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IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: 12.10.2023

CORAM:

THE HON'BLE MR. **JUSTICE SENTHILKUMAR RAMAMOORTHY**

(T) CMA (PT) No.22 of 2023
(OA/13/2021/PT/CHN)

STARPHARMA PTY LTD
of Baker Building 75 Commercial Road,
Melbourne Victoria 3004 Australia
Through its Authorized Representative ... Appellant

Vs.

The Assistant Controller of Patents and Designs
Bouddhik Sampada Bhawan
CP-2, Sector-V, Salt Lake City,
Kolkata - 700091 . ... Respondent

PRAYER : This Civil Miscellaneous Appeal filed under Section 117-A of the Patents Act, 1970, prays (i) allow the present Appeal and set aside/quash the impugned order dated September 11, 2020 passed by the Respondent in Indian Patent Application No. 10044/CHENP/2013; and (ii) allow said Indian Patent Application No. 10044/CHENP/2013 and direct grant of patent in respect thereof.

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For Appellant : Mr. Shatadal Ghosh
Mr.Abhishek Jan
Mr.Muthuselvam for
M/s. K and S Partners

For Respondent : Mr.Rajesh Vivekanandan,
Deputy Solicitor General

JUDGMENT

The appellant assails an order dated 11.09.2020 by which Indian Patent Application No.10044/CHENP/2013 was rejected. The appellant had filed an application for grant of patent in respect of an invention entitled "METHOD OF TREATMENT OR PROPHYLAXIS OF BACTERIAL VAGINOSIS". The said application was the national phase filing derived from the original application under the Patent Cooperation Treaty.

2. The appellant filed 38 claims along with the application [the original claims]. The said claims were in respect of a Method of treatment or prophylaxis of bacterial vaginosis, including by administration of a gel formulation. On 15.05.2015, the appellant requested for permission to amend its claims and submitted amended claims. Such amended claims were in respect of a gel formulation which inhibits bacterial vaginosis. By the impugned

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order, the amended claims were rejected as not allowable under Sections 57 and 59 of the Patents Act, 1970 (the Patents Act). The present appeal was filed in the said facts and circumstances.

3. Learned counsel for the appellant invited my attention to the original claims. With particular reference to original claims 1, 5 and 10, learned counsel contended that the amended claims are within the scope of these original claims. In order to substantiate his contention, learned counsel also referred to the complete specifications. By inviting my attention to lines 20 to 29 of the complete specification [Page 62 of the appeal paper book], learned counsel submitted that the gel formulation is referred to therein. Learned counsel further referred to page 76 of the appeal paper book wherein the structure of an exemplary dendrimer is set out.

4. Thereafter, learned counsel placed for consideration the amended claims. With respect to claim 1 of the amended

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claims, learned counsel pointed out that the structure of dendrimer set out at page 76 of the appeal paper book and that set out at page 149 of the appeal paper book is identical.

5. Since the amended claims fall within the scope of the original claims and the complete specification, learned counsel submitted that the rejection of the amended claims is untenable. In support of this submission, learned counsel placed for consideration the judgment of the Delhi High Court in *Allergan Inc. v. The Controller of Patents, 2023/DHC/000515*. Learned counsel submitted that the original claims in the said judgment were method claims pertaining to the treatment of an ocular condition. In view of Section 3(i) of the Patents Act, the said method claims were modified into device claims. In that factual context, learned counsel pointed out that the Delhi High Court concluded that the request for amendment should be accepted as long as the amended claims fall within the scope of the original claims read with disclosures made in the complete specification.

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6. In response to these contention, Mr.Rajesh Vivekanandan, learned Deputy Solicitor General, submitted that the impugned order does not call for interference. He further submitted that the claims have not been considered on merits as on date. Consequently, he submits that any remand should be made without expressing any opinion on the merits of the application.

7. Claims 1, 5 and 10 of the original claims are set out below:

> *"1. A method of treatment or prophylaxis of bacterial vaginosis in a subject, said method comprising administering to the subject an effective amount of a macromolecule comprising a polylysine, polyamidoamine, poly(etherhydroxylamine) or poly(propyleneimine) dendrimer of 1 to 5 generations and one or more sulfonic acid-containing moieties attached to one or more surface amino groups of the outermost generation of the dendrimer, wherein said effective amount is 40 mg to 100*

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mg of macromolecule per day.

5. A method according to any one of claims 1 to 4 wherein the macromolecule is administered in a gel formulation.

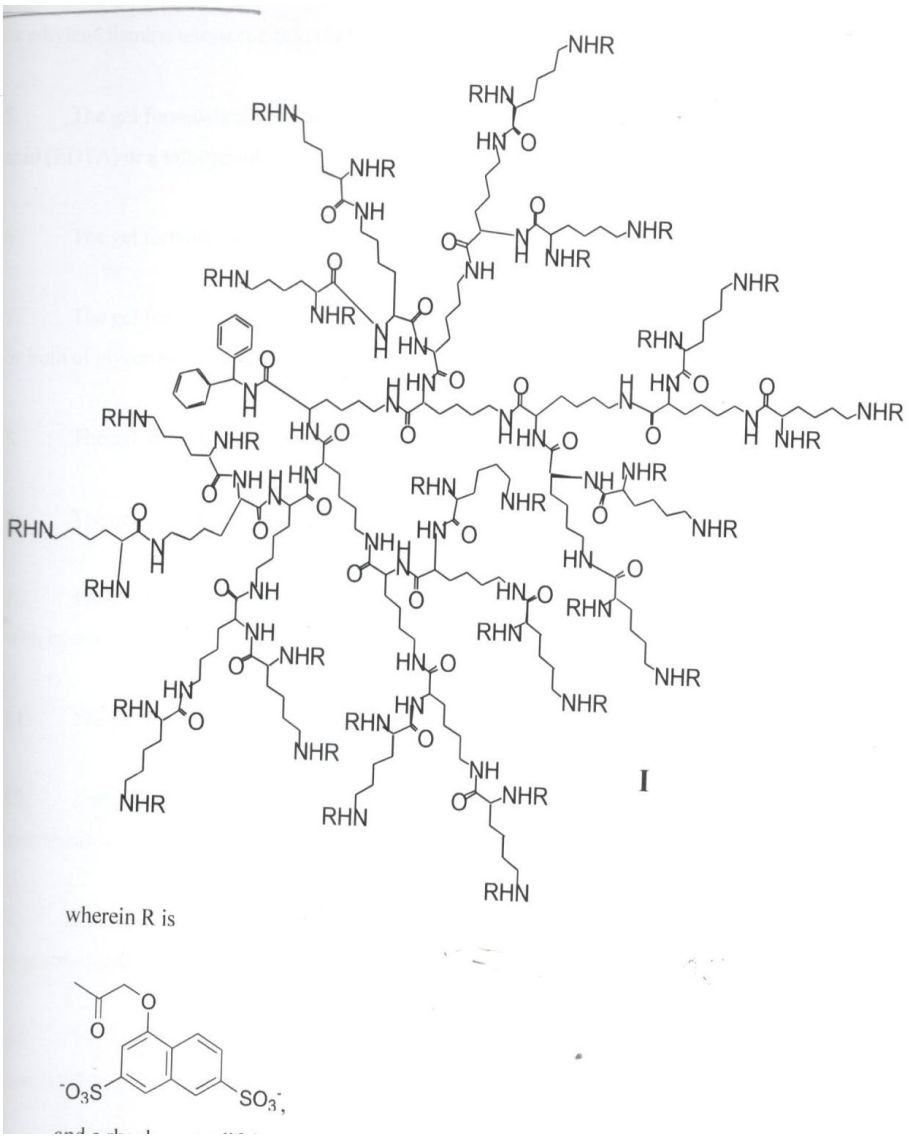
10. A method according to any one of claims 6 to 9 wherein the macromolecule is administered in gel formulation."

8. Claim 1 of the amended claim is as under:

"1. A gel formulation inhibitory against one or more Gardnerella vaginalis, Prevotella bivia and B. ovatus comprising a macromolecule or a pharmaceutically acceptable salt thereof comprising a dendrimer with the following structure

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and a rheology modifying agent which is Carbopol polymer in an amount of 2-10%, a chelating agent in an amount of 0.005% to 1%, a preservative selected from methyl paraben and propyl paraben, and having a pH between 4.5 and 5.5."

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9. Lines 20 to 29 of the complete specifications under the heading "Description of the invention" are as under:

> *20. In a particular embodiment, the macromolecule is formulated as a gel, especially a gel formulated with a pH between 4.5 and 5.5, especially about pH 5. Advantageously, this formulation may assist in reducing vaginal pH to between 4 and 5 or maintaining vaginal pH between 4 and 5. In some embodiments, the gel formulation of macromolecule comprises a rheology modifying agent, especially a Carbopol® polymer such as Carbopol® 971P. The rheology modifier may be present in an amount of 2-10%, especially about 5%. The gel formulation of macromolecule may also include a chelating agent, such as a polyaminocarboxylic acid. A particularly useful chelating agent is ethylenediamine tetraacetic acid (EDTA) and its salts. Suitable amounts of chelating agent are in the range of 0.001% to 2%, especially 0.005% to 1%.*

10. When the amended claims are compared with the original claims set out above in the light of the disclosures and descriptions contained in the complete specification, the request for amendments should not have been rejected. Therefore, the impugned order calls for interference.

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11. For reasons set out above, the impugned order dated 11.09.2020 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 the re-consideration.

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

(iii) No opinion is being expressed on the merits of the patent application.

(iii) (T)CMA(PT) No.22 of 2023 is disposed of on the above terms. 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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SENTHILKUMAR RAMAMOORTHY J.

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