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IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: **20.03.2025**

CORAM

THE HONOURABLE **MR.JUSTICE SENTHILKUMAR RAMAMOORTHY**

CMA(PT)/64/2024

Akebia Therapeutics, INC.
Represented by its Power of Attorney
Mr.Raghavan Ravindran Nair
Cambridge, MA 02142, USA.
Nationality: USA ... Appellant

-vs-

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

PRAYER: Civil Miscellaneous Appeal (Patents) is filed under Section 117-A of the Patents Act, 1970, pleased to set aside the impugned order dated 26.11.2021 passed by the Assistant Controller of Patents & Designs rejecting the grant of patent and consequently direct grant of the patent in respect of the appellant's Application No.201647000423.

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For Appellant : Mr.P.V.Balasubramaniam, Senior Advocate
for M/s.BFS Legal

For Respondent : Mr.J.Madanagopal Rao, SPC

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JUDGMENT

This appeal is directed against the order dated 26.11.2021 rejecting Patent Application No.201647000423.

2. The appellant filed the above mentioned application as the national phase application derived from the original PCT application. The application pertains to an invention titled "composition and methods for treating anemia". As obligated by Section 138(4) of the Patents Act, 1970 (the Patents Act), the application mirrored the PCT application. By examination report dated 08.01.2019, the respondent raised objections *inter alia* on grounds of lack of novelty and inventive step and on the ground of non patentability under Section 3(i) and 3(d) of the Patents Act. The appellant replied to the FER on 07.10.2019. By second extended hearing

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notice dated 05.10.2021, the respondent maintained objections under Section 59, Section 2(i)(j) and Section 3(i) and 3(e) of the Patents Act. The objection under Section 59 was on the ground that amended claim 1 recites a pharmaceutical composition in contrast to the original claim 1, which pertained to a method of treating anaemia. On that basis, the objection was that it does not meet the requirements of Section 59. The appellant filed written submissions pursuant to the hearing. The order impugned herein was issued thereafter on 26.11.2021.

3. By inviting my attention to the impugned order, learned senior counsel for the appellant submitted that the claimed invention was eventually rejected solely on the ground that the amended claims do not fall within the scope of Section 59 of the Patents Act. By emphasizing the fact that the appellant was constrained to make the national phase filing by retaining the complete specification from the PCT application, learned counsel submitted that the amended claims fall substantially within the scope of the original claims and clearly within the scope of the complete specification. In particular, he referred to the table set out in the written

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submissions, wherein a comparison is made between original claim 1 and amended claim 1. By referring to decisions such as *Allergan Inc. v. The Controller of Patent, 2023 SCC OnLine Del 295 (Allergan)*, learned senior counsel submitted that re-consideration is necessary since the principles formulated in such decisions apply squarely to this case.

4. In response, Mr.J.Madanagopal Rao referred to the impugned order and pointed out that sub-section (1) of Section 59 only permits amendments by way of disclaimer, correction or explanation. He contends that the change from a claim relating to a method of treatment to a composition claim does not fall within the scope of Section 59.

5. In the written submissions of the appellant, the appellant has drawn a comparison between the original claim 1 and amended claim 1. The said table is as under:

Original Claim 1	**Amended Claim 1**	**Amendments and Restrictions**
A method for treating anemia,	A pharmaceutical composition comprising	The composition of claim 1 is still directed treating

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Original Claim 1	Amended Claim 1	Amendments and Restrictions
comprising administering to a patient having anemia an effective amount of a compound which is {[5-(3-chlorophenyl)-3-hydroxypyridine-2-carbonyl]amino} acetic acid, or a pharmaceutically acceptable salt, solvate or hydrate thereof wherein a daily dose comprises about 150mg, about 300mg, about 450 mg, about 600mg or about 750 mg of the compound	administering to a patient having anemia an effective amount of a compound which is {[5-(3-chlorophenyl)-3-hydroxypyridine-2-carbonyl]amino} acetic acid, Compound **1** or a pharmaceutically acceptable salt, solvate, or hydrate thereof, wherein the pharmaceutical composition comprises microcrystalline cellulose, sodium starch glycolate, and 150 mg to 750 mg of Compound **1**	anemia. The compound is the same. The range of compound defined in claim 1 is the same. Infact, the scope of claim 1 is restricted in that the claim now requires that composition ought to also comprise microcrystalline cellulose, sodium starch glycolate.

6. Section 59(1) of the Patents Act reads as under:

"(1) No amendment of an application for a patent or a complete specification or any document relating thereto shall be made except by way of disclaimer, correction or explanation, and no amendment thereof shall be allowed, except for the purpose of incorporation of actual fact, and no amendment of a complete specification shall be allowed, the effect of which

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would be that the specification as amended would claim or describe matter not in substance disclosed or shown in the specification before the amendment, or that any claim of the specification as amended would not fall wholly within the scope of a claim of the specification before the amendment."

7. The above provision was construed in multiple judgments of the Delhi High Court and this Court. In particular, while construing Section 59(1) in Allergan, the Delhi High Court concluded that amended claims cannot be rejected under Section 59 solely on the ground that the patent applicant modified a method claim to a product or composition claim. The text of Section 59(1) indicates that amendments should only be by way of disclaimer, correction or explanation. It also stipulates that the amendment should not have the effect of modifying the specification in such a manner that a claim is made or a matter is described, which in substance, was not disclosed in the original application; and that the amended claim should fall wholly within the scope of the original claim.

8. In the impugned order, it is recorded, in relevant part, as under:

"Applicant's submissions dtd. 18/11/2021 as above are

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NOT *persuasive. Pending Claim-1 reciting a* ***"Pharmaceutical composition*** *"actually defines the nature and proportion of the specific active ingredient namely {[5-(3-chlorophenyl)-3-hydroxypyridine-2-carbonyl]amino} acetic acid, or it's acceptable salt, solvate or hydrate with microcrystalline cellulose, sodium starch glycolate, whereas originally filed Claim-1 defines a* ***Method for treating anemia****, comprising administering to a patient having anemia an effective amount of a compound which is {[5-(3-chlorophenyl)-3-hydroxypyridine-2-carbonyl]amino} acetic acid or a pharmaceutically acceptable salt, solvate, or hydrate thereof. Originally filed Claim-1 read along with Description of present PCT National application, para [0036], para [0095], para [00101] clearly indicates that said Claim-1 is a method of treatment claim specifically defined by an administration step with a dosing regime.*

Further, Written submissions dtd. 18/11/2021 are NOT clear with the overall scope of the pending pharmaceutical composition Claim-1. Pending Claim-1 reading as ..."A pharmaceutical composition comprising administering to a patient having anemia an effective amount of a compound which is {[5-(3-chlorophenyl)-3-hydroxypyridine-2-carbonyl]amino} acetic acid...."; infact includes an expression - ***"comprising administering to a patient having***

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anemia...”. *It is to be noted that a pharmaceutical composition can only be defined by critical features like nature and proportion of it's ingredients and NOT by the treatment method like steps of administering it to the patients. Mere inclusion of said expression* ***“comprising administering to a patient having anemia...”*** *into the revised pharmaceutical composition claim-1 does not imply that said claim falls within the scope of Method of treatment claim-1 as originally filed.”*

9. In effect, the respondent has rejected the claim substantially, if not entirely, on the ground that the appellant has amended the claim from a claim for a method of treating anaemia to a claim for a pharmaceutical composition which may be used for treating anaemia. As held in Allergan and concurred by me in an earlier decision in *Commonwealth Scientific & Industrial Research Organization and Anr. v. The Assistant Controller of Patents & Designs 2023/MHC/4501*, the rejection substantially or solely on such ground is not tenable. On comparing the original claims with the amended claims, I find that the scope of the claims remains the same, but the nature of the claims have changed from method to composition claims. Since objections were also raised on grounds of lack of inventive step and

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with reference to Sections 3(i) and 3(e), and those aspects were not discussed or determined in the impugned order, a remand is necessary.

10. Therefore, impugned order dated 26.11.2021 is set aside and the matter is remanded for re-consideration 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 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) For the avoidance of doubt, it is made clear that no observation has been made on the merits of the patent application.

11. CMA(PT)/64/2024 is 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

To

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

SENTHILKUMAR RAMAMOORTHY,J

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