



2026:DHC:2564



* **IN THE HIGH COURT OF DELHI AT NEW DELHI**
% Judgment delivered on: 23.03.2026
+ C.A.(COMM.IPD-PAT) 23/2022
DAEWOONG PHARMACEUTICAL CO. LTD. & ANR.....Appellants
versus
CONTROLLER GENERAL OF PATENTS DESIGNS AND
TRADEMARKSRespondent

Advocates who appeared in this case:

For the Appellants : Ms. Aditi Subramaniam and Mr. Sanuj Das,
Advocates.
For the Respondents : Ms. Rukhmini Bobde, CGSC with Mr. Jatin
Dhamija, Mr. Vinayak Aren, Ms. Aishwarya
Nigam, Advocates for Controller.

CORAM:
HON'BLE MR. JUSTICE TUSHAR RAO GEDELA

J U D G M E N T

TUSHAR RAO GEDELA, J. (ORAL)

1. The present appeal has been filed under Section 117A of the Patents Act, 1970 (hereinafter referred to as "*the Act*") as amended by the Tribunals Reforms Act, 2021, challenging the order dated 04.01.2022 passed by the learned Controller of Patents under Section 15 of the Act, in the matter of Indian Patent Application No. 201817048074 (hereinafter referred to as "*subject application*"). The impugned order rejected the patent application on the ground of non-patentability under Section 3(d) of the Act.
2. The present application was filed on 19.12.2018 as a National Phase Application of PCT International Application No.PCT/KR2017/006271. The filing date of the PCT application is 15.06.2017.
3. First Examination Report (hereinafter referred to as "*FER*") was issued

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on 20.09.2019 wherein, the patent office had raised objections related to lack of inventive step under Section 2(1)(ja) of the Act and lack of patentability under Section 3(d) of the Act. Thereafter, the appellant on 16.03.2020, filed the reply to the FER along with amended claims. The respondent issued the hearing notice *vide* letter dated 27.08.2021 scheduling the hearing for 03.09.2021 which was duly attended by the appellant.

4. Additionally, three Division Applications were filed out of the subject application which are as follows:

- On 13.03.2020, Divisional Application No. 202018010806 was filed out of Indian Patent Application No. 201817048074 based on method claims 1 to 14 which was subsequently granted on 05.01.2022.
- On 13.03.2020, Divisional Application No. 202018010805 was filed out of Indian Patent Application No. 201817048074 based on method claim 15 which was subsequently granted on 14.03.2022.
- On 16.09.2021, Divisional Application No. 202118041844 was filed out of Indian Patent Application No. 201817048074 based on product claim 18 to 20 thereof which is under examination.

5. Thereafter, post-hearing written submissions were filed on 14.10.2021 and 18.10.2021 along with amended claim.

6. The present invention is titled as “*METHOD OF PRODUCING DIPHENYLMETHANE DERIVATIVE*” and relates to a method for producing diphenylmethane derivative. As per the complete specification (hereinafter referred to as “CS”) of the subject application, the claimed invention is an improved method for producing diphenylmethane derivative which acts as an inhibitor of a sodium-dependent glucose cotransporter (SGLT). The technical field described in the CS of the present application is reproduced as follows:



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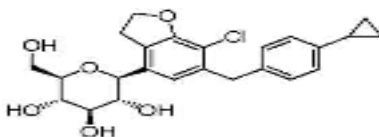
**“Technical Field**

The present invention relates to a method for producing a diphenylmethane derivative, and more particularly to an improved method for producing a diphenylmethane derivative which is useful as an inhibitor of a sodium-dependent glucose cotransporter (SGLT).”

7. The claim submitted by the appellant to the patent office with the post hearing written submissions on 14.10.2021 is reproduced as follows:

“We claim:

*1. A crystalline form of a compound of the following Formula c28:
[Formula c28]*



wherein the crystalline form has an X-ray diffraction (XRD) spectrum which includes peaks at diffraction angles (2θ) of $6.2^\circ \pm 0.2^\circ$, $7.2^\circ \pm 0.2^\circ$, $8.8^\circ \pm 0.2^\circ$, $17.6^\circ \pm 0.2^\circ$, $19.0^\circ \pm 0.2^\circ$, $22.5^\circ \pm 0.2^\circ$, and $25.1^\circ \pm 0.2^\circ$ in a case of being irradiated using a Cu-K α light source.”

8. The technical problem solved by the present invention is to provide an improved method for producing diphenylmethane derivative. The technical problem solved by the subject application is reproduced as follows:

“Detailed Description of Invention**Technical Problem**

Accordingly, an object of the present invention is to provide an improved method for producing a diphenylmethane derivative which is useful as an inhibitor of SGLT.”

9. The present appeal has been filed assailing the impugned order, which dismissed the subject application solely based on the aspect that the amended claim 1 of the subject application did not fulfil the criteria of the requirement of Section 3(d) of the Act. In so far as the objection under Section 2(1)(ja) of the Act about lack of inventive step is concerned, the learned Controller in para 7.1 has noted that “In view of the submission, presented data and

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amendments carried out by the applicant, the objection under Section 2(1)(ja) of the Act raised in hearing notice considered met.”

10. Thus, the only issue which arises in the present appeal is in respect of the rejection of the subject application on the ground that it does not fulfil the criteria in Section 3(d) of the Act.

11. The learned Controller, so far as the objection under Section 3(d) of the Act, is concerned, has noted as under:

*“Crystalline Form A also shows greater **dissolution rate** than the amorphous form disclosed in D1 and D2.*

Better dissolution profile leads to better therapeutic efficacy. Accordingly Form I has better therapeutic efficacy as a SGLT inhibitor compared to the amorphous forms. The Learned Controller is accordingly requested to waive the objection.

The submissions presented during the hearing and herein comply with the objections of the hearing notice. We respectfully submit that in the submission filed, all the objections raised by the Learned Controller have been met and all the requirements of the Indian Patent Act have been complied with. We, therefore, believe that the present application is in condition for grant and request the Learned Controller to issue a Letters Patent Document on the above-mentioned application.

As under the provisions of Section 15 of the Indian Patents Act, where the Controller is satisfied that the application or any specification or any other document filed in pursuance, thereof, does not comply with the requirements of this Act or of any rules made thereunder, the Controller may require the application, specification or the other documents, as the case may be, to be amended to his satisfaction before he proceeds with the application.

Therefore, in case, the Learned Controller is still not satisfied with any of the claim amendments or documents provided herewith, the Learned Controller is respectfully requested to provide the Applicants a further opportunity of being heard to meet the requirements and make any amendments required for placing this application in order for grant.

We will be happy to discuss the matter with the Learned Controller in the event the Learned Controller has any further issues.

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9. It is concluded that all the above discussed advantages presented by learned agent in hearing submission such as improvement in stability, Non-hygroscopicity, solubility, dissolution rate etc. considered carefully and found sufficient to meet the requirements of section 2(1)(ja) of the Act.

But the arguments and submission of learned agent was not found sufficient to cross the barrier of section 3(d) of the Act as the claimed compound of formula c28 was known in prior art D1 cited in FER and the drugs used in claim was well known for its pharmacological properties and now being presented as crystalline form-A with xrd data but applicant fail to provide any conclusive evidence to prove the enhancement in known therapeutic efficacy of the active drugs.

Though in the written submission learned agent presented several comparative data of the description and some additional data and also stressed on advantages achieved by making claimed crystalline form A such as "improvement in stability, Non-hygroscopicity, solubility, and dissolution rate" which are in my opinion are pharmacokinetic data/physical properties and do not amounts to therapeutic efficacy as required by the section 3(d) of the Act.

Therefore due to lack of evidential threshold applicant's agent failed to meet the requirements of section 3(d) of the Act and hence said objection still stands.

10. Having considered all the facts, submission and amendment made by the Applicant's Agent and in view of the above discussion, and observations, I conclude that the subject matter of amended claim 1 of the present application not fulfill the requirement of section 3(d) of the Patents Act 1970 (as amended). Under such circumstances, I hereby refuse the patent application number 201817048074 to proceed for grant of patent."

[Emphasis supplied]

12. It is apparent that when the subject application was being considered by the learned Controller, the data to show the efficacy of the subject application was not before the learned Controller. The impugned order states that submission of the appellant regarding showing the advantages of the present invention such as improvement in stability, Non-hygroscopicity, solubility, dissolution rate etc. were found sufficient to meet the requirements of Section 2(1)(ja) of the Act but failed to overcome the barrier of Section 3(d) of the

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Act. The impugned order states that the claimed compound of formula c28 was known in prior art D1 and its use was well known for its pharmacological properties.

13. The impugned order further states that the agent of the appellant has presented several comparative data as well as additional data to show the advantages like "*improvement in stability, Non-hygroscopicity, solubility, and dissolution rate*". However, the learned Controller opined that the submitted data shows the pharmacokinetic data/physical properties and failed to show the enhanced therapeutic efficacy as required by the Section 3(d) of the Act.

14. During the pendency of the present appeal, by way of the order dated 23.03.2023, this Court had permitted the appellant to file documents in the nature of an affidavit, containing the data, which was hereto before not filed or made available to the learned Controller.

15. The said documents were taken on record in exercise of the powers conferred upon this Court under Order XLI Rule 27 of the Code of Civil Procedure, 1908 (hereinafter referred to as '*CPC*').

16. This Court has considered the submissions of Ms. Rukhmini Bobde, learned CGSC appearing for the learned Controller.

17. Learned counsel appearing on behalf of the appellant submits that there are no specific precedents in terms of as to whether a matter of such nature, where the additional data is being furnished before the Court can be remanded back to the learned Controller for *de novo* reconsideration of the issue on the objection under Section 3(d) of the Act.

18. In the opinion of this Court, the issue in respect of the patentability under Section 3(d) of the Act was rejected purely on the fact that the evidential threshold was not met by the appellant as on the date of consideration of the subject application. The appellant has indeed filed an

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affidavit disclosing the requisite data, which has been permitted to be taken on record by this Court on 23.03.2023. It is to be noted that this Court in exercise of its appellate jurisdiction, is governed by Order XLI of CPC and in exercise of the procedure prescribed in Rule 27 thereof, has already taken such affidavit on record. Further, from a conjoint reading of Rules 28 and 29 of Order XLI of CPC, it appears that the additional evidence which has been permitted to be taken on record by the Court can be gone into, either by itself or by referring the said evidence to a sub-ordinate Court to take such evidence and re-transfer the same to the Appellate Court for a final decision.

19. In the present case, the additional data has been furnished before this Court under Order XLI Rule 27 of CPC and has to be, at the first instance, considered by the learned Controller to reach a satisfactory conclusion on the objection under Section 3(d) of the Act on patentability. Of course, the learned Controller would be at liberty to examine the issue from all respects. It is trite that ordinarily, the Appellate Court can deal with the additional evidence brought on record, albeit, after affording an opportunity to the other side for rebuttal evidence, if required, or remand the matter limited to recording evidence on the additional evidence and recall the matter for final disposal after evidence has been recorded. In the present case, the determination of the objection under Section 3(d) of the Act could not be reached conclusively by the learned Controller on account of the absence of the additional data.

20. During the arguments, the counsel for the appellant has submitted that during the period of proceedings of the present application before the patent office, Covid-19 pandemic was at its peak in India as well as in Korea and therefore, they were unable to make available the additional data in time. The said reason seems to be reasonable and sufficient, having regard to the critical

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situation the entire world was facing during Covid-19 pandemic, for not being able to produce the additional data. Therefore, this Court is of the view that in the interests of justice and keeping in view the exceptional circumstances in the present case, the appellant should be given the opportunity to submit the data that it failed to make available due to Covid-19 pandemic which the whole world was reeling under.

21. However, since the learned Controller had no data, which is made available by way of the said affidavit now, the learned Controller was constrained to reject the application since it did not meet the evidential threshold as required under Section 3(d) of the Act. Therefore, it appears, it would be apposite to require the learned Controller to consider the affidavit and the additional data mentioned therein to determine the efficacy of the present invention.

22. This is more so, for the reason that so far as the inventive step is concerned under Section 2(1)(ja) of the Act, the learned Controller has already considered the submissions made by the appellant and stated that the present invention has inventive step and removed the objection of lack of inventive step under Section 2(1)(ja) of the Act, in the impugned order.

23. In that view of the matter, it is deemed appropriate, while maintaining the conclusion reached in respect of the objection under Section 2(1)(ja) of the Act and considering the submissions made by the appellant, to direct the learned Controller to reconsider the objection under Section 3(d) of the Act in terms of the additional data now been provided under the affidavit dated 01.04.2022 and placed on record by the appellant.

24. This Court also notes that if the appellant is given an opportunity to submit the additional data, there is no bar on the learned Controller to consider the said data. In *University of Miami vs. The Controller of Patent*,

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OA/33/2015/PT/KO, the Intellectual Property Appellate Board (IPAB) has noted that submission of additional documents/ data/evidence to overcome the objection raised by the learned Controller is allowed under the Patent Law. The relevant paragraph is reproduced hereunder:

“35.The claims are novel and also inventive in view of the cited documents and completely supported by the specification as originally filed. Filing of additional documents, data and evidence in support of the invention, to overcome the objection raised and to attack a specific objection is something which is allowed under the Patent Law of not only India but also other foreign jurisdictions. Nothing has been discussed in the impugned order. We have not understood, how the respondent has taken the contrary view of the same invention which has been recognized in other countries of the world. The respondent is bound give valid reason if contrary is taken. The said reason are missing. The reason given in the impugned order contrary to law.”

25. While reconsidering the limited issue as determined above, the learned Controller shall afford an opportunity to the agent of the appellant to submit the affidavit of additional data and make the requisite submissions in that regard. The learned Controller shall issue a hearing notice, as per rules, to the appellant or its agent.

26. The present appeal is disposed of requesting the learned Controller to reconsider the aforesaid issue in a time bound manner, preferably within next four months from date of receipt of this order.

27. The learned Controller shall decide the application independently, without being influenced by the observations made in the present order, as it is decided without going into the merits of the matter.

28. Since this Court has already passed an order allowing the appeal and directing reconsideration on objection under Section 3(d) of the Act, the status of the subject application be reflected as pending rather than refused.

29. The necessary corrections may be carried out within seven days from the date of receipt of this order.

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30. The appeal is disposed of.

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