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

IPDPTA/30/2023

JANSEN PHARMACEUTICA NV (SR. NO.01/2019/PT/KOL)
VS
DEPUTY CONTROLLER OF PATENTS AND DESIGNS

Before:
The Hon'ble Justice RAVI KRISHAN KAPUR
Date: 4th March 2025

Appearance:
Mr. Debashish Banerjee, Adv.
Ms. Rajshree Kajaria, Adv.
Ms. Vinda Kedia, Adv.
…for appellant

Mr. Indrajeet Dasgupta, Adv.
Mr. Tapan Bhanja, Adv.
Ms. Puspita Bhowmick, Adv.
…for controller.

The Court: This appeal is directed against an order dated 31st July 2018 whereby Indian Patent Application No. 1337/KOLNP/2008 has been rejected.

Pursuant to the filing of the above application, the First Examination Report was issued on 12 august 2014. By a communication dated 11 August 2015, the appellant filed their objection. Thereafter, the respondent authorities issued a hearing notice dated 2 April 2018.

Briefly, the subject invention is to provide a dry formulation of tipifarnib which can be solubilized with a solution so as to allow to form a solution formulation of tipifarnib so that the same can be administered intravenously. The use of the various compounds at a particular pH and in a particular composition in the subject invention results in desirable effects of the claimed composition on patients who have an impaired oral intake which establishes that the present composition is not a mere admixture of already known compounds. Thus, it is contended that the same could not have been rejected under section 3(e) for non-patentability or on any other ground.

By the impugned order, the respondent no. 1 has rejected the application for patent on the ground that it did not reflect any technical advancement of the cited prior arts. Additionally, it has been held that the subject patent was lacking in inventive steps and was not patentable under section 3(e) of the Act.

On behalf of the appellant, it is submitted that there are no reasons in the impugned order in arriving at the above conclusion. The impugned order has been passed without adverting to the well-established principles in determining inventive steps. Moreover, the respondent no. 1 has acted contrary to the express provisions of section 3(e) of the Act. It is further contended that the subject application has been erroneously rejected for lack of inventive steps under section 2(1)(ja) of the Act. The impugned order fails to adhere to the well-settled principles as laid down in *F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd., [(2016 (65) PTC 1 (DB)* at paragraph 153], *Agriboard International LLC. V. Deputy Controller of Patents and Designs* [(Unreported judgement dated March 31, 2022 of the High Court of Delhi passed in CA.A (COMM.IPD-PAT)4/2022 at paragraph 24)].

It is submitted that the objections raised to the First Examination Report have neither been dealt with nor considered in the impugned order. In fact, the impugned order proceeds in a pre-meditated manner without furnishing any reasons. In passing the impugned order, there has been no discussion nor reasoning in arriving at the conclusions contained in the impugned order. The objections to the First Examination Report categorically dealt with each of the prior arts being D1, D2, D3. Nevertheless, there has been no discussion of the same. Insofar as the lack of inventive steps is concerned, the contention of the appellant that in the light of the revised

claim 1, the same necessarily indicated inventive steps over D1 and D2, has also not been taken into account.

The mere mentioning of the prior art documents without dealing with the contents of the same is a serious infirmity in the order. Similarly, the finding that no remarkable outcome like synergistic effect or higher efficacy associated with the subject invention is unsubstantiated and ignores the documentary evidence relied on by the appellant. The impugned order is vague, bereft of any reasons and ignores the evidence on record.

In arriving at the above conclusion, the Controller has in a cryptic and cursory manner concluded that there was no inventive step involved in the subject invention. The finding that "no remarkable outcome like synergistic effect or higher efficacy result associated with the claimed composition has been indicated in the complete specification" is also baseless.

The Controller was bound and should have dealt elaborately with each of the objections raised by the appellant and this is fatal to the impugned order. In fact, the specifications furnished by the appellant categorically provided for the manufacturing process, which also furnished clinical trials, study design, clinical assessment, manufacturing of formulation, etc. None of this has been adverted to or finds any mention in the impugned order. The summary finding rejecting the subject application under Section 2(1)(ja) by simply stating that the documents D1, D2 and D3 reveal tipifarnib mannitol and other sugar compounds fails to provide adequate reasoning or understanding of the subject invention.

The conclusion of lack of inventive steps in view of the prior art documents D1 to D3 is erroneous and completely based on hindsight analysis without referring to or dealing with the same in the impugned order.

There has simply been no discussion on the prior arts. As such, the impugned order is unsustainable and is liable to be set aside.

In addition, the respondent no. 1 in rejecting the application on the ground of lack of inventive steps under Section 2(1)(ja) of the Act has failed to apply the well established principles as laid down in *F. Hoffmann-La Roche Ltd. & Anr. vs. Cipla Ltd. [(2016) (65) PTC 1 (DB)]:*

> *"153. From the decisions noted above to determine obviousness/lack of inventive steps the following inquires are required to be conducted:*
>
> *Step No. 1 To identify an ordinary person skilled in the art,*
>
> *Step No. 2 To identify the inventive concept embodied in the patent,*
>
> *Step No. 3 To impute to a normal skilled but unimaginative ordinary person skilled in the art what was common general knowledge in the art at the priority date.*
>
> *Step No. 4 To identify the differences, if any, between the matter cited and the alleged invention and ascertain whether the differences are ordinary application of law or involve various different steps requiring multiple, theoretical and practical applications,*
>
> *Step No. 5 To decide whether those differences, viewed in the knowledge of alleged invention, constituted steps which would have been obvious to the ordinary person skilled in the art and rule out a hideside approach."*

In *Agriboard International LLC. V. Deputy Controller of Patents and Designs* [(Unreported judgement dated March 31, 2022 passed by the High Court of Delhi in CA.A (COMM.IPD-PAT)4/2022 it has been held as follows:

> *"24. In the opinion of this Court, while rejecting an invention for lack of inventive step, the Controller has to consider three elements-*
>
> - *the invention disclosed in the prior art,*
> - *the invention disclosed in the application under consideration, and*
> - *the manner in which subject invention would be obvious to a person skilled in the art."*

The impugned order also fails to provide any discussion on the aspect as to the manner in which the subject invention would be obvious to the person skilled in the art.

The respondent no.1 also erred in concluding that the subject application is non-patentable under section 3(e) of the Act. The respondent

failed to acknowledge the well settled proposition of law that a composition of known components resulting in synergistic properties is patentable under section 3(e) of the Act. In *Lallubhai Chakubhai Jarivala v. Shamaldas Sankalchand Shah (1934) 36 Bom LR 881* it has been held as follows;

> *"20. The point of a combination patent is that the elements of which the combination consists is to produce one result. The merit depends upon the result produced. Frost in Vol. 1 of his Patent Law and Practice, Edn. 4, observes as follows (p. 74):*
> *"The merit of a new combination very much depends on the result produced. When a very slight alteration turns that which was practically useless into what is useful and important, the Courts consider that, though the invention was apparently small, yet the result being the difference between failure and success, it is a fit subject-matter. Thus, the mere placing of two flat wicks parallel to each other in an gil lamp, two concentric round wicks having been previously combined, and fiat wicks being perfectly well-known, has been held sufficient to merit a patent…"*
>
> *21. The authority cited is 4 Ch. D. 607 In that case Jeesel, M.R., makes the following observation (p. 615):*
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> *"Where a slight alteration in a combination turns that which was practically useless before into that which is very useful and very important, Judges have considered that, though the invention was small, yet the result was so great as fairly to be the subject of a patent; and as far as a rough test goes, I know of no better."*
>
> *22. In patent cases the Courts attach great importance to the fact that the alleged invention was only arrived at by a series of experiments. The learned Judge at p. 64 of the paper book has referred to this principle and has cited an authority in support of it. It is beyond dispute that the plaintiff carried on numerous experiments from 1924 to 1930."*

In view of the above, the impugned order is unsustainable and is set aside. The matter is remanded back to the Controller to be decided within a period of three months from the date of communication of this order and after giving a right of hearing to the appellant. It is made clear that there has been no adjudication on the merits of the case and all questions are left open to be decided by the Controller or any Appropriate Officer in accordance with law.

With the above directions, IPDPTA 30 of 2023 stands disposed of.

(RAVI KRISHAN KAPUR, J.)

SK.