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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

\+ C.A.(COMM.IPD-PAT) 381/2022

BAXALTA INCORPORATED ..... Appellant

Through: Mr. Ankush Verma, Mr. Debashish Banerjee, Ms. Vaishali Joshi, Mr. Pankaj Soni, Mr. Vineet Rohilla, Mr. Rohit Rangi and Mr. Tanveer Malhotra, Advocates.

versus

THE CONTROLLER OF PATENTS ..... Respondent

Through: Ms. Pratima N. Lakra, CGSC with Ms. Vrinda Baheti and Ms. Kashish G. Baweja, Advocates.

CORAM:
HON'BLE MR. JUSTICE SANJEEV NARULA

O R D E R

% 15.03.2024

I.A. 2595/2024 *(for submitting an auxiliary claim set)*

1. The present appeal impugns order dated 31st July, 2019, passed by Assistant Controllers of Patents and Design, whereby Appellants' application bearing No. 756/DELNP/2011 titled "FACTOR VIII POLYMER CONJUGATES", (hereinafter '***the subject patent***') has been refused under Section 15 of the Patent Acts, 1970 (hereinafter '***the Act***'), on the ground of lack of novelty and inventive steps under Sections 2(1)(j) and 2(1)(Ja) of the Act respectively.

2. The patent application comprised of both product as well as method claims. The Impugned order while dealing with the application, delves only

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into the product claims which is discernible from the operative part of the impugned order which reads as under:

> *"The instant product and its preparation process must establish novelty/ inventive step independent of each other. Irrespective of whether the product in a claim is defined as obtainable, obtained, directly obtained, or by equivalent wording for a product-by-process claim, the claim is still directed to the product per se and has the absolute protection upon the product per se as a scope. If a given product or substance or compound is still substantially the same as the known forms in the prior art, it cannot be rendered novel nor inventive by the simple fact that it has been obtained by a new and inventive process, as long as no qualitative difference has been demonstrated and disclosed. The product claimed here in the instant application claim-5(A modified Factor VIII produced by the method) and claim 6(A proteinaceous construct) are not characterized by their structural features and hence cannot be distinguishable from the cited prior art. In the absence of that the claimed product claim 5(A modified Factor VIII produced by the method) and claim 6(A proteinaceous construct) may be presumed as same as that of prior art product. This product claimed in claim 5(A modified Factor VIII produced by the method) and claim 6 (A proteinaceous construct) here has failed to establish novelty or inventive step on their own compared to cited prior art.*
> *Order:*
> *In view of the above, the requirement of objection D of hearing notice is not met and hence, I refuse the instant patent application 756/DELNP/2011 under section 15 of the Act."*

3. However, at this stage, the Appellant has filed the instant application, seeking leave of the Court, to submit an auxiliary claim set as an additional document. Through this application, Appellant seeks to restrict the scope of claims presently on record to only "method claims" in respect of conjugating PEG, PSA or dextran to an oxidized carbohydrate moiety of Factor VIII. Counsel for Appellant/Applicant contends that such restriction in the scope of claims is permissible under Section 59(1) of the Act by placing reliance on the judgment of this Court in ***Nippon A&L Inc. v. The Controller of Patents***[1] *and* ***Societe Des Produits Nestle SA v. The Controller of Patents***

[1] (2022:DHC:2434)

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and Design & Anr. [2]

4. On the aforenoted application, the Controller of Patents has no objection and accordingly the same is allowed and the auxiliary claim set annexed with the application is taken on record.

5. The application is disposed of.

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6. In light of the above, it would be now appropriate that the Respondent would now look into the auxiliary claim set claim for the purpose of taking a final view regarding the patentability of the invention.

7. Accordingly, the present petition appeal is disposed of with the following directions:

i) Impugned order dated 31st July, 2019 is set aside and the matter is remanded to the Respondents for de novo consideration.

ii) The Appellant shall file the auxiliary claim set also with the Respondent within one week from today.

(iii) The patent application for the subject patent is restored to its original number.

(iv) Prior to deciding the matter afresh, Appellant shall be granted a hearing, and the notice of such hearing must clearly delineate the objection(s), if any.

(v) After completion of hearing, the decision thereon shall be rendered within a period of four months from the date of conclusion of hearing.

[2] (2023/DHC/000774).

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(vi) The Respondent shall decide the application uninfluenced by any observations made in the impugned order and all rights and contentions of the parties are left open.

(vii) While taking a decision on the subject patent application, the Respondent shall also take into consideration, the reply dated 31st January 2024 filed by them before the Court, wherein they have specifically stated as follows:

> *"Decision of refusal is for objected product claims 5-6. The decision is with reference to claims with respect to novelty and inventive step. The method claims 1-4 were not objected to due to the data in the affidavit below (provided by Professor Pasut, Prof Massimo Morbidelli and Dr. Samuel Zalipsky).*
>
> *Subject matter of claims 1-4 are related to the process which is novel and inventive but the claims 5-6 are product claims obtained by process claim 1-4.*
>
> *Product claims could not be considered as novel and inventive only because they are obtained from the Novel and inventive process, in spite, the product claims 5-6 are required to fulfill the novelty and inventive step requirement as per section 2(1)(j) separately".*

8. With the above directions, the appeal stands disposed.

SANJEEV NARULA, J

MARCH 15, 2024
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