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IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: **13.02.2025**

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THE HONOURABLE **MR.JUSTICE SENTHILKUMAR RAMAMOORTHY**

**CMA(PT)/34/2024**
**and C.M.P.No.16244 of 2024**

The Trustees of Columbia University
In the City of New York
Address for service in India
HASAN AND SINGH,
No.04, Sree Nilayam, Plot No.12, Camelot Layout,
Kondapur, Hyderabad-500 084. ... Appellant

-vs-

The Assistant Controller of Patents and Designs,
Patent Office Branch,
Intellectual Property office Building,
G.S.T.Road, Guindy, Chennai – 600 032. ... Respondent

**PRAYER**: Civil Miscellaneous Appeal (Patents) is filed under Section 117A of the Patents Act, 1970, pleased to set aside the impugned order dated 28.02.2024 issued by the respondent.

For Appellant : Mr. R.Sathish Kumar

For Respondent : Mr.S.Janarthanam,
Senior Standing Counsel

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**JUDGMENT**

This appeal is directed against the order dated 28.02.2024 rejecting the amended claims of the appellant as being impermissible under Section 59 of the Patents Act, 1970 (the Patents Act) and, consequently, rejecting Patent Application No.202047004043.

2. The appellant applied for a patent under the above mentioned application for a claimed invention titled "METHODS AND COMPOSITIONS FOR TREATMENT OF AMYLOID DEPOSITION DISEASES". Such application was the national phase application derived from the PCT application. As required by law, the application was originally filed on identical terms as the corresponding PCT application. Upon request, First Examination Report dated 01.06.2022 (the FER) was issued, wherein multiple objections were raised, including by citing Section 3(i) of the Patents Act. By response dated 24.02.2023, the appellant submitted amended claims 1 to 19 by also indicating the foundation for such claims in the complete specification. The impugned order was issued thereafter by holding that these amended claims do not fall within the scope of Section 59 of the Patents Act.



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3. Learned counsel for the appellant invited my attention to the complete specification. By referring to paragraph [0011], he submitted that the summary of the invention describes such invention as compositions and methods for treating amyloid deposition diseases. Further, by referring to paragraph [00115] of the complete specification, he pointed out that pharmaceutical compositions are recited therein and that specific reference is made to the ingredients thereof, including specific types of antibodies and antibody fragments. Therefore, learned counsel contends that the amended claims fall wholly within the scope of the complete specification. By relying on the judgment of the Delhi High Court in *Allergan Inc. v. The Controller of Patents (Allergan), 2023 SCC OnLine Del 295* and, in particular, paragraphs 23 and 24 thereof, he contends that the impugned order calls for interference. He also points out that the judgment of the Delhi High Court was cited before the respondent, but the respondent erroneously concluded that amended claims 1 to 19 lack corresponding explicit disclosure in the originally filed specification.

4. In response to these contentions, Mr.Janarthanam submits that the claimed invention was in respect of methods of treatment of amyloid



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deposition diseases. In the guise of amending the claims, he submits that the appellant should not be permitted to alter the fundamental nature of the invention. In support of his contention, he relies upon the judgment of the Delhi High Court in *Nippon A&L Inc. v. The Controller of Patents, 2022: DHC:2434 (Nippon A&L Inc.)*, particularly paragraphs 40 and 41 thereof. In effect, his contention is that an amendment application should be rejected unless it satisfies all the requirements set out in paragraph 40 thereof.

5. The claimed invention of the appellant is titled "METHODS AND COMPOSITIONS FOR TREATMENT OF AMYLOID DEPOSITION DISEASES". Paragraph [0011] thereof is as under:

> *"[0011] Described herein are compositions and methods for treating amyloid deposition diseases, specifically primary (AL) amyloidosis. The disclosed compositions and methods employ humanized or chimeric antibodies or fragments thereof that specifically bind to amyloid fibrils (e.g. Amyloid light chain fibrils) to target the fibrils for clearance by the immune system."*

6. The method of production of a chimeric antibody, which can be



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used in the compositions, is set out at paragraph [0014] of the complete specification, which is as under:

> *" A chimeric antibody useful in the sub methods and pharmaceutical compositions may be produced by co-transfection in mammalian cells of the vector constructs 11-1F4VK.pKN100 and 11-F4VH.pG1D200 or transfection in mammalian cells of the supervector construct pG1KD200-11-1F4. In some embodiments, the co-transfection of the vector construct pG1KD200-11-1F4 takes place in COS cells. The antibody produced is designated "chimeric 11-1F4 antibody"."*

Paragraphs [0097 to 00114] disclose the different kinds of antibodies which may be used in the composition.

7. Paragraphs 115 to 120 deal with pharmaceutical formulations and indicate that those pharmaceutical compositions include the disclosed humanized or chimeric 11-1F4 antibodies, humanized antibodies or antigen-binding antibody fragments and a pharmaceutically acceptable carrier or diluent.

8. The appellant's reply to the FER sets out amended claims 1 to 19 and the foundation or support for such claim in the complete specification.



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Such foundation is referenced with great specificity, including the relevant pages and lines of the complete specification.

9. In the impugned order, at paragraph 16, in relevant part, it is recorded as under:

> *"It is observed that the presently amended claims 1-19, which pertain to a specific pharmaceutical composition, lack corresponding explicit disclosure in the originally filed specification. While the initial specification mentions a pharmaceutical composition useful in treating human amyloid deposition disease, it fails to explicitly disclose the claimed composition."*

While recording this finding, the respondent has failed to deal with the paragraphs of the complete specification discussed above or the references set out in the appellant's reply to the FER.

10. In *Allergan*, the Delhi High Court examined the scope of Section 59 of the Patents Act and concluded that amended claims cannot be rejected



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solely because the claims were originally method claims and were subsequently sought to be converted into product claims. The test laid out therein was that the amendment should be permitted if it falls within the scope of disclosures made in the complete specification. In *Commonwealth Scientific and Industrial Research Organization and Another v. The Assistant Controller of Patents and Designs in(T)CMA(PT) No.14 of 2023*, I cited *Allergan* with approval and concluded that if the amended claims fall within the scope of the complete specification, the amendment is liable to be allowed in terms of Section 59. The judgment of the Delhi High Court in *Nippon A&L Inc.* emphasizes that all the conditions in Section 59 should be cumulatively fulfilled. While holding that all the conditions are required to be fulfilled, the respondent has failed to indicate as to which condition has not been fulfilled in the case at hand.

11. For reasons aforesaid, the order impugned herein is set aside and the matter is remanded for reconsideration. In order to preclude the possibility of pre-determination, an officer other than the officer who issued the impugned order shall undertake such reconsideration. After providing a reasonable opportunity to the appellant, including a personal hearing, a fresh



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order shall be issued within a period of ***four months*** from the date of receipt of a copy of this order. For the avoidance of doubt, it is made clear that no observation has been made herein on the merits of the application.

12. Therefore, CMA(PT)/35/2024 is disposed of on the above terms without any order as to costs. Consequently, C.M.P.No.16244 of 2024 is closed.

**13.02.2025**

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

To

The Assistant Controller of Patents and Designs,
Patent Office Branch,



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**SENTHILKUMAR RAMAMOORTHY,J**

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**and C.M.P.No.16244 of 2024**

**13.02.2025**



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