

THE PATENTS ACT, 1970

(AS AMENDED)

SECTION 15

**IN THE MATTER OF APPLICATION FOR
PATENT APPLICATION NO. 201/MUMNP/2007**

UCB FARCHIM S.A [AG-LTD] ----- Applicant

A Swiss Company at Z.I. Planchy,
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C.P. 411, CH-1630 Bulle

Hearing held on 17th March, 2011

Present:

1. Mr. Jitesh Kumar

Applicant's Agent

DECISION

An application for a patent bearing number 201/MUMNP/2007 was filed in Patent Office; Mumbai on 09th February, 2007 entitled “**COMPOUND OF GENERAL FORMULA (B)**” as a further application of the patent application 340/MUMNP/2005 dated 28th April, 2005. However, the above said application (340/MUMNP/2005) is divided from the original application IN/PCT/2002/00983/MUM dated 18/07/2002. As per the provision under Section 11-A of Patents Act, the said application was published on 13th July, 2007. A request for examination under section 11-B was filed on dated 06th August, 2007, and was assigned a Request No. 1397/RQ/2007.

The said case was examined under Section 12 and 13 of the Act and First Examination Report (henceforth referred to as FER) was issued on 28th May, 2008. The applicant filed their

response to the FER on 03rd December, 2008. Consequent to the submission of reply to FER, Second Examination Report (henceforth referred to as SER) was issued on 28th January, 2009 and the applicant filed their response along with amended claims on 15th April, 2009. The said case was further examined, and the applicant was asked to attend hearing on 17th March, 2011 at 3.00 P. M., vide letter 02nd March, 2011 containing the following objections;

1. The instant application (201/MUMNP/2007) is filed as a further application to the original application 340/MUMNP/2005 which is divided from the original application IN/PCT/2002/00983/MUM dated 18/07/2002. The original application IN/PCT/2002/00983/MUM dated 18/07/2002 and the 1st divisional application 340/MUMNP/2005 dated 28/04/2005 have already been granted. The criteria for filing a divisional application as contained U/S 16 of the Patents Act is: “A person who has made an application for a patent under this Act may, at any time before the grant of the patent, if he so desires, or with a view to remedy the objection raised by the Controller on the ground that the claims of the complete specification relate to more than one invention, **file a further application in respect of an invention disclosed in the provisional or complete specification already filed in respect of the first mentioned application**”. Since the instant application derives the priority of the first divisional application 340/MUMNP/2005 which is not the first mentioned application as per Law, divisional status of the application is not allowed. Furthermore, the first mentioned application i.e. IN/PCT/2002/00983/MUM has been published U/S 43(2) of the Act, on 02/03/2006 and the instant application is filed on 09/02/2007 which is after the date of grant of the first mentioned application can’t be treated as a divisional application. Again filing a divisional application without any objection by the Controller “that the claims of the complete specification relate to more than one invention” is against the spirit of Section 16 of patents Act.
2. Objections raised in para 2-4 of Second Examination Report dated 28/02/2009 has not been met.
3. The applicant is advised to furnish the information relating to the objections, if any, in respect of the novelty and patentability of the invention including the claims of the application allowed of the corresponding application prosecuted before European Patent Office and USPTO within prescribed period under Rule 12(3) of Patents Rule 2003, as amended.

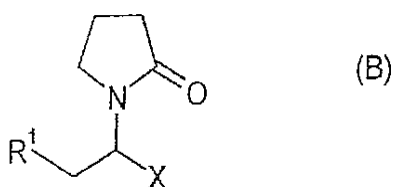
Hearing fixed as per the above schedule was attended by the applicant’s agent Mr. Jitesh Kumar of Remfry & Sagar. The basic issue of the hearing were exclusively related to the objections raised vide office letter dated 02nd March, 2011. During hearing, the applicant tried to defend the case by putting argument point wise to the objections of letter dated 02nd March, 2011. After the hearing, the applicant’s agent was advised to file a written submission of hearing which they submitted vide their letter dated 6th June, 2011, are as follows:

They submit that that the claims have been duly revised in accordance with the learned Controller's requirement. Claim 2 has been merged with claim 1 and claim 4 has been merged with claim 3. Further, the preamble of claim 1 has been duly amended as under:

“aevorotatory enantiomer of compound of general formula (B)_useful as synthetic intermediates for preparation of Levetiracetam, and pharmaceutically acceptable salts thereof”

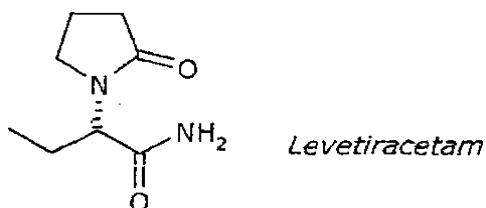
The amended claims thus do not fall within the purview of Section 3(d) as argued during the hearing based on the following submission:

(i) The amended claims relate to laevorotatory enantiomers of compounds of formula (B) wherein R¹ is methyl and X is either -COOMe or -COOEt.



(ii) Said compounds (B) are particularly valuable synthetic intermediates in the synthesis of i.e. a compound B wherein X is CONH₂, Levetiracetam,

Levetiracetam is the active pharmaceutical ingredient of the Applicant's brand drug KEPPRA® ((S)-(-)- ethyl -2-oxo-1-pyrrolidine acetamide) having market authorization in various countries (EP, US) for the treatment of epilepsy.



(iii) Thus, the industrial utility of the compounds according to the present claims is not supported by their pharmacological activity, but use in the synthesis of Levetiracetam and some analogs.

(iv) The transformation of compounds of formula (B) wherein X is -COOEt or -COOMe into compounds of formula (B) wherein X is CONH₂, i.e. Levetiracetam, is typically achieved by an ammonolysis reaction which is the subject matter of a separate international patent application published under n°WO 03/014080 also in the name of UCB Pharma.

(v) Compounds of formula (B) according to the present invention are obtained by asymmetric hydrogenation of compounds (A) in example S of the present application, i.e. claims 3 and 4 of

US patent 7,217,826 B2.

The compounds of formula (B) covered by the present application are novel synthetic intermediates which are involved in the process of manufacture of pharmaceutical compounds (B), and particularly in the industrial process for the preparation of our antiepileptic KEPPRA®, also known under the name of Levetiracetam.

Accordingly, the amended claims do not fall under the prohibition of Section 3(d). We understand that in view of the amendments carried out to the claims as per the learned Controller's requirement, the objection under Section 3(d) is waived.

With regard to the learned Controller's objection under Section 16 of the Act, it is once again humbly submitted that the aforementioned divisional application has been filed out of the parent application 00340/MUMNP/2005(1N234848) on February 09, 2007 i.e. before the grant of the said application.

Section 16 (1) allows the applicant to file a further divisional application in respect of an invention disclosed in the provisional or complete specification already filed in respect of the first-mentioned application wherein the first-mentioned application' refers to the application from which the divisional application has been filed. It is submitted that the aforesaid Section does not prohibit the filing of a further divisional application out of a divisional application.

In light of the facts as stated above, it is submitted that the present divisional application is a valid application and should be allowable.

Further, with regard to the learned Controller's objection that no objection of distinct inventions was raised in the parent application, it is most humbly submitted that Section 16 (1) also provides that a divisional application may be filed at any time before the grant of the patent, if the applicant so desires (suo muto). Taking into account the aforementioned submissions, the learned Controller is requested to kindly reconsider and waive the said objection.

All the remaining requirements have been complied with.

Grant of this application is respectfully requested. In an event if the Controller is not satisfied, he is respectfully requested to kindly give a reasoned decision in this matter.

Taking into consideration the above facts and documents on record, I draw the following conclusion whether the instant application can have the status of a further application from the application 340/MUMNP/2005 dated 28th April, 2005, which is again divided out from the first mentioned original application IN/PCT/2002/00983/MUM dated 18th July, 2002.

I find that the original Patent application, IN/PCT/2002/00983/MUM dated 18/07/2002 and the first divisional application, 340/MUMNP/2005 dated 28/04/2005 have already been proceeded to grant with patent numbers, IN 196025 and IN 234848, respectively. The criteria for filing a divisional application as contained U/S 16 of the Patents Act is: “A person who has made an application for a patent under this Act may, at any time before the grant of the patent, if he so desires, or with a view to remedy the objection raised by the Controller on the ground that the claims of the complete specification relate to more than one invention, **file a further application in respect of an invention disclosed in the provisional or complete specification already filed in respect of the first mentioned application**”.

From the plain reading of text of Section 16, it is understood that a divisional application can be filed from the original first mentioned application. It can't be interpreted that a divisional application can be filed from an existing divisional application as in the present case. If a divisional application can be filed from an existing divisional application, I foresee the depth of the erroneous action by the applicant that enables him to file as many divisional applications as he desires during the term of the patent. I refer to the contents of entry no. 7 of Form 1 wherein particulars for filing a divisional application is mentioned. The information to be mentioned in the respective column is against the original (first) application and not the divisional application. However, the applicant has furnished the information of the divisional application (340/MUMNP/2005) which is divided out of the first mentioned application (IN/PCT/2002/00983/MUM). This incorrect entry in the said column shows that the applicant has deliberately suppressed the correct information to gain advantage of filing a further application. The applicant had the chance to file further application from the original (first) application (IN/PCT/2002/00983/MUM) before its grant which they have failed to act. Again, I refer to entry no. 5 of Form 1 of the instant case wherein priority particulars of the application filed in convention country has been furnished. The priority information of the instant application as well as the original (first) application, (IN/PCT/2002/00983/MUM) are identical. It refers that

the instant application should have been filed before grant of original (first) application, (IN/PCT/2002/00983/MUM). The time line to file a further application as per the provisions under Patents Act, is before grant of the original first mentioned application and that should have been before 02nd March, 2006 in the instant case. However, the instant application was filed on 09th February, 2007, which is after the prescribed time period. In both the instances, the applicant has failed to meet the provision of filing a divisional application. I am scared that if such an act of the applicant would be allowed, there will be no prescribed time to file a divisional application from the original application. The applicant's argument and submission in this context is not convincing where they state that Section 16 of the Act, does not prohibit the applicant to file a divisional application out of an existing divisional application. My above findings says that the applicant has made a clear step of violation of the provision of the Act to file the so called divisional application, 201/MUMNP/2007 and that to after grant of a patent to the original (first) application, (IN/PCT/2002/00983/MUM) and I resist allowing such an action of the agent.

After having considered the submissions submitted by the applicant in the hearing, the written submission and amended claims on record, in view of the above discussions and findings of the undersigned, it is hereby ordered that the invention disclosed and claimed in the instant patent application possessing the title "**COMPOUND OF GENERAL FORMULA (B)**" is not considered as a further application Under Section 16 of Patents Act and I therefore, hereby refuse this Application No. 201/MUMNP/2007 to proceed further.

Dated this 17th June, 2011.

(Dr. Amarendra Samal)
Asst. Controller of Patents & Designs

Copy to:-

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