

OIPD-4

IN THE HIGH COURT AT CALCUTTA
ORIGINAL SIDE
(Intellectual Property Rights Division)

IPDPTA/22/2023

REATA PHARMACEUTICALS INC (OA/2/2018/PT/KOL)
VS
DEPUTY CONTROLLER OF PATENTS AND DESIGN

BEFORE:

The Hon'ble JUSTICE RAVI KRISHAN KAPUR

Date : 12th June, 2025.

Appearance:
Ms. Vindhya S.Mani, Adv.
Mr. Devesh Aswal, Adv.
Ms. Diya Mal, Adv.
...for the applicant.

Mr. Indrajeet Dasgupta, Adv.
...for controller.

The Court: This appeal has been filed under section 117A of the Act and is directed against an order dated 2 June 2017, passed by the respondent No. 1, rejecting patent application no. 512/KOLNP/2010 dated 9th February 2010.

Briefly, the appellant had filed an application titled “NOVEL FORMS Of CDDO METHYL ESTER”, claiming priority to PCT Application No.- PCT/US2008/009703 dated 14th August 2008.

On the receipt of the request for examination on 25 February 2011, the application was examined. The application originally filed 18 claims. The First Examination Report was issued on 14th October 2014. Subsequently, the applicant filed a detailed response against the objection based in the FER on 7th April 2015.

By, the impugned order, the subject application for patent was rejected on the ground of not being patentable under sections 3(d) and 3(e) of the Patents Act 1970.

It is contended on behalf of the appellant that in rejecting the above application for patent, the respondent no.1 failed to appreciate and deal with the evidence which had been filed by the appellant. In particular, the appellant had in the Written Notes of Submissions filed before the respondent no. 1 relied on data from two test studies [BEAM (Form A) and BEACON (Form B) (claimed)] which highlighted the therapeutic effect of CDDO-Me on human patients who suffered from chronic kidney disease. In addition, therapeutic efficacy was determined by the estimated glomerular filtration rate (eGFR), which is the standard measure of kidney function in a patient. In this connection, the appellant also relied on a Table filed along with the Written Submissions dated 5.7.2016.

It is contended on behalf of the appellant that a comparison of the above data would explain in detail studies undertaken in human patients suffering with chronic kidney disease to test the efficacy of the claimed invention. The results of the studies clearly show that the claimed invention is more effective than the previously known compounds and that too when administered in lower doses, patients showed greater receptiveness to the claimed invention. In such circumstances, it is contended that the respondent no. 1 erred in passing the impugned order without relying or dealing with the above technical and scientific evidence.

On behalf of the respondent authorities, it is fairly submitted that there is nothing to suggest that the respondent no. 1 in passing the impugned order has dealt with the above evidence which was admittedly relied on by the appellant in the Notes of Submissions filed before the respondent no. 1.

In *Novartis AG vs. UNI (2013) 6 SCC 1*, it has been held as follows:

“Just increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy. Whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data.”

Admittedly, the appellant had relied on and established the above data in the Written Notes of Submissions which were filed before the respondent no.1. The said data has been brought on record in terms of the decision in *Ischemix LLC vs. Controller of Patents, 2023 SCC Online Del 7519*. All the clinical trial data were brought on record in the form of comparative tables. Clear and elaborate explanations were also provided with regard to the enhanced therapeutic efficacy of the claimed data. Hence, it was obligatory on the respondent no. 1 to deal with such evidence, regardless of the merits or the demerits of the same. The respondent no.1 could not have determined the efficacy of the claimed data unless the experimental and comparative data provided were considered (*Oyster Point Pharma Inc. vs. Controller of Patents and Designs and Another, 2023 SCC Online Cal 2141*).

In addition, the respondent has also failed to provide reasons for considering the research data insufficient to establish the patentability of the claimed invention nor did the authority provided reasons for rejecting the application under section 3(d) or 3(e) of the Act.

Reasons are an integral part of any order which reflect the views of the decision maker. It is well settled that an order must be reasoned. In *The State Bank of India & Anr. vs. Ajay Kumar Sood* MANU/SC/1040/2022, it has been held as follows:

"A judgment culminates in a conclusion. But its content represents the basis for the conclusion. A judgment is hence a manifestation of reason. The reasons provide the basis of the view which the decision maker has espoused, of the balances which have been drawn. That is why reasons are crucial to the legitimacy of a judge's work. They provide an insight into judicial analysis, explaining to the reader why what is written has been written. The reasons, as much as the final conclusion, are open to scrutiny. A judgment is written primarily for the parties in a forensic contest. The scrutiny is first and foremost by the person for whom the decision is meant-the conflicting parties before the court. At a secondary level, reasons furnish the basis for challenging a judicial outcome in a higher forum. The validity of the decision is tested by the underlying content and reasons. But there is more. Equally significant is the fact that a judgment speaks to the present and to the future. Judicial outcomes taken singularly or in combination have an impact upon human lives. Hence, a judgment is amenable to wider critique and scrutiny, going beyond the immediate contest in a courtroom. Citizens, researchers and journalists continuously evaluate the work of courts as public institutions committed to governance under law. Judgment writing is hence a critical instrument in fostering the rule of law and in curbing rule by the law."

Similar views have also been held in *Agriboard International vs. Controller of Patents and Designs*, 2022 SCC OnLine Del 940 and *Sr. Sapna Nangia vs. The Assistant Controller of Patents and Designs* 2023 SCC OnLine Del 1098.

In view of the above, the impugned order is unsustainable and set aside. The matter is remanded back to the Controller to hear the parties afresh after

giving a right of hearing to the appellant. The above exercise is to be completed within three months of the date of communication of this order. It is made clear that there has been no expression or adjudication on the merits of the case and all questions are left open to be decided by the respondent no. 1 in accordance with law. With the above directions, IPDPTA/22/2023 stands allowed.

(RAVI KRISHAN KAPUR, J.)

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