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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

+ **C.A.(COMM.IPD-PAT) 23/2022 & I.As. 5666-67/2022**

**DAEWOONG PHARMACEUTICAL CO. LTD. &
ANR.**

..... APPELLANTS

Through: Mr. Sanuj Das and Mr. Manish
Kumar, Advocates. (M:9899844920)

versus

**CONTROLLER GENERAL OF PATENTS DESIGNS AND
TRADEMARKS**

..... RESPONDENT

Through: Mr. Harish V. Shankar, CGSC with
Ms. S. Bushra Kazim and Mr. Srish
Kumar Mishra, Advocates for UOI.

CORAM:

JUSTICE PRATHIBA M. SINGH

ORDER

% 12.04.2022

1. This hearing has been done through hybrid mode.

I.A.5666/2022 (u/O XLI Rule 27 CPC)

2. This is an application on behalf of the Appellants under Order XLI Rule 27 CPC seeking to place on record the additional documents in support of the present appeal in the form of an affidavit dated 01st April, 2022 of Dr. Hyun-Woo Lim, who is a research scientist working with the Appellant. By way of the present application, the Appellant seeks to place on record the data relating to the Oral Glucose Tolerance Test and the comparison of the Pharmacokinetic profiles of the crystalline form A of compound of the formula c28 over the amorphous form of compound of the formula c28.

3. Issue notice. Notice is accepted by Mr. Harish V. Shankar, Id. CGSC.

4. Let a reply be filed within two weeks. Rejoinder thereto, if any, be



filed within two weeks thereafter.

I.A.5667/2022 (for exemption)

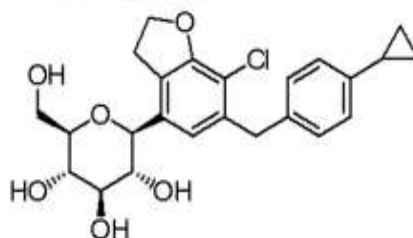
5. This is an application seeking exemption from filing duly executed and apostilled notarised affidavits. Let the same be filed within 8 weeks.

6. **I.A.5667/2022** is disposed of.

C.A. (COMM.IPD-PAT) 23/2022

7. The present appeal arises out of the impugned order dated 4th January, 2022 by which the Indian Patent Application No.201817048074 titled '**Methods for Producing Diphenylmethane Derivatives**' filed by the Appellant with priority date 17th June, 2016, has been rejected by the Assistant Controller of Patents & Designs, Patent Office, New Delhi. The application relates to a crystalline form A of a compound of the formula c28 as depicted below:

[Formula c28]



8. The said application has been rejected on the ground that the invention in question does not satisfy the test of Section 3(d) of the Patents Act, 1970 (*hereinafter 'Act'*) as the claimed compound of the formula c28 was known in prior art. The impugned order clearly holds that the invention has passed the test under Section 2(1)(ja) of the Act on account of improvement in stability, non-hygroscopicity, solubility, dissolution rates etc. qualifying the inventive step standard. However, on the question of



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Section 3(d), the Controller has come to the conclusion that the amended claims do not fulfill the requirement as the drug was well known for its pharmacological properties and the Appellant has failed to provide any conclusive evidence to prove the enhancement in known “therapeutic efficacy” of the active drug in crystalline form-A of the compound.

9. Post the filing of this application, three divisional applications have been derived out of the present application. Two applications bearing application nos. 202018010805 and 202018010806 were for method claims and one application bearing no. 202118041844 was for the crystalline form, out of which both of the applications for method claims have already been granted.

10. It is not in dispute that in the present patent application, the claim relates to the crystalline form of a compound of the formula c28. The amorphous form of the compound in question is already covered and granted in the document cited as D1, which is the patent document of the Appellant itself, covering the markush and various other compounds including the compound involved in the present application.

11. The submission of Mr. Das, Id. Counsel for the Appellant is that the Appellant has placed on record the data to show higher hygroscopicity and other advantages in the subject patent including stability, non-hygroscopicity, solubility, dissolution etc. This data was not contained in the specification, but was produced before the Patent Office later. He further submits that by way of additional documents, further evidence of enhanced efficacy has also been filed with the present Appeal.

12. In the opinion of the Court, the question that arises in this appeal would be twofold:



(1) Whether the further data in respect of the crystalline form of the compound which is the subject matter of the patent application can be filed and entertained post the filing of the patent specification and rejection of the same by the Patent office?

(2) Whether the crystalline form of the compound of the formula c28 satisfies the requirements of Section 3(d) of the Act.

13. Parties to place on record their written submissions and judgments on both these issues at least a week before the next date of hearing.

14. List on 17th August, 2022.

PRATHIBA M. SINGH, J.

APRIL 12, 2022/dk/sk