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IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: **06.03.2025**

CORAM

THE HONOURABLE **MR.JUSTICE SENTHILKUMAR RAMAMOORTHY**

(T)CMA(PT) No.46 of 2023
(OA/27/2020/PT/CHN)

Shaperon Inc.
606,174-10, Jagok-ro, Gangnam-gu,
Seoul, Republic of Korea. ... Appellant

-vs-

Assistant Controller of Patents and Designs,
Government of India, Patent Office,
Intellectual Property Rights Building,
GST Road, Guindy, Chennai - 600 032. ... Respondent

PRAYER: Transfer Civil Miscellaneous Appeal (Patents) filed under Section 117-A of the Patents Act, 1970, praying that the order dated 22 April 2020 issued by the respondent be set aside and the application No. 1667/CHENP/2015 for patent be allowed to proceed to grant with claims filed on 25th March 2020 in accordance with the provisions of the Act, and the Rules.

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For Appellant : Mr.P.V.Balasubramaniam, Senior Counsel for
Mr.A.Arvind Raj
for M/s.De Penning and De Penning

For Respondent : Mr.Rajesh Vivekanandan

JUDGMENT

The appellant applied for grant of patent for a claimed invention titled "COMPOSITIONS FOR PREVENTING OR TREATING ALLERGIC SKIN DISORDERS, CONTAINING GPCR19 AGENTS AS ACTIVE INGREDIENTS". Such application was rejected by impugned order dated 22.04.2020.

2. The above mentioned application was lodged on 05.03.2014. Pursuant to a request for examination, the First Examination Report (FER) dated 25.05.2018 was issued. In the FER, objections were raised *inter alia* on grounds of lack of novelty and inventive step by citing prior arts D1 to D4; and non-patentability under Section 3(e) of the Patents Act, 1970 (the Patents Act). The appellant responded to the FER on 22.02.2019 and filed

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amended claims. A hearing notice was issued on 06.02.2020. Pursuant to a hearing on 11.03.2020, the appellant filed written submissions on 25.03.2020 and submitted further amended claims on 25.03.2020. These were the claims rejected under the impugned order.

3. Learned senior counsel for the appellant referred to the FER and pointed out that the prior arts cited therein were distinguished in reply dated 22.02.2019. With regard to prior arts D1 and D3, he submitted that the GPCR19 agonist referred to therein was intended as a therapeutic agent for the treatment of sepsis, whereas the appellant's claims are limited to and target infectious skin disorders. As regards prior art D2, he pointed out that it relates to a new GPBAR1 agonist compound intended to treat inflammatory disorders. As regards prior art D4, he submitted that it discloses the GPCR19 agonist, chenodeoxycholic acid and ursodeoxycholic acid, and not sodium taurodeoxycholate compound.

4. In spite of such reply, learned senior counsel contends that the same objections were retained in hearing notice dated 06.02.2020 and that

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substantially similar language is used in the impugned order. By referring to the impugned order, learned senior counsel submitted that conclusions were recorded therein that the external preparation of claim 1 is not patentably distinct from the product disclosed in D1. While recording such conclusion, he contends that the Controller did not discuss or record any findings with regard to the appellant's reply wherein prior art D1 was distinguished. Likewise, he submits that the basis on which prior arts D2 to D4 were distinguished was also not discussed in the impugned order. Instead, he states that a conclusion was recorded that the claimed invention could have been arrived at through routine experimentation by a person skilled in the art on the basis of the disclosures made in prior arts D1 to D4.

5. As regards the conclusion that no details were provided by the appellant for the advantages or surprising effects/unexpected effects of the claimed invention in comparison to the prior arts, learned senior counsel referred to the affidavit of Seong, Seung-Yong (the inventor) to submit that the GPCR19 agonist has a very short half-life, if administered orally in the form of an injection, whereas, if administered topically, it exhibits advanced

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therapeutic effect. For these reasons, learned senior counsel submits that the matter requires reconsideration.

6. In response to these contentions, learned counsel for the respondent submitted that the claimed invention would be obvious to a person skilled in the art on the basis of the cited prior arts. By referring to a translated copy of prior art D1, learned counsel submitted that the preferred GPCR19 agonist, as per D1, is sodium taurodeoxycholate. In support of this contention, he refers specifically to paragraph [0042]. By referring to claim 25 of prior art D1, he submits that the composition disclosed therein is intended to treat a range of inflammatory conditions, including atopic dermatitis. By referring to paragraph [0038] of D1, he submits that it recites administration of the GPCR19 agonist through multiple modes, including transdermal administration. As regards prior art D2, by referring to claim 8 thereof, he points out that the monopoly claim therein is in respect of treating disorders mediated by GPBAR1 activity. As regards prior art D3, by referring to claims 15 & 21 thereof, he points out that the monopoly claim therein also relates to a method of treating an inflammatory disease, including through the topical route.

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7. Learned counsel referred to the principles pertaining to obviousness analysis, as formulated in *Windsurfing International Inc. v. Tabur Marine (GB) Ltd. [1985] RPC 59(Windsurfing),* and refined in *Pozzoli Spa v. BDMO SA, [2006] EWHC 1398 (Ch.)(Pozzoli)*, which were extracted with approval in *Indian Institute of Technology, Madras v. The Controller of Patents & Designs, 2024 : MHC : 2264; 2024-4-L.W. 505.* According to learned counsel, if the *Windsurfing* and *Pozzoli* tests are applied, the claimed invention would be obvious to a person skilled in the art.

8. By way of a brief rejoinder, learned senior counsel for the appellant submits that D1 is targeted at the treatment of sepsis, and this is clear on examining the complete specification thereof. As regards claim 25 of D1, he states that all the inflammatory diseases, including atopic dermatitis, are merely set out without providing any data with regard to the efficacy of the claimed method for treating atopic dermatitis. He also submitted that the claimed invention was granted patent in multiple jurisdictions, such as the United States of America, Japan and Europe. With

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specific reference to the EPO grant, he pointed out that the same prior arts were considered therein while granting the patent.

9. The complete specification of the claimed invention discloses that it relates to a pharmaceutical composition containing a G Protein-coupled Receptor19 (GPCR19) agonist, specifically sodium taurodeoxycholate (HY2191), as an active ingredient for preventing or treating allergic skin diseases. Thus, it is clear that the claimed invention is targeted solely and exclusively at the treatment of allergic skin diseases. Current claim 1, which is an independent claim, is as under:

> *"A form of external preparation containing a G protein-Coupled Receptor19 (GPCR19) agonist as an active ingredient for preventing or treating allergic skin diseases, wherein the G protein-Coupled Receptor19 (GPCR19) agonist is sodium taurodeoxycholate."*

10. The respondent raised objections *inter alia* with regard to lack of novelty and inventive step in the FER. In response to the FER, the appellant stated, in relevant part, as under, with regard to the difference between prior art D1 and the claimed invention:

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"The technical feature of D1 lies only in expanding bone marrow-derived immune regulatory cells and immune regulatory B cells by activating GPCR19 pathway in vivo or ex vivo. But it has no disclosure on the use of GPCR19 agonist for treating allergic dermatitis at all.

.. .. ..

Therefore, it can be derived from the disclosures of Dl only that the GPCR19 agonist can be a therapeutic agent for treating sepsis, in particular, H-MDSC produced as a result of treating a GPCR19 agonist can be a therapeutic agent for treating sepsis."

Indeed, the appellant specifically dealt with claim 25 of D1 as under:

"Based on the examples and experimental data disclosed in D1, it is so difficult to predict treating GPCR19-agonist can show the therapeutic effect for all the above exemplified diseases. The pathological mechanism of diseases is complex and thus the therapeutic effect and adverse effect can vary by the kind of disease. Thus, the clinical trial should be conducted to confirm the therapeutic effect of a candidate drug."

11. As regards prior arts D2 and D3, the appellant stated as under:

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"D2 relates to new GPBAR1 agonist compounds, in particular, D2 discloses that the new GPBAR1 agonist compounds, 4-(3-hydroxy-10, 13-dimethyl-hexa deca hydrocyclopenta[a]phenanthren-17-yl] pentanoic acid amides, can be used for the treatment of disorders (diseases) associated with inflammation, e.g. including (chronic) inflammatory disorders... (omitted).. hypotension... (omitted)..ischemic reperfusion injury, ..(omitted)... cancer and AIDS, reheumatoid arthritis, inflammatory bowel disease, systemic lupus erytomatosis, multiple sclerosis, psoriasis. (D2 [0083]-[0130]):

D3 discloses that the sodium taurodeoxycholate can be used for the ***treatment of sepsis****.*

The following was stated with reference to prior art D4:

"D4 discloses that the specific compound which is one of GPCR19 agonists also, chenodeoxycholic acid and ursodeoxycholic acid, can be used for the treatment of atopic dermatitis. "

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12. On examining the impugned order, the following conclusion has been recorded with regard to independent claim 1:

> *"The external preparation of claim 1 is not patentably distinct from the product disclosed in D1 and an intended use doesn't impart a patentable limitation to a claimed product. "*

While recording the above conclusion with regard to the claimed invention being obvious to PSITA from D1, the respondent did not discuss or record any findings with regard to the appellant's contention that D1 is targeted at sepsis and that no data was provided in D1 with regard to the efficacy of the methods described or disclosed therein in the treatment of atopic dermatitis. As would be evident from the extracts set out above, a similar contention was raised with regard to prior art D3. As regards prior art D4, it was stated in the reply to the FER and in the written submissions that D4 uses chenodeoxycholic acid or ursodeoxycholic acid and not sodium taurodeoxycholate. This aspect was also not discussed.

13. The impugned order also records as under:

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"The Applicant's agent's arguments in this regard are not tenable as they failed to establish that claimed external preparation is not obvious to a person skilled in the art in view of the cited disclosures in Dl to D4 when these documents clearly teaching or suggesting the active agent of the claimed product. It is well known practice and routine experimentation for a person skilled in the art for devising the specific chosen form with the known functional ingredient/s and hence external preparation claimed in amended claim 1 is obvious to a person skilled in the art vis-à-vis disclosures of DI to D4. .... There are no details provided for the advantages or surprising effects/unexpected effects by this selected form of the external preparation vis-à-vis prior art known formulations or forms. The applicant's agent have not demonstrated any unexpected/surprising effect of the claimed external preparation over the known formulations/preparations and in the absence of that the claimed external preparation is obvious to a person skilled in the art in view of disclosures/teachings in cited document D1 combined with D2, D3 and D4. Therefore, it is concluded that the external preparation claimed in amended claim 1 is obvious to a person skilled in the art

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vis-à-vis disclosures of D1 to D4."

14. The appellant had placed on record the affidavit of Seong, Seung-Yong, PhD from Seoul National University. He had opined with regard to the unexpected therapeutic effect of (HY2191) when administered transdermally for the treatment of atopic dermatitis in contradistinction to the administration thereof orally or by injection. This aspect also does not appear to have been considered.

15. Learned counsel for the respondent pointed out that the transdermal administration of the GPCR19 agonist is recited in paragraph [0038] of D1. This aspect would have to be considered upon remand in the context of the contention of learned senior counsel for the appellant that D1 is targeted at the treatment of sepsis and not atopic dermatitis.

16. Before concluding, one final aspect should be noticed. The claimed invention was granted patent in multiple jurisdictions, including the United States of America, Japan and Europe. It appears from the EPO grant

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that all four prior arts cited by the respondent were considered by the EPO. Undoubtedly, the determination by the EPO is not binding on the Patent Office. Nonetheless, in view of the prior arts being considered by the EPO, the grant by the EPO and the other jurisdictions should have been taken into consideration as one of the factors in the decision-making process.

17. For reasons set out above, impugned order dated 22.04.2020 is set aside and the matter is remanded for reconsideration on the following terms:

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

(ii) After providing a reasonable opportunity to the appellant, a reasoned order shall be issued within four months from the date of receipt of a copy of this order.

(iii) For the avoidance of doubt, it is made clear that no opinion has been expressed herein on the merits of the patent application.

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18. Therefore, (T)CMA(PT) No.46 of 2023 stands disposed of on the above terms, without any order as to costs.

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Index : Yes / No
Internet : Yes / No
Neutral Citation: Yes / No

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To

Assistant Controller of Patents and Designs,
Government of India, Patent Office,
Intellectual Property Rights Building,
GST Road, Guindy, Chennai - 600 032.

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