

**THE PATENTS ACT, 1970
(AS AMENDED)**

SECTION 15

IN THE MATTER OF AN APPLICATION FOR PATENT,
APPLICATION NO. **IN/PCT/2002/1243/MUM**

ABBOTT LABORATORIES,

a corporation organized and existing under the laws of USA,
OF Dept. 377 Bldg Ap6A-1, 100 Abbott Park Road,
Abbott Park, ILLINOIS 60064-6008 USA.....

Applicant

ORDER

An application for a patent bearing number **IN/PCT/2002/1243/MUM** was filed in Patent Office, Mumbai on 11th September, 2002 entitled "Crystalline Pharmaceutical" which is the national phase application of PCT application (PCT/US01/09112) dated 21st March, 2001. A request for examination under section 11-B was filed on 29th December, 2005 and was assigned a Request No. 2643/RQ/05. As per the provision under Section 11-A of Patents Act, the said application was published on 26th June, 2004.

The said application was examined under Section 12 and 13 of Patents Act and First Examination Report (henceforth referred to as FER) containing a statement of objections was forwarded on 16th October, 2006 and the applicant's agent filed response to FER on 9th October, 2007 vide their reference 14050(P-13). As per the provisions under Section 13 (3) of Patents Act, the said amended case after reply to FER, was examined and investigated in like manner as the original specification and the applicant was offered a hearing on 18th August, 2009 vide official communication dated 20th July, 2009 containing statement of objections which are as follows:

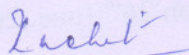
1. Your submissions in letter dated October 9, 2007 have been considered carefully, however the requirements of paras 1, 2 and 4 of FER have not been met. Referring to para 1 requirements, the claims 1 to 23 claiming for various crystalline forms of lopinavir are not inventive in view of the disclosure is D1-US 5914332 & D2-WO9857648. Since amorphous lopinavir and its use as an HIV protease inhibitor is already known in D1 (claims 6 to 12) and it is well known in the art that a crystalline form is pure compared to an amorphous form, crystalline forms of lopinavir are regarded as obvious solution to the

technical problem solved by the instant invention. Hence claims 1 to 23 do not constitute invention u/s 2(1) (j) of the Act.

2. Referring to para 2 of FER, the claimed compounds are new forms of a known compound lopinavir (D1) and these forms do not have the enhanced efficacy over the known compounds, hence the crystalline forms claimed are not patentable u/s 3(d) of the Act.
3. Referring to para 4 of FER, drawings are not as per Rule 15 of the Patent Rules, 2003.
4. Title is not precise.
5. Your submission in the letter that the claims have been thoroughly revised and claims 2-23 have been deleted is not clear.
6. A hearing is fixed on 18th August, 2009 at 11 a.m

The applicant's agent did not appear for hearing on the above said date to meet the requirements of this Office letter dated 20th July, 2009 which are still outstanding. So in view of the facts and circumstances of the case as above, I hereby refuse to proceed further with the application no. **IN/PCT/2002/1243/MUM** entitled "Crystalline Pharmaceutical".

Dated this 27th September, 2010.



DR. RUCHI TIWARI)
DY. CONTROLLER OF PATENTS AND DESIGNS

Copy to:-

ANAND AND ANAND, B-41, Nizamuddin East, New Delhi-110 013 [**Applicant' agent**]