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

% Judgment delivered on: 24/11/2025

\+ **C.A.(COMM.IPD-PAT) 16/2024**

MEDILABO RFP INC .....Appellant

versus

THE CONTROLLER OF PATENTS .....Respondent

Advocates who appeared in this case

For the Appellant : Mr. Debashish Banerjee, Ms. Vaishali Joshi & Mr. Ankush Verma, Advocates.

For the Respondent : Mr. Nishant Gautam, CGSC with Mr. Prithviraj Dey, Advocate.

CORAM:
HON'BLE MR. JUSTICE TEJAS KARIA

JUDGMENT

INTRODUCTION

1. This Appeal has been filed under Section 117A of the Patents Act, 1970 ("**Act**") against the order ("**Impugned Order**") dated 21.12.2023, passed by the Assistant Controller of Patents and Designs ("**Respondent** / **Controller**"), refusing the Patent Application No. 202117034705 ("**Subject Application**") on the grounds under Section 3(i) of the Act.

FACTUAL MATRIX

2. The Impugned Order passed by the learned Controller, refusing the Subject Application titled '*PROPHYLACTIC OR THERAPEUTIC DRUG FOR NEURODEGENERATIVE DISEASES*' under Section 3(i) of the Act.

3. The subject matter of the invention relates to a medicine / drug composition / pharmaceutical formulation useful for the treatment of a neurodegenerative disease, as well as capable of reducing adverse side effects.

4. The originally filed Claims 3 to 13 disclose a prophylactic / therapeutic drug where rifampicin, as well as resveratrol, are administered as a dosage regimen depending on the body weight of the subject through trans nasal administration over a period of a specified time.

5. The Appellant filed a request for examination on 26.12.2022. The First Examination Report dated on 20.01.2023 ("**FER**") was issued by the Patent Office in connection with the Subject Application.

6. Thereafter, the Appellant filed the response to FER at the Patent Office within the extended deadline under Rule 24B(5) of the Patents Rules.

7. On 21.09.2023, the Respondent notified the Appellant that an official hearing had been appointed. Thereafter, the Appellant, on 06.10.2023, filed the written submissions along with amended claims.

8. The Respondent passed the Impugned Order on 21.12.2023, rejecting the Subject Application on the ground that the claims do not meet the criteria of patentability under Section 3(i) of the Act.

SUBMISSIONS ON BEHALF OF THE APPELLANT

9. The learned Counsel for the Appellant submitted that the learned Controller has wrongfully refused the Appellant's Subject Application under

Section 3(i) of the Act as the Respondent has failed to recognise that the invention claimed in Claim 1 of the Subject Application pertains to a composition and not a method of treatment. Further, this is evident from a plain reading of Claim 1 in light of the complete specification, as Claim 1 is a product claim and not a method claim. Hence, the refusal of Claim 1 under the objection of Section 3(i) of the Act is manifestly erroneous. According to the Appellant, Claim 2 of the invention under the Subject Application also relates to a '*kit*', a product that includes the medicinal agent of Claim 1. Claim 2 does not contain '*method of treatment*' steps.

10. The learned Counsel for the Appellant submitted that the Respondent's refusal of the Subject Application under Section 3(i) of the Act is patently incorrect, as reading of the claims with the complete specification clearly indicates that the claimed subject matter is a prophylactic / therapeutic drug composition.

11. The learned Counsel for the Appellant further submitted that this interpretation of the Respondent goes against the object of the Act, which recognizes product / formulation patents subject to the requirements of Section 3(e) of the Act being met. Section 3(i) of the Act is inapplicable to composition claims.

12. The learned Counsel for the Appellant relied upon the following decisions while making the above submissions:

a. ***Bayer Pharma Aktiengesellschaft v. The Controller of Patents and Design***, Neutral Citation: 2024:DHC:2395
b. ***Societe Des Produits Nestle SA v. Controller of Patents and Design and Another***, 2023 SCC OnLine Del 582; and
c. ***University of Miami v. The Controller of General Patent***,

13. Relying on ***Bayer*** (*supra*), the learned Counsel for the Appellant submitted that such reasoning is unsustainable, as the scope of an invention must be determined from the claims in accordance with Section 10(4)(c) of the Act and not based on the end-use or application of the invention.

14. The learned Counsel for the Appellant submitted that the Respondent has adjudicated the entire claim on the basis of the language of the preamble to the independent claim. On the other hand, as per well-established jurisprudence, the preamble of the claim must not be read as a limitation to the claim unless it recites essential structure or steps.

15. The learned Counsel for the Appellant further submitted that the Impugned Order is vitiated as the Respondent has refused the Subject Application on the ground that the claims dated 10.07.2023 mentioned that the product was for "*trans nasal administration*". According to the Appellant, these claims were not the final claims for adjudication, as post-hearing amended claims were filed, and the reference to the mode of administration was specifically deleted, intentionally, to clarify beyond doubt that the invention lies in the claimed composition and not the route of administration.

16. The learned Counsel for the Appellant submitted that it is a well-established jurisprudence that the preamble of the claim must not be read as a limitation to the claim unless it recites essential structure or steps, or if it is "*necessary to give life, meaning, and vitality*" to the claim. If the phrase "*for a neurodegenerative disease*" is removed from the preamble of the claim, the integrity and meaning of Claim 1 would remain unchanged, as the preamble merely extolls the benefits / purpose of the claimed invention and

therefore cannot be held to limit the scope of the claim. While making this submission the Appellant relied on the following decisions in:

a. ***Pitney Bowes, Inc. v. Hewlett-Packard Co***., 182 F.3d 1298, 1305 (Fed. Cir. 1999);

b. ***Catalina Mktg. Int'l v. Coolsavings.com, Inc.,*** 289 F.3d 801, 62 U.S.P.Q.2D (BNA) 1781 (Fed. Cir. May 8, 2002); and

c. ***The Manual of Patent Office Practice and Procedure***, 2019

17. Accordingly, the Impugned Order is liable to be set aside.

SUBMISSION ON BEHALF OF THE RESPONDENT

18. The learned Counsel for the Respondent submitted that even if the Appellant has deleted the claims related to dosage regimen and the disease condition in the written submission submitted after the hearing on 06.10.2023, the scope of the claim is not restricted only to the combination of the drugs *per se*, but their dosage regimen, which is a treatment method.

19. The learned Counsel for the Respondent submitted that the scope is determined by the claims, which must be interpreted in light of the description and examples of the specification of the invention. In the Subject Application, if one reads the claims and the description in toto, it will be evident that the application is related to a dosage regimen rather than a composition *per se*. The learned Counsel for the Respondent relied on the decision in ***Bayer*** (*supra*) while making this submission.

20. The learned Counsel for the Respondent submitted that all working examples in the specification of the Subject Application clearly highlight that the composition has been administered as a dosage regimen in an experimental model (mice), which is extrapolated to humans to treat dementia.

21. The learned Counsel for the Respondent further submitted that the claimed composition is not rejected because it is eventually used for curing a disease. It is rejected because the claimed composition is related to a dosage regimen that attracts Section 3(i) of the Act under the method of treatment.

22. The learned Counsel for the Respondent submitted that the Impugned Order states that the claims of the Subject Application are implicitly directed towards a method of treatment as the claimed invention does not have technical effect in its entirety of scope without administrating the combination of rifampicin and resveratrol in a dosage regimen for a period of administration to one month or more which amounts to a method of treatment not a combination product *per se*. Therefore, the Impugned Order should not be set aside.

ANALYSIS AND FINDINGS

23. The Subject Application, titled '*PROPHYLACTIC OR THERAPEUTIC DRUG FOR NEURODEGENERATIVE DISEASES*' relates to a medicine / drug composition / pharmaceutical formulation (product) that is useful for the prevention / treatment of a neurodegenerative disease.

24. The Independent Claim 1 of the Subject Application is reproduced hereunder:

> *"1. A prophylactic or therapeutic drug composition for a neurodegenerative disease,*
> *comprising rifampicin compound selected from the group consisting of* rifampicin*, a derivative of rifampicin and a salt of rifampicin or the*
> *derivative, and*
> *a resveratrol compound selected from the group consisting of* resveratrol *and a derivative of resveratrol,*
> *wherein the derivative of rifampicin is a derivative that has an aphthohydroquinone or naphthoquinone structure and is pharmaceutically acceptable, and the derivative of resveratrol is a*

derivative that is pharmaceutically acceptable and had a derivative group selected from the group consisting of N-phenylacetyl group 4,4 – dimethoxytrityl (DMT) group, a protein, a peptide, a sugar, a lipid, a nucleic acid, polystyrene, polyethylene, polyvinyl polyester, and an ester group; and

wherein resveratrol compound is contained in an amount of 1/500 to 500 parts by weight relative to 1 part by weight of the rifampicin compound."

25. The technical field of the invention, as stated in Paragraph No. [0001] of the complete specification, relates to a medicine useful for the treatment or prevention of a neurodegenerative disease. The reproduction of the technical effect is hereunder:

"The present invention relates to a medicine which is useful for the prevention or treatment of a neurodegenerative disease and has reduced side effects"

Emphasis supplied

26. The Paragraph No. [0012] of the complete specification states that the objective of the claimed invention is to provide a pharmaceutical formulation of rifampicin. Furthermore, Paragraph No. [0014] of the specification states that the second objective of the present invention is to provide a prophylactic or therapeutic drug. The paragraphs are reproduced hereunder:

"[0012] In these situations, the first objective of the present invention is to provide a pharmaceutical formulation of rifampicin which can have reduced adverse side effects and can be administered for a long period.

*** *** ***

[0014] therefore, the second objective of the present invention is to provide a ***prophylactic or therapeutic drug*** *for a neurodegenerative disease which can be administered for a long period and a brain function improving food which can be taken for a long period."*

27. The complete specification under the heading *'Advantages of the Invention'*, states that rifampicin is formulated in the form of a combination preparation with resveratrol that does not induce the obvious side effects associated with long-term consumption of rifampicin. The relevant paragraph is reproduced hereunder:

> *"According to the prophylactic or therapeutic drug of the present invention, when rifampicin is formulated in the form of a combination preparation with resveratrol, the adverse side-effects of rifampicin can be reduced and the long-term administration of rifampicin for a neurodegenerative disease becomes possible."*

28. According to the Appellant, the Respondent has wrongly misconstrued the scope of the original claims and the same is apparent from the following extract of the Respondent's observation in the Impugned Order:

> *"It can be seen from the originally filed claims that the combination is a dosage regimen given to a patient in need of treatment of neurodegenerative disease like dementia for a period of one month or longer".*

29. The learned Counsel for the Appellant submitted that a plain reading of Claim 1 in light of the complete specification, it is evident that Claim 1 is a product claim and not a method claim. The amended Claims filed in response to the FER are hereunder:

> *"WE CLAIM:*
> *1. A combination of a prophylactic or therapeutic drug for a neurodegenerative disease for transnasal administration and a container for nasal administration that packs the prophylactic or therapeutic drug therein,*
> *wherein the prophylactic or therapeutic drug comprises a combination of a rifampicin compound selected from the group consisting of rifampicin, a derivative of rifampicin and a salt of rifampicin or the derivative and a resveratrol compound selected from the group consisting of resveratrol and a derivative of*

resveratrol,

wherein the derivative of rifampicin is a derivative that has a naphthohydroquinone or naphthoquinone structure and is pharmaceutically acceptable, and the derivative of resveratrol is a derivative that is pharmaceutically acceptable and has a derivative group selected from the group consisting of N-phenylacetyl group, 4,4'-dimethoxytrityl (DMT) group, a protein, a peptide, a sugar, a lipid, a nucleic acid, polystyrene, polyethylene, polyvinyl, polyester, and an ester group.

2. The combination as claimed in claim 1, wherein the resveratrol compound is contained in an amount of 1/500 to 500 parts by weight relative to 1 part by weight of the rifampicin compound.

3. The combination as claimed in claim 1 or 2, wherein a dose of the rifampicin compound is 3.75 mg/kg·day or less.

4. The combination as claimed in any one of claims 1 to 3, wherein the dose of the rifampicin compound is 0.001 to 1.5 mg/kg·day.

5. The combination as claimed in any one of claims 1 to 4, wherein a dose of the resveratrol compound is 3.75 mg/kg·day or less.

6. The combination as claimed in any one of claims 1 to 5, wherein the dose of the resveratrol compound is 0.001 to 2.5 mg/kg·day.

7. The combination as claimed in any one of claims 1 to 6, wherein the prophylactic or therapeutic drug is used for prevention or treatment of dementia.

8. The combination as claimed in any one of claims 1 to 7, wherein the prophylactic or therapeutic drug is a combination drug of the rifampicin compound with the resveratrol compound.

9. The combination as claimed in any one of claims 1 to 7, wherein the prophylactic or therapeutic drug is a kit including a medicinal agent comprising the rifampicin compound and a medicinal agent comprising the resveratrol compound.

10. A combination of a prophylactic or therapeutic drug for a neurodegenerative disease for transnasal administration and a container for nasal administration that packs the prophylactic or therapeutic drug therein,

wherein the prophylactic or therapeutic drug comprises a resveratrol compound selected from the group consisting of resveratrol and a derivative of resveratrol, wherein a dose of the resveratrol compound is 0.28 mg/kg·day or less,

wherein the derivative of rifampicin is a derivative that has a naphthohydroquinone or naphthoquinone structure and is pharmaceutically acceptable, and the derivative of resveratrol is a derivative that is pharmaceutically acceptable and has a

derivative group selected from the group consisting of N-phenylacetyl group, 4,4'-dimethoxytrityl (DMT) group, a protein, a peptide, a sugar, a lipid, a nucleic acid, polystyrene, polyethylene, polyvinyl, polyester, and an ester group.

11. The combination as claimed in claim 10, wherein the prophylactic or therapeutic drug is used for prevention or treatment of dementia.

12. The combination as claimed in claim 10 or 11, wherein a period of administration is 1 month or longer.

13. A brain function improving food containing a resveratrol compound selected from the group consisting of resveratrol and a derivative of resveratrol, wherein an amount of intake of the resveratrol compound is 0.28 mg/kg·day or less,

wherein the derivative of rifampicin is a derivative that has a naphthohydroquinone or naphthoquinone structure and is pharmaceutically acceptable, and the derivative of resveratrol is a derivative that is pharmaceutically acceptable and has a derivative group selected from the group consisting of N-phenylacetyl group, 4,4'-dimethoxytrityl (DMT) group, a protein, a peptide, a sugar, a lipid, a nucleic acid, polystyrene, polyethylene, polyvinyl, polyester, and an ester group."

30. The hearing conducted on 31.09.2023 was attended by the Appellant, and thereafter the post-hearing written submissions were filed along with the amended claims. The amended filed after the hearing is hereunder:

"1. A prophylactic or therapeutic drug composition for a neurodegenerative disease, comprising rifampicin compound selected from the group consisting of rifampicin, a derivative of rifampicin and a salt of rifampicin or the derivative, and

a resveratrol compound selected from the group consisting of resveratrol and a derivative of resveratrol,

wherein the derivative of rifampicin is a derivative that has a naphthohydroquinone or naphthoquinone structure and is pharmaceutically acceptable, and the derivative of resveratrol is a derivative that is pharmaceutically acceptable and has a derivative group selected from the group consisting of N-phenylacetyl group, 4,4'-dimethoxytrityl (DMT) group, a protein, a peptide, a sugar, a lipid, a nucleic acid, polystyrene, polyethylene, polyvinyl, polyester, and an ester group; and

wherein resveratrol compound is contained in an amount of

1/500 to 500 parts by weight relative to 1 part by weight of the rifampicin compound.
2. The composition as claimed in claim 1, wherein the prophylactic or therapeutic drug is a kit including a medicinal agent comprising the rifampicin compound and a medicinal agent comprising the resveratrol compound."

31. According to the learned Counsel for the Appellant, the learned Controller has decided the Impugned Order considering the earlier filed claims and not the amended claims. As per the Appellant, these claims were not the final claims for adjudication, as post-hearing amended claims were filed, and the reference to the mode of administration was specifically deleted, intentionally, to clarify beyond doubt that the invention lies in the claimed composition and not the route of administration. In this regard, the Respondent submitted that even if the Appellant has deleted the claims related to dosage regimen and the disease condition in the post-hearing written submission, the scope of the claim is not restricted only to the combination of the drugs *per se*, but their dosage regimen, which is a treatment method.

32. The original Claim 1 and the proposed amended claims made subsequently are reproduced hereunder:

	Originally filed claims	**Amended claims filed with Response to FER.**	**Amended claims filed with post hearing written submissions.**
Claim No.	**Date of filing: 02.08.2021**	**Date of filing: 10.07.2023**	**Date of filing: 06.10.2023**
Claim 1	**A prophylactic or therapeutic drug** for a neurodegenerative disease, **comprising a**	**A combination of a prophylactic or therapeutic drug** for a neurodegenerative disease for transnasal administration and a	**A prophylactic or therapeutic drug** composition for a neurodegenerative disease,

	combination of a rifampicin compound selected from the group consisting of rifampicin, a derivative of rifampicin and a salt of rifampicin or the derivative **and a resveratrol compound** selected from the group consisting of resveratrol and a derivative of resveratrol.	container for nasal administration that packs the prophylactic or therapeutic drug therein, **wherein the prophylactic or therapeutic drug comprises a combination of a rifampicin compound** selected from the group consisting of rifampicin, a derivative of rifampicin and a salt of rifampicin or the derivative and a resveratrol compound selected from the group consisting of resveratrol **and a derivative of resveratrol,** wherein the derivative of rifampicin is a derivative that has a naphthohydroquinone or naphthoquinone structure and is pharmaceutically acceptable, and the derivative of resveratrol is a derivative that is pharmaceutically acceptable and has a derivative group selected from the group consisting of N-phenylacetyl group, 4,4'-dimethoxytrityl (DMT) group, a protein, a peptide, a sugar, a lipid, a nucleic acid, polystyrene,	**comprising rifampicin compound** selected from the group consisting of rifampicin, a derivative of rifampicin and a salt of rifampicin or the derivative, **and a resveratrol compound** selected from the group consisting of resveratrol and a derivative of resveratrol, wherein the derivative of rifampicin is a derivative that has a naphthohydroquinone or naphthoquinone structure and is pharmaceutically acceptable, and the derivative of resveratrol is a derivative that is pharmaceutically acceptable and has a derivative group selected from the group consisting of N-phenylacetyl group, 4,4'-dimethoxytrityl (DMT) group, a protein, a peptide, a sugar, a lipid, a nucleic acid, polystyrene, polyethylene,

		polyethylene, polyvinyl, polyester, and an ester group.	polyvinyl, polyester, and an ester group; and wherein resveratrol compound is contained in an amount of 1/500 to 500 parts by weight relative to 1 part by weight of the rifampicin compound.
Claim 2	The combination as claimed in claim 1, wherein the resveratrol compound is contained in an amount of 1/500 to 500 parts by weight relative to 1 part by weight of the rifampicin compound.	The combination as claimed in claim 1, wherein the resveratrol compound is contained in an amount of 1/500 to 500 parts by weight relative to 1 part by weight of the rifampicin compound.	The composition as claimed in claim 1, wherein the prophylactic or therapeutic drug is a kit including a medicinal agent comprising the rifampicin compound and a medicinal agent comprising the resveratrol compound.

33. It is important to note that the amended claims submitted after the hearing on 06.10.2023 have removed the mode of administration and combination reference form Claim 1.

34. The relevant paragraph of the Impugned Order which discusses the Claims is reproduced hereunder:

> *"The subject-matter of claims 1 & 2 are directed to a prophylactic or therapeutic drug composition for a neurodegenerative disease comprising resveratrol compound is contained in an amount of 1/500 to 500 parts by weight relative to 1 part by weight of the rifampicin compound. The claims 1 & 2 attract Section 3(i) of the act since the claims are implicitly directed to method of treatment of a disease.* ***It can be seen from the originally filed claims that the combination is a dosage regimen given to patient in need of***

> ***treatment of neurodegenerative disease like dementia for a period of one month or longer.*** *Although the claims are worded as a prophylactic or therapeutic drug combination****, the claims are intended to treat disease by nasally administering the combination in a specific range for a specific period.*** *Therefore, claims 1 & 2 are not allowed u/s 3(i) of the act."*

35. It is important to note that the mode of administration is deleted in the amended claims, while the learned Controller, while considering the original claims, has raised the arguments regarding the same.

36. The learned Counsel for the Appellant submitted that such reasoning is unsustainable, because the scope of an invention should be determined from the claims in accordance with Section 10(4)(c) of the Act and not based on the end-use / application of the invention in question. The learned Counsel for the Appellant has relied on the decision in ***Bayer*** (*supra*) in which the Court discussed the involvement of Section 10(4)(c) of the Act.

37. According to the Appellant, the complete specification clearly indicates that what is being claimed is a drug composition which has a "*prophylactic effect*".

38. The discussions in Paragraph Nos. 1, 12 and 14 of the complete specification indicate the formulation. The complete specification, under the heading '*Advantages of the Invention*', states that rifampicin, which is formulated in the form of a combination preparation with resveratrol. Additionally, it also states that the objective of the present invention is to provide a prophylactic or therapeutic drug. Therefore, the submission of the Respondent that the complete specification discusses the method of treatment, may not be acceptable.

39. The learned Controller in the Impugned Order has not provided the details as to how the claimed invention is a composition and not a method of

treatment. The learned Controller has not specified from the specification of the Subject Application that how the boundaries of the claim extend to the "*method of treatment*".

40. The Impugned Order also stated that the Subject Application cannot be accepted as the claims are intended to treat a disease by nasally administering the combination in a specific range for a specific period. However, the Appellant filed the amended claims, which purposefully deleted the reference to the mode of administration to clarify that the invention lies in the claimed composition and not the route of administration.

41. It is important to note that each pharmaceutical product has a specific mode of delivery like oral administration, sublingual and buccal (enteral), intravenous (parenteral) administration, subcutaneous, inhalation, transdermal, intramuscular administration, topical (dermal), intranasal, intrathecal / intraspinal, vaginal, rectal, ocular, etc. Further, under Section 10(4)(a) of the Act requires the operation or use and the method by which it (the invention) is to be performed. This is also discussed in ***Bayer*** (*supra*) that the claims must be clear, specific, and supported by the description of the patent application, and the working examples are intended to show that the invention is feasible and workable and how it can be carried out in practice.

42. In ***Societe Des Produits Nestle SA*** (*supra*), this Court held that:

> *"11. From the above, it is clear that Section 3(i) of the Act covers within its scope any process for the prophylactic treatment of human beings to render them free of disease or to increase their economic value. Therefore, any claim directed towards a process for the prophylaxis or prophylactic treatment are not patentable as per the Act.*

*** *** ***

> *16. In my view, the subject Claims are directed towards a composition, comprising DGLA, EPA and DHA. The contention of the appellant is that the said composition has been developed for the purpose of using the same in prophylactic treatment of allergic diseases. The appellant has also claimed that the said composition is useful in preventing or reducing the risk of development of allergies.*
>
> *** *** ***
>
> *18. After considering the text of Section 3(i) of the Act, the Manual and various judicial orders as also quasi-judicial orders, I conclude that the subject Patent Application is not directed towards a method or process for prophylactic treatment. Therefore, in my considered view, I do not find merit in the order of the Assistant Controller of Patents and Designs for refusal of grant of the Patent Application under Section 15 of the Act on the ground that the patent was barred under Section 3(i) of the Act."*

43. Similarly, under the Subject Application, the Independent Claim 1 is directed towards a composition, comprising of rifampicin compound selected from the group consisting of rifampicin, a derivative of rifampicin and a salt of rifampicin or the derivative, and resveratrol compound selected from the group consisting of resveratrol and a derivative of resveratrol. The composition is developed for the purpose of using it for prophylactic treatment or prevention of diseases.

44. In ***Bayer*** (*supra*), this Court observed that the recitations of the unit numbers of the components in the claim cannot render it ineligible under Section 3(i) of the Act. The relevant paragraphs are reproduced hereunder:

> *"8. Regarding the objection under Section 3(i) of the Act, the Court observes that the impugned order lacks a substantive basis for dismissing the subject application on this specific ground. Moreover, under Section 10(4)(c) of the Act, to consider the invention as articulated by the Applicant, it is imperative to interpret the scope of the claims. Claim 1, as delineated, clearly indicates to the Court that it pertains exclusively to a product rather than a*

process. ***Consequently, based on the claim's composition and its representation within the application, the Court determines that Section 3(i) of the Act, which pertains to methods of treatment, does not apply to the case at hand.***

9. Therefore, the Court finds merit in the contention of Mr. Banerjee that ***mere recitations of the unit numbers of the components in claim 1 cannot render it ineligible for patent protection under Section 3(i) of the Act****. Notably, in the said claim, as defined, there is neither any reference to a particular disease/ treatment, nor any reference regarding the modes/ manner of administration of the composition. In patent law, the claims of a patent define the boundaries of the patent protection. That is, they set out the legal limits of what the patent covers. The claims must be clear, specific, and supported by the description within the patent application. They are the most critical part of a patent application because they determine the extent of protection granted by the patent. Working examples, on the other hand, are provided in the subject application to demonstrate the practical implementation of the invention.* ***These examples are intended to show that the invention is feasible and workable and how it can be carried out in practice. They provide support and understanding for the claimed invention, showing that it is not just a theoretical concept, but has practical applicability****. Thus, while working examples are essential for demonstrating the feasibility and workability of an invention, they do not define the patent's scope. The scope is determined by the claims, which must be interpreted in light of the description and any examples provided. The reasoning for applying Section 3(i) of the Act to the subject application is therefore, misplaced. Mr Banerjee also relies on the decision of this Court in* ***Societe Des Produits Nestle SA v. The Controller of Patents and Design and Anr.****,2 where, in a similar situation, the Court referenced the Manual of Patent Office, Practice and Procedure, which gives the guidance for examination with respect to exclusion of medical, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment, and held that the claims in respect of the composition are patentable, and not hit by Section 3(i) of the Act. In the present case as well, the claim 1, as defined, in the opinion of the Court, does not render the application to be non-patentable."*

45. In ***University of Miami*** (*supra*), it is held that the expression treatment in the claim in question does not render it non-patentable under

Section 3(i) of the Act. There are many patents granted by the patent office in which the expression "*composition for the treatment*" has been used in the preamble of many claims. The relevant paragraph is reproduced hereunder:

> ***"17.*** *Claims do not relate to method of treatment and do not fall under Section 3(i) of the Act.*
> ***The claims of the present application are directed to a pharmaceutical composition which has been clearly defined with its components in the claim.*** *The claims are not directed to a method of treatment and therefore cannot fall under Section 3(i) of the Indian Patents Act.*
> ***The use of expression <u>treatment</u> in the claim does not render a claim falling under Section 3(i) of the Indian Patents Act.*** *The expression "composition for the treatment" has been used in the preamble of many claims which have been granted by the office of Respondent No. 1 and is only a way of defining the composition and in no way the claimed composition can be a method performed by a physician for treatment of disease. There are plenty of compositions claimed wherein the composition is defined in the preamble with the disease/condition that is being treated with the composition.*
> *The objection of Section 3(i) on composition claims therefore shows non-application of mind by the Respondent No. 1 and is a clear error apparent on face.*
> *Claims do not fall under Section 2(1)(j) of the Act."*

46. Additionally, in ***Chinese University of Hong Kong & Anr. vs Assistant Controller of Patents,*** Neutral Citation: 2023:MHC:4617, it is held that process for prophylactic treatment of human beings is excluded under Section 3(i) of the Act.

47. According to the Appellant, the learned Controller has adjudicated the entire claim based on the language of the preamble to the independent claim. In this regard, the Appellant submitted that it is a well-established jurisprudence that the preamble of the claim must not be read as a limitation to the claim unless it recites essential structure / steps, or if it is "*necessary to give life / meaning, and vitality*" to the claim. The learned Controller

should determine that whether the removal of the phrase "*for a neurodegenerative disease*" from the preamble would change the integrity and meaning of Claim 1.

48. As per the ***Manual*** (*supra*), a claim usually consists of three parts, which are Preamble, Transitional phrase, and Body. The Preamble is an introductory part that identifies the category of invention and sometimes the purpose of the invention. The relevant paragraph is reproduced hereunder:

> *"..n) A claim usually consists of three parts:*
> *- Preamble,*
> *- Transitional phrase; and*
> *- Body.*
> *o) An introductory phrase(Preamble) identifies the category of invention and sometimes the purpose (for example, a machine for waxing paper, and a composition for fertilizing soil)…"*

49. Therefore, the learned Controller must decide the patentability of the invention under the Subject Application in the light of the amended claims. The learned Controller has failed to specify in the complete specifications how the boundaries of the claim extend to the '*method of treatment*'.

50. The ***Manual*** (*supra*) indicates in Paragraph No. 09.03.05.08 exclude the following form patentability:

> *"Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products is not an invention.*
> *This provision excludes the following from patentability:*
>
> *a) Medicinal methods: for example a process of administering medicines orally, or through injectables, or topically or through a dermal patch.*
> *b) Surgical methods: for example a stitch-free incision for cataract removal.*
> *c) Curative methods: for example a method of cleaning plaque from teeth.*

d) *Prophylactic methods: for example a method of vaccination.*
e) *Diagnostic methods: Diagnosis is the identification of the nature of a medical illness, usually by investigating its history and symptoms and by applying tests. Determination of the general physical state of an individual (e.g. a fitness test) is considered to be diagnostic.*
f) *Therapeutic methods: The term _therapy' includes prevention as well as treatment or cure of disease. Therefore, the process relating to therapy may be considered as a method of treatment and as such not patentable.*
g) *Any method of treatment of animal to render them free of disease or to increase their economic value or that of their products. As for example, a method of treating sheep for increasing wool yield or a method of artificially inducing the body mass of poultry.*
h) *Further examples of subject matter excluded under this provision are: any operation on the body, which requires the skill and knowledge of a surgeon and includes treatments such as cosmetic treatment, the termination of pregnancy, castration, sterilization, artificial insemination, embryo transplants, treatments for experimental and research purposes and the removal of organs, skin or bone marrow from a living donor, any therapy or diagnosis practiced on the human or animal body and further includes methods of abortion, induction of labour, control of estrus or menstrual regulation.*
i) *Application of substances to the body for purely cosmetic purposes is not therapy.*
j) *Patent may however be obtained for surgical, therapeutic or diagnostic instrument or apparatus.*
k) *Also the manufacture of prostheses or artificial limbs and taking measurements thereof on the human body are patentable."*

51. In ***Societe Des Produits Nestle SA*** (*supra*) while referring to the ***Manual*** (*supra*) it is held that the claims in respect of the composition are patentable, and not hit by Section 3(i) of the Act.

52. Therefore, the Impugned Order lacks a substantive basis for dismissing the Subject Application under Section 3(i) of the Act. The learned Controller has ignored Section 10(4)(c) of the Act, which is imperative to interpret the scope of the claims.

53. Therefore, it can be stated that the ***Manual*** (*supra*) does not classify

the pharmaceutical composition with a therapeutic / curative effect under the ambit of Section 3(i) of the Act. Therefore, the learned Controller cannot determine the patentability of the Subject Application under Section 3(i) of the Act without discussing the amendment made in the claims and examining the same from the specifications.

54. The learned Counsel for the Appellant submitted that the learned Controller has not considered the other objection raised in the FER and hearing notice. The relevant paragraph of the Impugned Order is reproduced hereunder:

> *"The other objections in hearing noticed are not addressed as the present application is not patentable under Section 3(i) of the act. Consequently, the outstanding objections of the said hearing notice are maintained and claim 1 & 2 are not allowed. This application for grant of patent is refused under Section 15, The Patents Act, 1970."*

55. It is important to note that the hearing notice had other objections under Sections 2(1)(ja), 59 and 3(d) of the Act. These objections are not addressed in the Impugned Order. In ***Adama Makhteshim Ltd v. The Controller of Patents & Designs,*** C.A. (Comm IPD-PAT) 167/2022, it is held that the Controller should examine all grounds of objection while deciding an application, even if the application is found to be nonpatentable on any one of the preliminary or technical grounds.

56. Accordingly, the Impugned Order dated 21.12.2023 is set aside and the Subject Application is remanded back to the Respondent for fresh consideration including the amended Claims.

57. It is clarified that the merits of the case have not been examined and the Respondent shall decide the Subject Application in accordance with law without being influenced by any observations made by this Court in this

Judgment and the same will be decided within a period of six months from the date. The Appellant shall be granted a fresh hearing before deciding the Subject Application.

58. Accordingly, the Appeal is disposed of with the aforesaid direction.

59. A copy of the Order shall be sent to the learned Controller General of Patents, Designs and Trademarks at the e-mail address – llc-ipo@gov.in for the necessary administrative action.

TEJAS KARIA, J

NOVEMBER 24, 2025
'KC' / 'N'