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Act. 412 REPOSPRESRECU Folios: 12

Señor

SUPERINTENDENTE DE INDUSTRIA Y COMERCIO

E. S. D.

REF: Expediente No. PCT/10-066630

TÍTULO SOLICITADO: "NOVEDOSO DERIVADOS DE 1,3-DIHIDRO-5-
ISOBENZOFURANCARBONITRILO COMO
INHIBIDORES SELECTIVOS DE LA RECAPTACIÓN
DE SEROTONINA Y COMPOSICIÓN
FARMACÉUTICA DE LOS MISMOS."



PUBLICACIÓN: Gaceta 628 del 20/05/2011, N° de publicación 531.

SOLICITANTE: DONG-A PHARMACEUTICAL CO. LTD.

APODERADO: JUAN PABLO CADENA SARMIENTO.

TRÁMITE: Recurso de Reposición y en subsidio el de apelación en
contra de la Resolución 4976 de febrero 19 de 2013 por la
cual se concede una patente de invención tramitada bajo
el número de expediente PCT/10-066630.

TITO NOÉ PARRA MURILLO, mayor de edad, identificado como aparece al pie de mi
firma, reconocido apoderado de la sociedad LAFRANCOL S.A.S. en el asunto de la
referencia, de manera respetuosa, y dentro de los términos de ley, presento **Recurso de
Reposición y en subsidio de apelación** contra la Resolución 4976 de febrero 19 de 2013
por la cual se concedió a la solicitud PCT/10-066630 el privilegio de patente de invención.

I. PETICIÓN

Sírvase, Señor Superintendente, reponer íntegramente la Resolución 4976 de febrero 19 de
2013, por la cual se declaró infundada la oposición presentada y se otorgó el privilegio de

patente solicitado en el expediente de la referencia, y en su remplazo emitir otra que, con fundamento en los argumentos expuestos en el escrito de observación y en el presente escrito, declare fundada dicha oposición y niegue el privilegio de patente mencionado, procediendo luego al definitivo archivo del expediente en cuestión.

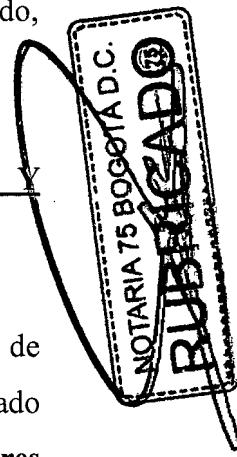
II. ARGUMENTOS SOBRE LOS FUNDAMENTOS DE LA CONCESIÓN Y MOTIVOS DE INCONFORMIDAD

La Resolución 4976 de febrero 19 de 2013, que concede el privilegio de patente de invención solicitado para el capítulo reivindicatorio del expediente 10-066630 titulado **“Novedosos derivados de 1,3-dihidro-5-isobenzofurancarbonitrilo como inhibidores selectivos de la recaptación de serotonina y composición farmacéutica de los mismos”**, viola flagrantemente la Decisión 486 si se tiene en cuenta que existían motivos suficientes para afectar los requisitos de novedad y nivel inventivo de la solicitud en mención. Es evidente que el solicitante y la Resolución cometen un error cuando afirman que la oposición presentada por mi representada no muestra ningún tipo de argumento soportado técnicamente, ni desvirtúa la patentabilidad del objeto de estudio, declarándola infundada por cuanto, al momento de presentación del escrito de oposición se dejó en claro que para el presente caso nos encontramos frente a una combinación de compuestos, lo cual indudablemente afecta el requisito de nivel inventivo, éste mismo indispensable para acceder a cualquier beneficio patentario.

Así las cosas, me permito reiterar que la concesión de patente objeto del presente escrito se ve afectada por los documentos del estado del arte que fueron presentados inicialmente en el escrito de observación, por lo cual, basado en lo siguiente, solicito respetuosamente a ese Despacho dar análisis completo y a cabalidad sobre los siguientes documentos, los cuales sin lugar a dudas objetan la concesión en mención, toda vez que develan de manera expresa y sucinta lo que se pretende proteger en la presente solicitud.

Dicho así, me permito manifestar que agentes tales como Citalopram, Escitalopram, entre otros, han sido ampliamente divulgados en el sector químico-farmacéutico, y concretamente se han develado materias muy similares, las cuales ruego a ese Despacho analizar, en los siguientes documentos:

- EP 347066
- DE 2657013



US 4136193

US 4943590

US RE 34712

Así como resulta imprescindible manifestar que los anteriores documentos deben ser analizados a profundidad y cabalidad para así determinar finalmente si afectan o no la novedad y nivel inventivo de la presente solicitud, toda vez que en nuestra opinión se revelan materias muy similares, también es necesario reiterar que la solicitud de la referencia pretende proteger mediante el derecho patentario objetos que no son considerados invenciones. Es claro que una invención es toda creación humana que permita transformar la materia o energía que existe en la naturaleza, para su aprovechamiento por los seres humanos y satisfacer sus necesidades concretas. De igual modo, como ya se mencionó, según los parámetros de la Decisión 486 y normas concordantes, serán patentables las invenciones que cumplan con los requisitos de novedad, nivel inventivo y aplicación industrial. No obstante, puede observarse que la solicitud en comento pretende reivindicar combinaciones, las cuales no se consideran invenciones. En este sentido, la mezcla (Combinaciones) de productos (Moléculas) conocidos y su variación, bien sea en uso, forma, dimensión o de materia, NO se consideran invenciones por cuanto no son susceptibles de aplicación industrial, nivel inventivo y novedad, luego NO pueden acceder a beneficios patentarios. Por lo tanto, se suma una circunstancia más que imposibilita definitivamente la concesión de la solicitud en mención.

Y sobre el particular, es imprescindible señalar que un efecto sinérgico nuevo no se considera inventivo como tal, dado que puede ser obvio para una persona versada en la materia, cosa que sucede en el presente caso. En palabras del Doctor Carlos Correa, *"El efecto sinérgico entre dos o más drogas se puede considerar un "descubrimiento" y no una "invención", dado que la sinergia ocurre en el cuerpo y se descubre a través de ensayos clínicos. Asimismo, cabe destacar que, en algunos casos, las reivindicaciones de combinaciones pueden equivaler, en términos prácticos, a reivindicaciones sobre tratamientos médicos (cuya patentabilidad está excluida en la mayoría de los países), cuando sólo brindan un método para administrar una combinación de drogas conocidas. Asimismo, la combinación de drogas para evitar la resistencia particular a una de ellas es una práctica normal en el desarrollo farmacéutico y, por lo general, es evidente para el hombre del oficio de nivel medio"* (Pautas para el examen de patentes farmacéuticas, CEIDIE, Pág. 8). En estos términos, está claro que nos encontramos frente a un tema

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NOTARIA 75 BOGOTÁ D.C.

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REPUBLICA
MARCELO
NOTAR

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totalmente sensible que merece toda la evaluación por cuanto las combinaciones deben considerarse excluidas de beneficios de patente.

en caso que ese Despacho decidiera insistir en el cabal cumplimiento de los requisitos exigidos para acceder al beneficio de patente, me permito allegar copia del International Search Report y el respectivo Written Opinion Of The International Searching Authority, documentos en los cuales se resalta que la presente invención no cumple con los requisitos de novedad y nivel inventivo por cuanto existen documentos citados del estado del arte que afectan de manera definitiva tales exigencias. Lo anterior deja entrever, sin lugar a equívocos, que la presente solicitud no debió ser concedida, por lo cual es procedente la revocatoria de la Resolución objeto de este escrito.

En este sentido, reitero con el debido respeto la necesidad de analizar a profundidad los requisitos de novedad y nivel inventivo para así determinar si la presente solicitud es merecedora de concesión de privilegio de patente.

ANEXOS

- 1- International Search Report y el Written Opinion Of The International Searching Authority de la equivalente internacional WO 2009/057974.

En subsidio apelo.

Señor Superintendente,

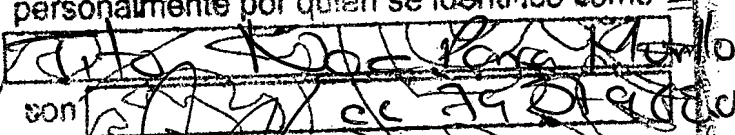
TITO NOÉ PARRA MURILLO

C.C. 79.579.680 de Bogotá

T.P. 71168 del C. S de la J.

REPÚBLICA DE COLOMBIA
RAMÓN ALBERTO LOZADA DE LA CRUZ
NOTARIA 75 - BOGOTÁ D.C. 05 ABR. 2013
Presentación Personal
Reconocimiento Contenido, Firma y Huella

Doy fe que este documento fue presentado ,
personalmente por quien se identificó como

con 

quien declara, que reconoce
contenido, firma y huella



5/482/13

75 Aprobado reconocimiento

SP FORGUA 515.314

R.A. LOZADA B.
3132682

REPÚBLICA DE COLOMBIA
HILDA MARCELA RODRÍGUEZ TENJO
NOTARIA ENCARGADA
75 NOTARIA 75 - BOGOTÁ D.C.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: LEE Won-Hee 8th Fl.Sung-ji Heights II642-16 Yoksam-dong Kangnam-ku Seoul 135-080 Republic of Korea

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 8fpo-10-19		Date of mailing (day/month/year) 28 MAY 2009 (28.05.2009)
FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/KR2008/006445	International filing date (day/month/year) 31 OCTOBER 2008 (31.10.2008)	Priority date(day/month/year) 02 NOVEMBER 2007 (02.11.2007)
International Patent Classification (IPC) or both national classification and IPC C07D 307/87(2006.01)i		
Applicant DONG-A PHARMACEUTICAL. CO.,LTD et al		

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 be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that 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 3 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/KR Korean Intellectual Property Office Government Complex-Daejeon, 139 Seonsa-ro, Seo-gu, Daejeon 302 -701, Republic of Korea Facsimile No. 82-42-472-7140	Date of completion of this opinion 14 MAY 2009 (14.05.2009)	Authorized officer KANG, TAI HYUN Telephone No.82-42-481-5627
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/KR2008/006445

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Box No. I Basis of this 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
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, 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

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ 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.

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/KR2008/006445

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. 20

because:

☒ the said international application, or the said claims Nos. 20

relate to the following subject matter which does not require an international search (*specify*):

The subject matter of claim 20 does not require a written opinion of ISA, as it is directed to methods of treatment by therapy for the human or animal body (Rules 43 bis.1(b), Rule 67.1(iv)).

☐ 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 (*specify*):

☒ no international search report has been established for said claims Nos. 20

☐ 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 Searching 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 Searching 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 Rule 13ter.1(a) or (b).

☐ 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 Searching 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 Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/KR2008/006445

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

1. Statement

Novelty (N)	Claims	4-14, 16, 18	YES
	Claims	1-3, 15, 17, 19, 21	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-19, 21	NO
Industrial applicability (IA)	Claims	1-19, 21	YES
	Claims	NONE	NO

2. Citations and explanations :

The following documents are referred to in this report. Their numbering will be adhered to for the rest of the procedure.

- D1: Atmaca, M. et al, International journal of impotence research, 2002, Vol. 14, No. 6, pages 502–505.
D2: US 4136193 (23 January 1979)
D3: WO 2003/042202 A1 (22 May 2003)

The present invention of claims 1–19, 21 relates to compounds of formula 1 for treating or preventing premature ejaculation, a process for preparing the same and their pharmaceutical composition.

Document D1 discloses that citalopram are useful for the treatment of premature ejaculation.

Document D2 discloses phthalane derivatives[Lu 10–202, Lu 10–171(=citalopram)] as a antidepressant.

Document D3 discloses that isobenzofuran derivatives of formula IX, X, XI & XII have antidepressant activity.

I. Novelty [PCT Article 33(2)]

a. Regarding claims 1–3, 15, 17, 19, 21:

(1) The subject matter of claims 1–3, 17, 19, 21 is not novel because compounds of formula 1, a process for preparing the same and their pharmaceutical composition have already been disclosed in the prior art documents D1 or D2, See:

- D1 : abstract; table 1
- D2 : table[Lu 10–202, Lu 10–171(=citalopram)]; claims 1–18

(2) The subject matter of claims 1–3, 15, 17, 19, 21 is not novel because compounds of formula 1, a process for preparing the same and their pharmaceutical composition have already been disclosed in the prior art documents D3, See:

- D3 : examples 1–4; claims 1, 13–17.

Therefore, the subject matter of claims 1–3, 15, 17, 19, 21 of the present application is not considered novel over D1, D2 or D3 under PCT Article 33(2).

(Continued on Supplemental Box)

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of :

Box. V.

b. Regarding claims 4-14, 16, 18:

However, the present compounds of claims 4-14, 16, 18 and the compounds disclosed by D1-D3 are the same in the backbone structure, but different in the substituents.

Therefore, the subject matter of claims 4-14, 16, 18 of the present application is considered novel over D1-D3 under PCT Article 33(2).

II. Inventive step [PCT Article 33(3)]

a. Regarding claims 1-3, 15, 17, 19, 21:

Since the novelty of claims 1-3, 15, 17, 19, 21 cannot be acknowledged over D1, D2 or D3, the inventive step of them cannot be acknowledged, either.

b. Regarding claims 4-14, 16, 18:

The closest prior art is considered to be D1, since D1 discloses structurally very similar compounds to those claimed, which have the inhibitory activity of the symptom of premature ejaculation. The difference between the present compounds of the formula 1 and the compounds disclosed by D1 is the fact that the present compounds have substituents undisclosed by D1. The replacement of the substituents is commonly made in the field of pharmaceutical chemistry. Moreover, it would be obvious to the skilled person that the same qualitative effect would be maintained in such similar compounds. To show the inventive step of the novel subject matter, the applicant needs to prove a significantly improved effect of the novel compounds based on the comparative test. However, the present application does not show that the claimed compounds have any unexpected and beneficial effects, compared with those of D1. Therefore, the subject matter of claims 4-14, 16, 18 does not meet the requirements of inventive step under PCT Article 33(3).

Therefore, the subject matter of claims 4-14, 16, 18 does not meet the requirements of inventive step under PCT Article 33(3).

III. Industrial Applicability [PCT Article 33(4)]

The subject matter of claims 1-19, 21 of the present application appears to be industrially applicable under PCT Article 33(4).

INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR2008/006445

A. CLASSIFICATION OF SUBJECT MATTER <i>C07D 307/87(2006.01)i</i> According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC: C07D 307/87 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) STN, PubMed-online		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	ATMACA, M. ET AL., " THE EFFICACY OF CITALOPRAM IN THE TREATMENT OF PREMATURE EJACULATION: A PLACEBO-CONTROLLED STUDY", INTERNATIONAL JOURNAL OF IMPOTENCE RESEARCH, 2002, Vol. 14, No. 6, pages 502-505. See abstract; table 1.	1-19, 21
X	US 4136193 A (BOGESO, K.P. ET AL.) 23 January 1979 See table(Lu 10-202, Lu 10-171); claims 1-18	1-3, 17, 19, 21
X	WO 2003/042202 A1 (RANBAXY LABORATORIES LIMITED) 22 May 2003 See examples 1-4; claims 1, 13-17.	1-3, 15, 17, 19, 21
P,X	EILDAL, J.N.N. ET AL., "FROM THE SELECTIVE SEROTONIN TRANSPROTER INHIBITOR CITALOPRAM THO THE SELECTIVE NOREPINEPHRINE TRANSPORTER INHIBITOR TALOPRAM: SYNTHESIS AND STRUCTURE-ACTIVITY RELATIONSHIP STUDIES", JOURNAL OF MEDICINAL CHEMISTRY, 22 May 2008, Vol. 51, No. 10, pages 3045-3048. See compound 6; table 1; figure 3.	1-3, 7-9, 18, 19, 21
☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 14 MAY 2009 (14.05.2009)		Date of mailing of the international search report 28 MAY 2009 (28.05.2009)
Name and mailing address of the ISA/KR  Korean Intellectual Property Office Government Complex-Daejeon, 139 Seonsa-ro, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140		Authorized officer KANG, TAI HYUN Telephone No. 82-42-481-5627 

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 20
because they relate to subject matter not required to be searched by this Authority, namely:
Claim 20 pertains to method for treatment of the human or animal body by therapy and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

- Remark on Protest
- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/KR2008/006445

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4136193 A	23.01.1979	JP 52105162 A2	03.09.1977
		JP 61035986 B4	15.08.1986
		GB 1526331 A	27.09.1978
		DE 2657013 A1	28.07.1977
		CA 1094087 A1	20.01.1981
		AU 2107377 A1	13.07.1978
WO 2003/042202 A1	22.05.2003	IN 0192863 A	22.05.2004