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

BEFORE:
The Hon'ble Justice Ravi Krishan Kapur

IPDPTA/50/2023

TOPOTARGET UK LIMITED (SR/12/2020/PT/KOL)
VS
THE CONTROLLER GENERAL OF PATENT AND DESIGNS, MUMBAI AND ORS.

For the petitioner : Mr. Subhatosh Majumder, Advocate
Mr. Paritosh Sinha, Advocate
Mr. K. K. Pandey, Advocate
Ms. Mitul Dasgupta, Advocate
Ms. Sonia Nandy, Advocate
Mr. Teesham Das, Advocate
Ms. Mallika Bothra, Advocate

For Controller : Mr. Swatarup Banerjee, Advocate
Mr. Shankharit Chakraborty, Advocate

Heard on : 16.12.2025

Judgment on : 30.01.2026

Ravi Krishan Kapur, J.:

1. This is an appeal under section 117A of the Patents Act, 1970 against an order dated 29 November 2019 passed by the Deputy Controller of Patents & Designs, Kolkata in Patent Application No. 4712/KOLKNP/2007 which has been rejected *inter-alia* on the ground of insufficiency of disclosure, lack of inventive step, obviousness and under section 3(d) of the Act.
2. The application was filed in India being the National Phase Application in 2007, when a pre-grant opposition had been filed by the respondent no 3, Fresenius Kabi Oncology Limited under section 25(1) of the Act. The impugned order is a composite order passed both under section 15 as well as under section 25(1) of the Act.

3. Briefly, the invention relates to a pharmaceutical composition for a drug used in cancer treatment. The invention comprised of: (a) A histone deacetylase (HDAC) inhibitor wherein HDACi is a compound of the given formula or a pharmaceutically acceptable salt. This is the active pharmaceutical ingredient. (b) A basic in situ salt former, wherein the salt former comprises of arginine or meglumine i.e. the inactive ingredient.
4. It is contended that the invention has surprising and unexpected solubility. The basic in situ salt former increased the solubility of the HDACi - PXD101. This resulted in a higher amount of the actives being used. Further, arginine and meglumine do not show any instability when diluted. There was also no precipitation of the active when diluted. In this background, it is contended that the invention resulted in the following advantages: (a) A higher solubility (with higher concentration of active HDACi - PXD 101 but showing no instability). (b) Increased stability when formulation is in a concentrated liquid form (e.g for storage). (c) Increased stability when in a diluted liquid form (e.g when ready for administration).
5. It is alleged that no prior arts were cited by the Examiner in FER. However, the Deputy Controller found 4 (four) prior arts cited in IPRP to be the most appropriate documents. Ultimately, nine prior arts cited by respondent no.3 different from the International Preliminary Report on Patentability (IPRP) and the FER were taken into consideration. Though, the respondent no. 2 concluded that his views were concurrent with that of the Examiner, there is a total absence of any independent reasoning in arriving at such conclusion. It is also contended that a new case of obviousness was made out in the hearing notice where a new combination of prior arts were cited neither of which were explained or clarified. In any event, the respondent

no 2 misconstrued the invention in considering the composition as a salt and that the same fell within the purview of section 3(d) of the Act. The respondent no 2 also erred in raising objections both under section 3(d) of the Act against the same set of claims. In passing the impugned order, the respondent no 2 only looked into components of the invention claimed and compared them with the prior arts instead of considering the invention as a whole. The impugned order fails to provide any reasons in arriving at the conclusion of insufficiency of disclosure under section 10(4) of the Act. It is also contended that the impugned order ignores the experimental and technical data in concluding that the composition claimed would not produce the desired solubility.

6. On behalf of the respondent authorities, it is contended that there are no grounds to interfere with the impugned order. The finding under section 10(4) of the Act that the pharmaceutically acceptable salt of solvate as claimed in the invention had not been clearly described is adequately reasoned. Similarly, the existence of prior art imparting the same knowledge as claimed, having a priority date earlier than that of the subject claimed patent gives rise to the objection of lack of inventive steps under section 2(1)(j)(a) of the Act alongwith the absence of novelty. It is contended that in the absence of any kind of therapeutic efficacy, the invention was contrary to section 3(d) of the Act and this must be critically and strictly analysed. In support of such contentions, reliance was placed on *Novartis AG v Union of India (2013) 6 SCC 1*.

7. In passing the impugned order, the respondent no.2 has overlooked the clearly defined and limited role of an Examiner under the Act. An Examiner is to examine an application for patent and submit a report to the

Controller. In discharging its statutory functions, the Examiner was only to make a Report to the Controller. An Examiner is not entitled to participate or make submissions during the hearings of the proceedings. In such circumstances, the Controller was obliged to apply his mind independently to the objections and submissions made and adjudicate the matter and not merely endorse the Examiner's opinion. In any event, the Controller has relied on additional prior art documents which were never cited in the First Examination Report and an entire new case was made out in hearing notice dated 31.08.2016 where a new combination of prior arts were cited.

8. Section 2(1)(ja) of the Act reads as follows :-

> ***"2(1)(ja).*** *"inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art."*

9. On a plain reading of the above provision, an invention should provide technical advancement to the already existing knowledge having economic significance which should not be obvious. In the present case, both the parties acknowledged that the compound "PXD-101" is a known ingredient. The appellant did not claim PXD-101 or HDACi as its invention but claimed to provide a composition of two elements wherein one is an active component and the other is an inactive component which is a basic in situ salt former. The appellant's invention is an engineered pharmaceutical composition which consisted of PXD-101 as a HDAC inhibitor, which is a known substance. The main inventive step lies in identifying the specific basic in situ salt formers namely arginine and meglumine. This aspect of the matter has not been adverted to in the impugned order.

10. Insofar as the prior arts relied on are concerned, the contention of the appellant was that D1 discloses PXD-101, i.e. the active component of the invention. However, the invention also had a basic in-situ salt former as an inactive component which has not been taken into consideration in the impugned order. Significantly, D2 explained wholly new HDAC inhibitors and did not co-relate to other compounds like PXD-101. It does not classify arginine even under pharmaceutical salts of the active. D3 disclosed new hydroxamic acid derivatives instead of HDACi. D4 merely discloses the general possibility of forming salts using pharmaceutically acceptable bases. It did not teach or suggest the specific use of arginine or meglumine as in-situ salt formers to simultaneously achieve enhanced solubility and formulation stability. D5 is related to antibacterial sulphonamide which is different compound from PXD-101. D6 related to arginine and meglumine used with entirely different compounds, namely iminohydroxamic acid derivatives and metalloproteinase inhibitors, and is unrelated to PXD-101 or HDAC inhibitors. D6 did not disclose nor suggest the use of arginine or meglumine as an in-situ basic salt former to enhance both solubility and stability. D7 related to cyclodextrin complexes with or without salts such as arginine but does not concern HDAC inhibitors or PXD-101. D8 disclosed general solubilization enhancement techniques, including cyclodextrin Arginine, Lysine but it is unrelated to HDAC inhibitors or PXD-101. It neither teaches the use of arginine or meglumine as in-situ salt formers nor addresses the critical requirement of formulation stability upon dilution. D9 disclosed antibacterial and cosmetic applications and was not connected to cancer related drug. D9 also revealed that the use of arginine and meglumine could lead to an increase in solubility by more than 7000% but

acknowledged instability of the resulting complexes. This document did not address one of the main claims of the invention "Increased stability when in a diluted liquid form". The impugned order although mentions the prior arts, however fails to show how are they more effective than the claimed invention.

11. In any event, the prior art documents must disclose the whole of the invention which enables the invention and deals with the invention in completeness. The contention of the appellant that none of the cited prior art disclose or teach the claimed composition, namely PXD-101 in combination with arginine or meglumine in the specific manner so as to achieve both enhanced solubility and stability has not even been considered in the impugned order. As a consequence, the finding of obviousness by the Controller on the ground of hindsight reconstruction rather than prior arts is vitiated. In this context, it has been repeatedly held that a hindsight reconstruction by using the patent in question as a guide through the maze of prior art references in the right way so as to achieve the result of the claim is to be *avoided*. [*Groz-Beckert KG vs. Union of India & Ors. 2023 SCC OnLine Cal 111* and *Takeda Pharmaceutical Co. Ltd. vs. Controller of Patents and Desings & Ors. 2025 SCC OnLine Cal 3105*]

12. It is well settled that a combination of multiple documents is permissible only where the prior arts themselves provide a clear lead or motivation to combine their teachings. This requires the existence of a coherent technical thread linking the cited prior arts to the claimed invention. In such circumstances, the finding of obviousness and applicability of the prior art are unsustainable and require reconsideration. [*Guangdong Oppo Mobile*

Telecommunications Corp. Ltd. v. Controller of Patents and Designs 2023 SCC OnLine Cal 6650].

13. Section 3(d) of the Act is as follows :-

> "***3(d)*** *the mere discovery of a new form of a known substance which does not 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 of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.*
> *Explanation - For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."*

Section 3(d) is only applicable when the invention is a new form of a single known substance and is put to the test of "therapeutic efficacy". Section 3(d) is also applicable to combinations involving derivatives of a known substance whether alone or with the known substance itself. A combination of two separate active drugs cannot be treated as derivatives of each other and therefore do not fall within the scope of section 3(d) of the Act. In the present case, the appellant had claimed that the invention is directed towards a composition and not a salt of PXD-101. Arginine and meglumine are inactive ingredients and not derivatives of PXD-101. In such circumstances, the invention was claimed to be a multi-component composition and fell outside the scope and ambit of section 3(d) of the Act. This aspect of the matter has not even been dealt with in the impugned order and vitiates the finding under section 3(d) of the Act.

14. Section 10(4)(a) and (b) of the Patents Act, 1970 is as follows:-

> *"**10(4)** Every complete specification shall--*
> *(a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed;*
> *(b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection."*

15. It is clear that section 10(4) of the Act requires an applicant to fully and particularly describe the invention and its operation or use and the method of performing such invention alongwith the best method known to the applicant. However, this requirement does not necessitate that the specification must contain illustrative examples for every conceivable embodiment or specific combination falling within the scope of the claims. The claims are by nature, generalisations of the examples disclosed and were required to be read broadly and in a technically meaningful manner. At the same time, functional terms used in the claims cannot be interpreted in open contradictions with the overall teaching of the specification. To this extent, an invention must be facilitating. In passing the impugned order, the Controller has also misconstrued the invention. The claim involved a *pharmaceutical composition* comprising an active ingredient and a specific inactive ingredient functioning as an in-situ salt former. The invention is neither a claim to a salt *per se* nor to a new form of PXD-101. Despite the above being highlighted by the appellant, the Controller has not dealt with the same nor provided any reasoning in the impugned order. To this extent, the findings in the impugned order of insufficiency of disclosure and simultaneously lacking of inventive steps under section 2(1)(ja) of the Act are irreconcilable and contradictory. [*Basf Se vs. Joint Controller of Patents and Designs and Others 2025 SCC OnLine Cal 2049*].

16. In view of the above, the impugned order is unsustainable and set aside. To this extent, IPDPTA 50 of 2023 stands allowed. The matter is remanded to a different Controller other than the Controller who heard the matter and is to be decided afresh in accordance with law after giving a right of hearing to all parties. The above exercise is to be completed within a period of three

months from the date of communication of this order. It is made clear that there has been no expression on the merits of the case and all questions are left open to be adjudicated upon afresh.

(Ravi Krishan Kapur, J.)