THE PATENT ACT 1970

(AS AMENDED)

SECTION 15

IN THE MATTER OF PATENT APPLICATION No. …...…….…… 305/DELNP/2009

DECISION

The patent application no. 305/DELNP/2009 was filed on 14/01/2009 by the applicant entitled "Crystal Form of Epothilone B and use in Pharmaceutical Compositions". As per the provision under section 11-A of Patents Act, the said application was published on 22/05/2009.

The said application was examined under section 12 and 13 of Indian Patents Act 1970 and First Examination Report was issued. The applicant filed response to FER within stipulated time. Since, the objections raised in FER were not met vide the reply to FER, the applicant was offered a hearing on 09/08/2018 containing the objections which were to be discussed during hearing.

Objections:
1. Subject matter of the claims do not constitute an invention under section 2[1(j)] of the Indian Patents Act, 1970 because it does not involve novelty and inventive step in view of prior art cited documents listed below D1: EP-A2-1 428 826 (NOVARTIS AG[CH); NOVARTIS PHARMA GMBH[AT)) 16 June2004 (2004-06-16) D2: WO02/14323A2 (SQUIBB BRISTOL MYERS CO[US); DIMARCO JOHN D[US];GOUGOUTAS JACK Z[U) 21 February 2002 (2002-02-21)2) Inventive step (Under Section 2(1)(ja)of the Indian Patents Act, 1970):The self-evident fact that a novel polymorph exists does not contribute anything to the existence of an inventive step without a proof that this polymorph has properties superior to the prior art polymorphs. The preparation of a polymorph for a pharmaceutical compound is quite obvious and depends merely on the time and money investment for such an investigation. Since the applicant has argued that the claimed polymorph has a high stability (page 5, line 1), but no proof in comparison to any prior art has been provided, no inventive step for present claims 1-5 can be acknowledged. The subject-matter of claims 1-5 are not inventive in the view of D1- D2 under section 2(1)(ja)of the Indian Patents Act, 1970.

2. Claim 5 of alleged invention are directed to method of treatment and therefore not patentable under section 3(i) of the Patent Act.

3. Claims 1-3 fall under section 3(d) of the Patents (Amended) Act, 2005 as the said claims defines new use and/or new form of the known compound (as cited by the prior art documents as described in the report). In the absence of experimental data, it is not clear if the claimed compound and the composition thereof act to provide an enhancement of the known efficacy i.e., demonstrate a greater technical effect and/or differ significantly in propertiesw.r.t the known compound.

4. Claim 4 refer to a pharmaceutical composition comprising a compound according to anyone of Claims 1 to 3, or a pharmaceutically acceptable salt thereof, together with a pharmaceutically acceptable diluent or carrier. A synergistic composition should show unexpectedly new property or better efficacy than a mere aggregation of the properties of its components. There is no other essential component in the claimed composition that could justify a synergistic effect with compounds according to anyone of Claims 1 to 3, to validate a composition claim. Hence claim 4 is not allowable under section 3(e).

5. Claims do not sufficiently define the invention. In view of too many independent claims in the same category with overlapping scope and different major features, the exact nature and scope of the alleged invention is not clear for which protection is sought. These claims do not fall in the same category u/s 10(5) of the Act.

In view of the above said final objections the attorney was given an opportunity of being heard and to submit his arguments in favour of their application u/s 14. The date of hearing was fixed on 09/08/2018. The agent of the applicant attended the hearing on scheduled date of hearing and filed the written arguments and amended claims on 24/08/2018.

With respect to the hearing the applicant submitted the following:
Regarding objection 1, the agent for the applicant submitted that D1 discloses a new crystal form of epothilone. Further, the crystalline form discloses in D1 is different with respect to the present invention. D2 also discloses the crystalline form of epothilone. Further, the crystalline form is different with respect to the present invention. The crystalline form of present invention is different. The crystalline form as disclosed in present invention is stable and therefore more suitable as an active ingredient for solid form of administration.

Regarding objection raised in paragraph 2, 3 and 4, the agent of the applicant submitted regarding Non-Patentability u/s 3 Section 3(d): The crystalline form of the present invention is more stable and therefore, are more suitable for solid formation. The objection is in rendered moot. Objection regarding Section 3(e): The applicant submits that the amended claims do not fall within the scope of Section 3(e). And objection regarding Section 3(i) the applicant has deleted claim 5.

The submission regarding inventive step of the alleged invention is found to be not persuasive and not satisfactory. Inventive step (Under Section 2(1)(ja)of the Indian Patents Act, 1970):The self-evident fact that a novel polymorph exists does not contribute anything to the existence of an inventive step without a proof that this polymorph has properties superior to the prior art polymorphs. The preparation of a polymorph for a pharmaceutical compound is quite obvious. Since the applicant has argued that the claimed polymorph has a high stability, but no proof in comparison to any prior art has been provided, therefore, no inventive step for present claims 1-4 can be acknowledged. Therefore, the subject-matter of claims 1-4 are not inventive in the view of D1- D2 under section 2(1)(ja)of the Indian Patents Act, 1970.

The applicant in the submission fails to show any enhancement of the efficacy in claimed compound with respect to prior cited art and claimed compound are mere new form of known substance, in the absence of experimental data, it is not clear if the claimed compound and the composition thereof act to provide an enhancement of the known efficacy i.e., demonstrate a greater technical effect and/or differ significantly in properties w.r.t the known compound, therefore, objections regarding of under section 3(d) and 3(e) are sustained.

After considering the written submission made by the applicant the application lack inventive step and therefore the instant application does not meet the objections raised under section 2(1)(ja), 3(d) and 3(e) of the Indian Patents Act, 1970. Therefore, in view of above fact the instant application has been refused to grant of patent.

Dated: 28/12/2018

Dr. Archana Gupta

(Assistant Controller of Patents and Designs)