The Patents Act 1970
Section (15)

In the matter of the application for

Patent Application No. 2056/KOLNP/2010 filed on 04/06/2010
(International Application No. PCT/US2008/085456, filed on 04/12/2008)

VERTEX PHARMACEUTICALS INCORPORATED…….. Applicant

Applicant's agent – M/s D. P. AHUJA & CO., KOLKATA.

Hearing held on – 18/03/2016

Decision

The above patent application was filed as a national phase application of the PCT international application having the title of invention as "SOLID FORMS OF 3-(6-(1-(2,2-DIFLUOROBENZO[D][1,3] DIOXOL-5-YL) CYCLOPROPANECARBOXAMIDO)-3-METHYLPYRIDIN-2-YL) BENZOIC ACID". The application was published on 03/09/2010 and Request for examination (F18) was filed on 25/11/2010. The application was examined and First Examination Report was issued on 20/08/2014.

On examination of the amended documents received after FER, it was found that the application was not put in order as per the Patent's Act, 1970 and many objections were pending for this application. As the last date was already over, the remaining objections were communicated to the agent of the applicant through hearing letter (dated 01/03/2016) and a hearing was finally held on 18/03/2016. There were nine (09) objections mentioned in the hearing letter including major technical objections on the grounds of novelty, inventive step and non-patentability of the claimed subject matter u/s 3(d) of the 'Act.

Arguments

Dr. I. S. Bhattacharya, attorney of the applicant has attended the hearing and argued very strongly in favour of the claimed Form I (polymorphic form) of the already known compound 3-(6-(1-(2,2-DIFLUOROBENZO[D][1,3] DIOXOL-5-YL) CYCLOPROPANECARBOXAMIDO)-3-METHYLPYRIDIN-2-YL) BENZOIC ACID. She explained that the above crystalline and free solid polymorphic form which has been characterized by XRD data is novel and inventive in the light of supportive technical data filed as affidavit along with reply statement in respect of pre-grant opposition already filed under section 25(1) for the instant application. The technical data has explained the better pharmacokinetic properties / superior bioavailability of the formulation of claimed polymorphic Form I compared to the hydrochloride salt of the compound.

Reasoning / Analysis

The actual compound 3-(6-(1-(2,2-DIFLUOROBENZO[D][1,3] DIOXOL-5-YL) CYCLOPROPANECARBOXAMIDO)-3-METHYLPYRIDIN-2-YL) BENZOIC ACID is already known in the art. The present polymorphic Form I has been selected out of the cited prior art document WO2007/056341 dated 18/05/2007. To establish the selection invention in favour of the claimed solid crystalline Form I no supportive technical data for better technical effect or any surprising result were mentioned in the complete specification. Till today the entire complete specification is devoid of such result / data. Anything beyond the disclosure of complete specification is not acceptable. However, even if the data mentioned in the affidavit is considered for the sake of

argument, it is revealed that the comparison of Form I (free solid) has been done with hydrochloride salt of the same compound. Therefore, it is natural to have different pharmacokinetic properties / superior bioavailability results. There is no direct evidence for betterment of therapeutic efficacy in respect of claimed Form I free solid crystalline form. Better bioavailability does not necessarily lead to better efficacy. Applicant has failed to provide any superior therapeutic efficacy data in respect of claimed Form I, as characterized by the XRD data.

In view of the above, claimed Form I is not considered to have solved any technical problem in a better way as compared to the other forms of the already existing compound. In the absence of better efficacy data, the selection of present Form I does not involve any inventive step and very much obvious to a person skilled in the art. The present selection 'invention' is found to be not inventive and therefore, novelty is also not acknowledged.

Final Opinion

All the product and process claims (as amended after FER) are considered as not patentable as not being novel and inventive. The claimed polymorphic forms and process of preparation in the absence of better efficacy result are considered as mere new form and process respectively and thus, not patentable under section 3(d) of the 'Act.

The application is hereby refused for grant of patent under section 15 of the 'Act.

N.B.:- The pre-grant opposition has also been filed under section 25(1) by Indian Pharmaceuticals Alliance, Mumbai for the instant application. All the grounds of opposition along with cited prior art documents are taken into consideration and incorporated as objections of the hearing letter dated 01/03/2016 and heard on 18/03/2016. Therefore, no separate hearing for Section 25(1) under Rule 55 is required, particularly when the normal examination procedure of this office and view of the opponent are reaching to same conclusion. The petition u/s 25(1) is accepted while refusing the grant of the patent application no. 2056/KOLNP/2010.

Dated, 31st March, 2016

(Soumen Ghosh)
Dy. Controller of Patents & Designs.