2024:MHC:3058

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IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: **08.08.2024**

CORAM

THE HONOURABLE **MR.JUSTICE SENTHILKUMAR RAMAMOORTHY**

CMA(PT)/23 of 2024

M/s.Guangzhou Ocusun Ophthalmic
Biotechnology Company Limited,
Room No.402, No.223, West Huanshi Avenue,
Nansha District, Guangzhau City, China. ... Appellant

-vs-

Joint Controller of Patents & Designs,
The Patent Office, Intellectual Property Building,
G.S.T.Road, Guindy, Chennai-600 0032, India. ... Respondent

PRAYER: Transfer Civil Miscellaneous Appeal (Patent) filed under Section 117-A (2) of the Patents Act, 1970, pleased to pass an order setting aside the impugned order dated 15.02.2024 passed by the Respondent in respect to the Application No.202147005676 and allow Patent Application No.202147005676.

For Appellant : Mr.Tarun Khurana
for Khurana and Khurana

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For Respondent : Mr.S.Janarthanam, SPCGSC

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ORDER

This appeal is directed against the order dated 15.02.2024 by which Patent Application No.202147005676 was rejected.

2. The appellant filed the above mentioned patent application titled "CRYSTAL FORM OF LANOSTEROL PRODRUG COMPOUND AND APPLICATION THEREOF" before the Patent Office, Chennai, on 10.02.2021. The said application was filed as a national phase application, which was derived from PCT application No.PCT/CN2019/097773. The appellant claimed priority from 25.07.2018. Pursuant to a request for examination, the First Examination Report(FER) was issued on 21.06.2022. By such FER, objections were raised *inter alia* on the ground that the claimed invention is patent ineligible under Section 3(d) of the Patents Act, 1970 and that it lacks an inventive step in view of prior art documents D1 and D2. The appellant replied to the FER on

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21.12.2022 and also amended the claims by filing amended claims 1 to 5. After a hearing on 23.01.2024, the application was rejected by the order impugned herein.

3. Learned counsel for the appellant submits that the application was in respect of a crystal form of lanosterol prodrug compound and not in respect of a crystal form of lanosterol. He points out that a prodrug exhibits pharmacological activity only upon being metabolized in the body after the drug is administered. He submits that the appellant applied for and obtained a patent in respect of the lanosterol pro-drug compound from the Indian Patent Office. He also submits the crystal form of the pro-drug was granted patent in multiple jurisdictions, including China, United States of America, Europe and Japan.

4. With regard to the rejection under Section 3(d) of the Patents Act, learned counsel contends that the Joint Controller failed to identify the known substance. He submits that the lanosterol pro-

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drug compound for which the appellant was granted a patent was published after the priority date in respect of the current application. Consequently, he contends that D1 is not really a prior art document. For this principle, he relies upon the judgments in *Mr.Tony Mon George, Constituted Attorney of AbbVie Inc. v. Deputy Controller of Patents and Designs, judgment dated 20.12.2023 in (T)CMA(PT)No.150 of 23* and *Pfizer Products Inc. v. Controller of Patents & Designs, 2020 SCC OnLine IPAB 19.*

5. Without prejudice to this contention, and assuming without admitting that Section 3(d) of the Patents Act applies, he submits that the appellant demonstrated therapeutic efficacy by including experimental results in the complete specification. Consequently, he contends that the claimed invention passes through the exemption filter in Section 3(d). He relies upon experimental examples 2 and 3 at internal pages 16 to 21 of the complete specification, in this regard, and points out that it is categorically stated therein that the cataract symptoms were significantly reduced after lanosterol pro-drug 026

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eye drops were administered for 42 days compared to the symptoms before administration, and that the cataract symptom showed no evident change before and after administration of Kary Uni eye drops and lanosterol eye drops.

6. As regards the inventive step analysis, learned counsel submits that D2 discloses a Markush structure with hundreds of prophetic compounds. Without the benefit of hindsight, learned counsel submits that it would not be obvious to PSITA to even arrive at lanosterol on such basis. As regards the pro-drug of lanosterol, he contends that it would not be obvious from D2 by any stretch of the imagination.

7. Mr.Janarthanan, learned special panel counsel, appears on behalf of the respondent. By relying upon the counter affidavit of the Deputy Controller of the Patent and Designs, Dr.V.Parimalavarsini, and on the impugned order, he contends that the crystal form of lanosterol can be easily derived from prior art document D2. He also

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contends that the crystal form of the pro-drug of lanosterol merely increases stability and permeability and that these properties, at best, enhance bioavailability and not therapeutic efficacy.

8. D1 is on record and the date of publication thereof is 24.01.2020. The priority date of the application forming the subject of this appeal is 25.07.2018. Consequently, as noticed by the respondent in the impugned order, D1 cannot be construed as prior art. In such circumstances, in order to apply Section 3(d) of the Patents Act, it would be necessary for the respondent to identify the known substance. On reading the impugned order, while it appears that the respondent considered lanosterol as the known substance, no explanation is provided for doing so in view of the claims being in respect of a crystal form of the pro-drug lanosterol.

9. Even proceeding on the assumption that Section 3(d) is applicable, it becomes necessary to examine whether the new form exhibits enhanced efficacy, including significant enhancement in

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properties, in terms of Section 3 (d) and the Explanation thereto. In the complete specification, the appellant has set out the experimental data and results from internal pages 11 to 21 thereof. By way of illustration, paragraphs 90, 91, 94 and 95 are set out below:

> *"**[0090] 4.** Experimental results*
>
> ***[0091]** 1)Slit lamp observation:Fig. 5 shows that sodium selenite could induce cataract in neonatal New Zealand rabbit lens. **Slit lamp observation shows the cataract symptoms were significantly reduced after lanosterol prodrug 026 drops were administered for 42 days (Fig. 5-I) compared with the symptoms before administration (Fig. 5-J). The cataract symptoms showed no evident change before and after the administration of** Kary Uni eye drops (Fig.5-E, 5-F) and **lanosterol eye drops (Fig. 5-G, 5-H).***
>
> ***[0094]** 5. Conclusion*
>
> ***[0095]** The above results indicate that the lanosterol prodrug 026 eye drops are capable of alleviating the cataract symptoms of neonatal New Zealand rabbits induced by sodium selenite and improving lens transparency and lens GSH-*

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PX activity."

Similar conclusions are recorded with regard to experimental example 3.

10. In the impugned order, the following findings were recorded in the penultimate paragraph:

> *"In context to the above discussion I do not find substantial therapeutic efficacy of claimed compound 1 as pharmacokinetic and pharmacodynamics activities in treating cataract of crystal form A of compound of formula 1 is better than of Lanosterol as claimed as shown in Table 1 to 6 in the disclosure are related to pharmacokinetic and pharmacodynamics properties and indicated AUC value. Further, it is known that increased steability and permeability is related to drug bioavailability, which is directly proportional to total amount of unchanged drug that reaches systematic circulation. So in my consideration the said data is not related to therapeutic efficacy which is maximum response*

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achievable to elicit a therapeutic response. A drug's efficacy is a measure of the ability of the drug to treat whatever condition it is indicated for. Efficacy means therapeutic efficacy data per se needs to be substantiated by the comparative clinical data w.r.t the closest compound(s) of prior art/commercial product for establishing patentability. Nowhere in the written submission as well as in specification I found that the trial of applicant to prove upon the therapeutic efficacy other that data related to pharmacokinetic and pharmacodynamic properties as discussed above. Finally, I opine that the subject application failed to overcome section 3(d) of the Act as well as section 2(1)(j) of the Act being a mere crystal with regard to above discussion and as a result of the same the application is not patentable within provision of the law."

While there is a reference to Table 1 to 6 in the above extracts, there is no consideration of the claim made in the experimental results, especially in the portions emphasised in bold font in the above extract, with regard to therapeutic efficacy. It is pertinent to notice in this regard that both experimental example 2 and 3 are described as

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pharmacodynamic studies, i.e. studies that deal with the effect of the drug on the body as opposed to pharmacokinetic studies that deal with the effect of the body on the drug. The significance and implication thereof has also not been appreciated. Therefore, the impugned order cannot be sustained and the matter requires reconsideration.

11. For reasons set out above, impugned order dated 15.02.2024 is set aside and the matter is remanded for reconsideration on the following terms:

(i) In order to preclude the possibility of pre-determination, reconsideration shall be by an officer other than the officer who issued the impugned order.

(ii) The observations set out in this order shall be taken into consideration while undertaking reconsideration, but it is made clear that no opinion has been expressed on the merits of the patent application.

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(iii) After providing a reasonable opportunity to the appellant, a reasoned decision shall be issued within six months from the date of receipt of a copy of this order. There shall be no order as to costs.

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Index : Yes / No

Internet : Yes / No

Neutral Citation: Yes/No

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To

The Joint Controller of Patents & Designs,
The Patent Office, Intellectual Property Building,
G.S.T.Road, Guindy, Chennai-600 0032, India.

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SENTHILKUMAR RAMAMOORTHY J.

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