, 19-31, 33-49, 53, 56-60, 62-69
Inventive step (IS)	Yes: Claims	
	No: Claims	1-7, 9-16, 19-49, 53, 56-60, 62-69
Industrial applicability (IA)	Yes: Claims	see separate sheet
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY

International application No.
PCT/EP2005/004777

11/17
10/17

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/EP2005/004777

Re Item III

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

1) Claims 1-3, 6, 7, 19-42, 44-47, 53, 56, 59, 60 and 64-69 and 12-28 encompass a genus of compounds defined only by their function ("another synthetic or natural estrogen"), wherein the relationship between the structural features of the members of the genus and said function have not been defined. In the absence of such a relationship either disclosed in the as-filed application or which would have been recognized based upon information readily available to one skilled in the art, the skilled artisan would not know how to make and use compounds that lack structural definition.

The fact that one could have assayed a compound of interest using the claimed assays does not overcome this defect since one would have no knowledge beforehand as to whether or not any given compound (other than those that might be particularly disclosed in an application) would fall within the scope of what is claimed. It would require undue experimentation (be an undue burden) to randomly screen undefined compounds for the claimed activity.

The claims cover all synthetic or natural estrogens, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for estradiol only.

In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible.

2) Present claims 1-7, 9-16, 19-49, 53, 56-60 and 62-69 relate to an extremely large number of possible administration forms. In fact, the claims contain so many options, variables, possible permutations and provisos, such as:

- "for a first minimum period for as long as desired by the female after which the female initiates a break in said administration of said active preparation of 1 to 6 days, and wherein said break is followed by at least one further administration cycle of at least the duration of the first minimum period",

- "the period of as long as desired by the female is until bleeding occurs which is unacceptable to the female", etc...

that a lack of clarity (and/or conciseness) within the meaning of Article 6 PCT arises to such an extent as to render a meaningful search of the claims impossible.

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/EP2005/004777

3) Consequently, the search has been carried out for those parts of the application which do appear to be clear (and/or concise), namely the parts relating to pharmaceutical compositions for monophasic continuous administration of ethinyl estradiol or estradiol with drospirenone or diegonest for use in a method of female hormonal contraception wherein the periods of administration are clearly and unambiguously defined in the claims.

4) Claims 1-7, 9-16, 19-49 and 53 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 IV

Lack of unity of invention

The application is considered to lack unity of invention (Rules 13.1, 13.2 and 13.3 PCT) for the reasons put forward in the annex to form PCT/ISA/206.

As the applicant only had an International Search Report drawn up on the subject-matter of claims 1-7, 9-16, 19-47, 53, 56-60, 62-69 (all partially), 48 and 49, the application will be prosecuted on the basis of the inventions in respect of which a search has been carried out, i.e. inventions 1, 2, 12, 13, 89, 90, 100 and 101 as listed in the annex to form PCT/ISA/206.

Re Item V

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

Attention is drawn to the fact that the present statement expressed as to novelty, inventive step and industrial applicability refers only to matter for which an International Search Report has been drawn up.

1) DOCUMENTS USED IN EXAMINATION

The following documents are referred to in this communication: