

## **PATENT OFFICE, NEW DELHI**

Patent Application No.00295/DELNP/2003

Applicant: Smithklinebeechem PLC, England.

Agents: Remfry & Sagar.

### **HEARING U/S 14 read with 15 of the Patents Act, 1970**

Dated: 06.01.2009.

#### **PRESENT-**

1. Applicants' Representatives - Mr. Shukadev Khuraijam and Mr. Debashish Banerjee.
2. Examiner- Dr. Archana Gupta.
3. Controller- Shah Alam, Assistant Controller.

During the course of prosecution of the instant Application in the Patent Office the latest 05 Objections were communicated to the applicants through this office's letter of even number dated 10.12.2008 which forms part of this file. Claim No.1 *regarding novelty*, Claim No.2 *regarding mere discovery/new property/new use* and claim No.3 *regarding inventiveness* are inter-dependent. The Objection Nos. 4 and 5 have been met out. The Core objection No. 2 therein raised is u/s 3(d) of the Patents Act 1970. Consequently the applicants had requested in this context to offer them hearing u/s 14 of the Patents Act 1970, accordingly opportunity had been granted and the hearing has been held today.

The invention claimed for the Patent as per instant application pertains to derivatives of known Parent Compound (Thiazolidione) i.e. 5-[4-[2-[N-methyl -N-(2-pyridyl) amino) ethoxy] benzyl] thiazolidine-2, 4-dione. The derivatives of Known Parent Compounds are not patentable unless they differ significantly in properties with regard to *efficacy* vide Section 3(d) of the Patents Act 1970. The contents of said Section 3(d) are reproduced here as under-

*"The mere discovery of a new form of known substance which does no result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of known process, machine or employs at least one new section.*

*Explanation; for the purposes of this clause, salts, esters, ethers, polymorphs metabolite, pure form, particle size, isomers, mixture of isomers, complexes, combination and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."*

At the outset of the hearing the above mentioned representatives of the applicants have referred to their Written Submissions (W.S.) dated 30.12. 2008 which is also part of the instant application and stated that they need no amendments in the instant application as well any oral arguments. The said W.S. dated 30.12.2008 stresses that the claimed compound i.e. sulphonate salt (derivative) of the Parent Compound has good stability, good aqueous solubility and good bulk flow properties. The W.S. encloses the photocopies of the extracts of the publications of the related field as 04 different Annexures mentioned hereinafter ;

- (1) Annexure (I) is the extract from "Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, Eight Edition, Lippincott Williams & Wilkins" in support of the good aqueous solubility. This paper does not show the solubility of Parent compound so the efficacy with respect to good aqueous solubility of the compound as claimed in the instant Patent Application in comparison with parent compound is not established.
- (2) Annexure (II) is the extract from "Principles and Practice of Pharmaceutical Medicine, Second Edition, Wiley" in support of stability testing of drugs. This paper does not show the stability of the parent compound so the efficacy with respect to stability of the claimed compound as claimed in the instant Patent Application in comparison with parent compound is not established.
- (3) Annexure (III) is the text book "Handbook of stability Testing in pharmaceutical Development, Springer", in support of chemical stability 'disintegration rate, dissolution profile, friability and hardness of the tablet dosage form for stability. This paper does not indicate the property of the parent compound and is irrelevant with respect to said efficacy.
- (4) Annexure (IV) is the article " Drugs as Materials; Valuing Physical Form in Drug Discovery, November 2004, volume 3, PP 926-934, Nature in support of flow properties of Ethane sulphonate. This paper also does not indicate the property of the parent compound.

The above publication papers do not support that the Thiazolidione derivative(**Ethane Sulphonate salt**) as claimed in the instant Patent Application is better in efficacy with respect to the parent compound as known in prior art.

The thiazolidione derivatives are known in prior art vide European Patent Application number EP 0306228 which relates to certain thiazolidinedione derivatives(cf. example 30 regarding 5-[4-[2-[N-methyl -N-(2-pyridyl) amino] ethoxy] benzyl] thiazolidine-2,4-dione). International Patent Application No. WO 94/05659 discloses certain salts of the compounds of aforesaid application No. EP0306228. Moreover the other International Patent Application like WO 99/331093, WO 99/31094 and WO 99/31095 (SmithKline Beechem PLC) also disclose certain hydrates of maleic acid salt(derivatives) of said parent compound i.e. 5-[4-[2-[N-methyl -N-(2-pyridyl) amino] ethoxy] benzyl] thiazolidine-2, 4-dione.

### DECISION and ORDER

The applicants could not establish that the compound as claimed in the instant Patent Application is better in terms of the efficacy with respect to the parent compound as known in prior art, hence in lack of the efficacy the instant Patent Application can not be allowed. Accordingly the instant Patent Application No. 00295/DELNP/2003 is **refused**.

Dated: 06.01.2009.

(SHAH ALAM)  
Assistant Controller of Patents