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Solicitante BOEHRINGER INGELHEIM PHARMA GMBH & CO
KG

Asunto Solicitud de patente para NUEVOS DERIVADOS DE
M-AMINO FENIL-IMINO IMIDAZOLIDINA PARA
EL TRATAMIENTO DE LA INCONTINENCIA DE
ORINA.

Fecha de presentación 14 de abril de 2003

Yo, Emilio FERRERO, obrando como apoderado de la solicitante en
el asunto antes identificado, atentamente presento el reporte del examen
preliminar de la solicitud de patente internacional No PCT/EP01/11764

Bogota, 23 JUL 2003
Señora Jefe,



EMILIO FERRERO
T.P.A No 31 929



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PATENT COOPERATION TREATY

No 12636

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 72.2)

From the INTERNATIONAL BUREAU

To:

BOEHRINGER INGELHEIM PHARMA KG
A Patente
55216 Ingelheim am Rhein
Germany

Eingang CD Patents

11 Juli 2003

SS gesehen erledigt

Date of mailing (day/month/year) 28 June 2003 (28 06 03)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 1/1153 PCT(II) GF/gf	
International application No. PCT/EP01/11764	International filing date (day/month/year) 11 October 2001 (11 10 01)
Applicant BOEHRINGER INGELHEIM PHARMA KG	

1 Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority

2 Transmittal of the copy of the translation to the elected Offices

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation

CA,CN,JP,KP,KR

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request

AP,EA,EP,AE,AG,AL,AM,AT,AU,AZ,BA,BB,BG,BR,BY,BZ,CH,CO,CR,CU,CZ,DE,DK,DM,DZ,EC,EE,ES,FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,MW,MX,MZ,NZ,PH,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW,OA

3 Reminder regarding translation into (one of) the official language(s) of the elected Office(s)

The applicant is reminded that, 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 (Rule 74.1) See Volume II of the PCT Applicant's Guide for further details

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Hélène CAMPIN (Fax 338 8970)
Facsimile No (41 22) 740 14,35	Telephone No (41 22) 338 9718

Translation

PATENT CO-OPERATION TREATY

PCT

№ 1 2 6 3 6

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1/1153-PCT(II) GE/gi	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No PCT/EP01/11764	International filing date (day/month/year) 11 October 2001 (11 10 01)	Priority date (day/month/year) 14 October 2000 (14 10 00)
International Patent Classification (IPC) or national classification and IPC C07D 233/50		
Applicant BOEHRINGER INGELHEIM PHARMA KG		

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>5</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 _____ sheets
3	This report contains indications relating to the following items: I ☒ Basis of the report II ☐ Priority III ☒ Non-establishment of opinion 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 (reasons 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 03 May 2002 (03 05 02)	Date of completion of this report 11 November 2002 (11 11 2002)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP01/11764

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I. Basis of the report

1 With regard to the elements of the international application *

- ☒ the international application as originally filed
- ☒ the description
pages 1-22, as originally filed
pages, filed with the demand
pages, filed with the letter of
- ☒ the claims
pages 1-18, as originally filed
pages, as amended (together with any statement under Article 19
pages, filed with the demand
pages, filed with the letter of
- ☐ the drawings
pages, as originally filed
pages, filed with the demand
pages, filed with the letter of
- ☐ the sequence listing part of the description
pages, as originally filed
pages, filed with the demand
pages, 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 Rule 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 written 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 (Rule 70.16 and 70.17)

** Any replacement sheets containing such amendments must be referred to under item 1 and annexed to this report

No 1 2 6 3 6

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP01/11764

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. 18

because:

☒ the said international application, or the said claims Nos. 18 relate to the following subject matter which does not require an international preliminary examination (specify):

See supplemental box

☐ 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 said claims Nos. _____

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions.

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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Supplemental Box

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

Continuation of III

Claim 18 refers to a method for treatment of the animal or human body, hence no preliminary examination is required (PCT 67 1(iv)). The PCT does not have uniform criteria for assessing the industrial applicability of Claim 18 in its present form. Patentability under national patent laws may depend on the wording of the claims. The EPO, for example, does not recognize the industrial applicability of claims to the medical use of a compound; it does, however, allow claims to the first medical use of a known compound or to the use of such a compound in the manufacture of a drug for a new medical application.

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)	Claims	1-18	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-18	NO
Industrial applicability (IA)	Claims	1-17	YES
	Claims		NO

2 Citations and explanations

As far as the international search report and the prior art cited by the applicant in the description are concerned, compounds (I) and (II) according to Claim 15 differ with respect to document EP-A-0 081 924 (D2) and with respect to document DE-A-28 06 811 (D3), in that the m-amino group is substituted differently, document WO-A-96/32939 (D1), in particular the overlapping areas of the preferred substituent definitions at the bottom of page 5, differ on the basis of the present definition of R¹ (compared to R¹=H,Me) or on the basis of the disclaimer in the present Claim 1. The requirements of PCT Article 33(2) are thus considered to be satisfied for Claims 1-14 and 15-18.

The invention consists in the use of the compounds of Formulae (I) and (II) to produce medicaments for treating bladder and stress incontinence. Document D1 describes a similar activity. The applicant has not demonstrated an unexpected effect with respect to the closest prior art (D1). Furthermore, reference is made to the fact that the present compounds (I) and (II) have no common structural feature with respect to D1 that could form the basis for any improved activity. That also raises the question of whether all compounds of Formulae (I) and (II) also solve

the problem addressed by the application or show the desired activity. The requirements of PCT Article 33(3) are thus not considered to have been satisfied for Claims 1-14 and 15-18.

Finally, reference is also made to the absence of a reaction sequence in the description on page 14 and in process Claim 17, which is only implicitly mentioned in back reference to (D1).