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

% ***Judgment Reserved on : 30th November, 2022***
Judgment Delivered on : 03rd February, 2023

\+ **C.A.(COMM.IPD-PAT) 22/2022, I.A. 5588/2022 (stay), I.A. 5589/2022 (O-XI R-1(4) of CPC) and I.A. 16487/2022 (of waiver of costs)**

SOCIETE DES PRODUITS NESTLE SA ..... Appellant
Through: Ms. Mamta Jha, Mr. Siddhant Sharma and Ms. Surbhi Nautiyal, Advocates

versus

THE CONTROLLER OF PATENTS AND DESIGN & ANR. ..... Respondents
Through: Mr. Harish Vaidyanathan Shankar, CGSC with Mr. Srish Kumar Mishra, Mr. Sagar Mehlawat and Mr. Alexander Mathai Paikaday, Advocates

CORAM:
HON'BLE MR. JUSTICE AMIT BANSAL

JUDGMENT

AMIT BANSAL, J.

Background

1. The present appeal under Section 117A of the Patents Act, 1970 (hereinafter referred as "Act") impugns the order dated 29th December, 2021 passed by the Assistant Controller of Patents and Designs, Patent Office, Delhi (Patent Office) refusing the application for grant of patent application No.201817040811 for an invention title "*Composition for use in the Prophylaxis of Allergic Disease*".

2. Oral submissions in the matter were heard on 29th November, 2022 and 30th November, 2022. Vide order dated 30th November, 2022, the judgment was reserved in the appeal, giving liberty to the parties to file written submissions. Written submissions were filed on behalf of the appellant as well as the respondent.

Brief Facts

3. Brief facts necessary for deciding the present appeal are set out below:

I. On 10th March, 2017, the appellant filed PCT international application No.PCT/EP2017/055680 claiming priority from a European Patent Application, i.e., EP16172431.5 dated 1st June, 2016.

II. On 29th October, 2018, the appellant filed the National Phase Application in India as Indian Patent Application No.201817040811 titled as "*Composition for use in the Prophylaxis of Allergic Disease*".

III. On 22nd February, 2019, the patent application was published in the official Journal of Patent Office and subsequently, the appellant filed a Request for Examination of the Patent Application on 20th May, 2020.

IV. On 29th January, 2021, the first examination report (FER) containing objections to the grant of the patent was issued by the respondent no.2.

V. On 28th July, 2021, the appellant filed response to the first examination report.

VI. On 23rd August, 2021 and 23rd September, 2021, hearing notice were issued by the respondent no.2. Hearing notice dated 25th October,

2021 was issued by the respondent no.2, fixing the date of hearing on 23rd November, 2021.

VII. On 23rd November, 2021, arguments were advanced on behalf of the appellant.

VIII. On 7th December, 2021, the appellant filed written note of submissions in support of the arguments advanced during the hearing.

IX. On 29th December, 2021, the impugned order was passed by the Assistant Controller of Patents and Designs refusing the application for grant of patent filed on behalf of the appellant under Section 15 of the Act.

4. The impugned order passed by the Patent Office held that:

(i) Claims of the patent application of the appellant defined a method for '*treatment of human body*' and were therefore, not patentable as the scope of the Claims fell under Section 3(i) of the Act.

(ii) The amended Claims filed by the appellant were not permissible in terms of Section 59 of the Act, as the amended Claims sought to confer greater scope of protection, in comparison to the originally filed Claims, which Section 59 of the Act prohibits.

(iii) The data given by the appellant for the claimed composition was not demonstrating stabilized synergism and the appellant failed to provide data comparing individual effects of each drugs/active ingredients with combination of them so as to prove synergy. Therefore, the patent application did not meet the requirements of Section 2(1)(ja) and Section 3(e) of the Act.

5. The appellants being aggrieved by the decision of the Assistant

Controller of Patents and Designs have filed the present appeal.

Submissions

6. Counsel appearing on behalf of the appellant assails the impugned order on the following grounds:

(i) The original set of Claims, specifically Claim 4, was directed towards a 'composition' and not towards a 'method of treatment'. Therefore, the amendment did not enlarge the scope of Claims and description.

(ii) In any event, the amendments were carried out to overcome the objections raised by the Patent Office in the FER dated 29th January, 2021 and the hearing notices dated 23rd August, 2021 and 25th October, 2021. Therefore, the same were within the scope of the originally filed Claims and therefore, permissible under Section 59 of the Act.

(iii) So long as the invention is disclosed in the specifications and the Claims are restricted to the disclosures made in the specification, the amendment ought not to have been rejected. Reliance is placed on the judgment dated 5th July, 2022 of a Coordinate Bench in C.A. (COMM.IPD-PAT) 11/2022 titled ***'Nippon A & L Inc v. The Controller of Patents'***.

(iv) The finding of the Patent Office that the Claims relate to a method of treatment is wholly erroneous. The Claims were towards a composition and were not towards a method of treatment. Reliance in this regard is placed on the judgment of the IPAB dated 25th August, 2020 in OA/33/2015/PT/KOL titled ***University of Miami* v. *Controller of Patents***.

(v) The finding of the Patent Office that there is insufficient data of synergy is completely misconceived. The appellant has provided extensive data in support of synergism of the composition claimed in the application.

(vi) It is a settled position of law that the appellant is not required to give each and every possible embodiment falling within the scope of the Claims and the appellant is only required to maintain an illustrative data in support of the Claim. Reliance in this regard is placed on the IPAB order dated 18th October, 2012 in ***TRA/1/2007/PT/MUM*** titled '***Tata Global Beverages Limited* v. *Hindustan Unilever Limited***'.

(vii) The subject matter of the Claims of the patent application satisfy the requirements of Inventive Step under Section 2(1)(ja) of the Act. The teachings from the documents cited by the Controller as prior art are not individually or collectively leading any person skilled in the art to the subject matter of the present patent application.

7. Counsel for the respondents made the following submissions in support of the impugned order passed by the respondent no.2:

(i) The Claims refused patent protection in the impugned order were amended from being purpose-limited product Claims which conferred limited scope of protection to Claims on a composition. This amendment of Claims from purpose-limited product Claim to pure composition Claims contravenes Section 59 of the Act.

(ii) The Claims of the patent application are hit by Section 3(i) of the Act as the body of the Claims is defined as:

> "*for use in the prophylaxis of allergic disease in an offspring of a mammalian subject, <u>comprising</u>*

administration of the composition to said subject pre-pregnancy and/or during pregnancy and/or during lactation"

(iii) The body of the Claims defines medicinal use in terms of the method of treatment/prophylaxis, which is a non-patentable subject matter in terms of Section 3(i) of the Act.

(iv) The appellant has not submitted sufficient data to demonstrate stabilized synergism as the present application lacks data on the individual effects of each drug (when each drug is used alone). The following deficiencies with respect to the data are still existing:

- Figures 1-6, lack results of DGLA only, which is necessary to analyse stabilized synergism.
- Figure 5 also lacks results of DHA only (when DHA was used alone); EPA only (when EPA was used alone) and Fish oil only (when fish oil was used alone).
- Figure 6 only shows the result of control, and fish oil + DGLA.

Analysis and Findings

8. The first objection raised by the Assistant Controller of Patents and Designs is that the Claims of the Patent Application are directed towards a method of treatment and therefore, not patentable under Section 3 (i) of the Act. Accordingly, I shall first address this issue, if the Claims were defining a method of treatment/prophylaxis.

9. The relevant portion of the impugned order of the Assistant Controller of Patents and Design with regard to the objection of Section 3(i) of the Act reads as:

*1. **It is found that this claim defined a method for***

treatment of the human body and therefore was not allowable u/s 3(i). *The composition claim of the amended claims was not allowable under section 59 of the Patents Act 1970. The subject-matter protected by the original claim was a composition, when use in treatment. It is explained that in general terms, if a claims only included claims defining the a method of treating prophylaxis of allergic disease in an offspring of a mammalian subject, and therefore containing both "composition" and "method features", and the proposals to amend the claims during proceedings included claims which only contained "composition", the proposed amendment was not allowable having regard to u/s 59 of the Patents Act 1970, because the claims as originally filled conferred protection upon the compound only when it was in use so as to carry out the method of treatment, whereas the proposed amended claims would confer protection upon the composition whether or not it was in use, and would therefore confer additional protection compared to the claims as originally filled.*

2. *Therefore, in view of the aforesaid, it is concluded that the subject matter of the composition claim of the amended claims was not allowable under section 59 of the Patents Act 1970.* ***As such, the substantive objection under the header "Non-Patentability u/s 3" of the said Hearing notice still hold good. Therefore, the claimed subject is not patentable u/s 3(i) of The Patents Act, 1970 (as amended).***

10. Section 3(i) of the Act reads as under:

(i) ***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.*

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.

12. The impugned order passed by the Assistant Controller of Patents and Designs was examining the following Claims, which were filed along with the Written Submissions dated 7th December, 2021:

> *1. A composition comprising DGLA wherein the composition is enriched in DGLA and contains an omega-3 polyunsaturated fatty acid, selected from the group consisting of DHA and EPA or a combination of DHA and EPA, wherein said DGLA is comprised in said composition in a concentration of at least 35wt%, relative to the total fatty acid content of the composition; and wherein the concentration of DHA is 20 to 26wt% and concentration of EPA is 7wt%.*
>
> *2. The composition comprising DGLA as claimed in claim 1, wherein the composition further comprises omega-6 polyunsaturated fatty acid, selected from the group consisting of LA and GLA or a combination of LA and GLA.*
>
> *3. The composition comprising DGLA as claimed in claim 2, wherein the the concentration of GLA is 2.6wt% and the concentration of LA is 6.4wt%.*

13. Now, I shall assess the decision of the Assistant Controller of Patents and Designs that the said Claims were non-patentable due to falling within the scope of Section 3(i) of the Act.

14. In this regard, a reference may be made to the judgment in ***University of Miami*** (supra). In the said case also, one of the grounds for rejection of

the patent application was that under Section 3(i) of the Act relating to method of treatment. While dealing with the ground of rejection under Section 3(i) of the Act, the IPAB observed as under:

> *"17. ...The use of expression treatment 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."*

15. Reference can be made to the ***Manual of Patent Office Practice and Procedur****e* (*hereinafter 'the Manual'*) issued by the office of the CGPDTM on 26th November, 2019. The relevant portion of the said Manual, which gives guidance for examination with respect to exclusion of medical, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment is as follows:

> *"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."*

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.

17. In addition, even the previously filed Claims were in respect of a composition comprising DGLA and not towards a process of prophylactic treatment. The expression '*composition comprising DGLA directed towards treatment*' was used only for defining the composition and not directed towards a method of treatment.

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.

Amendment of Claims

19. Next, I propose to deal with the issue of amendment of the Claims.

20. The relevant portion of the impugned order of the Assistant Controller

of Patents and Design with regard to objection pertaining to the amendment of Claims in accordance with Section 59 of the Act reads as:

> 3. *It is found that this claim defined a method for treatment of the human body and therefore was not allowable u/s 3(i). The composition claim of the amended claims was not allowable under section 59 of the Patents Act 1970. The subject-matter protected by the original claim was a composition, when use in treatment. It is explained that in general terms, if a claims only included claims defining the a method of treating prophylaxis of allergic disease in an offspring of a mammalian subject, and therefore containing both "composition" and "method features", and the proposals to amend the claims during proceedings included claims which only contained "composition", the proposed amendment was not allowable having regard to u/s 59 of the Patents Act 1970, because* ***the claims as originally filled conferred protection upon the compound only when it was in use so as to carry out the method of treatment, whereas the proposed amended claims would confer protection upon the composition whether or not it was in use****, and would therefore confer additional protection compared to the claims as originally filled.*
>
> 4. ***Therefore, in view of the aforesaid, it is concluded that the subject matter of the composition claim of the amended claims was not allowable under section 59 of the Patents Act 1970.*** *As such, the substantive objection under the header "Non-Patentability u/s 3" of the said Hearing notice still hold good. Therefore, the claimed subject is not patentable u/s 3(i) of The Patents Act, 1970 (as amended).*

21. With regard to the amendment of Claims, the stand taken by the respondent in the original written submissions was that the original Claim was a purpose-limited product Claim and the proposed amendment seeks enlarged protection compared to the Claims as originally filed and was

therefore, rejected by the Patent Office.

22. The pending Claim 1 at the time of hearing was as follows:

> *"1. A composition comprising DGLA for use in the prophylaxis of allergic disease in an offspring of a mammalian subject, comprising administration of the composition to said subject pre-pregnancy and/or during pregnancy and/or during lactation and preferably wherein said composition is a composition enriched in DGLA wherein said composition also contains an omega-3 polyunsaturated fatty acid, selected from the group consisting of DHA and EPA or a combination of DHA and EPA, wherein said DGLA is comprised in said composition in a concentration of at least 3wt% relative to the total fatty acid content of the composition and more preferably in a concentration of at least 5wt%, at least 10wt%, at least 20wt%, at least 30wt%, at least 35wt%, or at least 40wt% relative to the total fatty acid content of the composition; and wherein the concentration of DGLA is greater than the concentration of DHA or EPA."*

23. After hearing, the Claim was amended to read as follows:

> *"1. A composition comprising DGLA wherein the composition is enriched in DGLA and contains an omega-3 polyunsaturated fatty acid, selected from the group consisting of DHA and EPA or a combination of DHA and EPA, 5 wherein said DGLA is comprised in said composition in a concentration of at least 35wt%, relative to the total fatty acid content of the composition; and wherein the concentration of DHA is 20 to 26wt% and concentration of EPA is 7wt%."*

24. It is evident that the aforesaid amendment was made by the appellant on account of an objection taken by the Patent Office under Section 3(i) of the Act, in the hearing notice dated 25th October, 2021. The said objection is set out below:

> ***"Non-Patentability***
> *The subject matter as claimed in claims falls under section 3(i) of the Patents Act, 1970 as amended by the Patents*

(Amendment) Act 2005, therefore not allowable."

25. Pursuant to the said objection, the appellant filed written submissions accompanied with amended Claims.

26. While amending the Claims, the original scope of the Claims stood expanded and the protection claimed was enhanced, as instead of being a purpose-related Claim, it became a general Claim over the composition.

27. This aspect was considered after the judgment was reserved in the present case on 30th November, 2022 and hence, the matter was listed for directions on 19th December, 2022 and the counsels for the parties were heard on this aspect. The relevant extracts from the order passed on 19th December, 2022 are set out below:

> *5. In the impugned order dated 29th December 2021, the aforesaid amended claims have been rejected under Section 59 of the Patents Act, 1970 on account of expanding the scope of the claim. In the prima facie view of the court, the objection taken by the respondents in the hearing notice with regard to Section 3(i) of the Patents Act, 1970 was untenable. It was only on account of the aforesaid objection, the claim 1 was amended by the appellant so as to delete features related to method of treatment. The relevant extracts from the written submissions in this regard are set out below:*
>
> *"Section 3(i):*
> *The applicant submits to the Ld. Controller that the claims 4 and 5 have been deleted without prejudice. Further, features related to method of treatment are deleted from claim 1. In view of deletion the objection stands moot. The Ld. Controller is requested to take the same on record and withdraw the present*

objection."

6. The aforesaid amendment to the claims of the patent application was rejected by the respondent in the impugned order under Section 59 of the Patents Act, 1970 on the ground of expanding the original claim. It was put to the counsel for the appellant whether the appellant would wish to pursue the previously filed claims. To which, the counsel for the appellant replied in affirmative.

7. In view of the fact that claims were amended twice on behalf of the appellant, it would be appropriate if the appellant places on record the final set of claims to be considered so that there is no ambiguity in respect of the claims to be considered. The said claims to be filed by 23rd December, 2022. Thereafter, both the parties may file their written submissions by 3rd January, 2023 on the aspect of amendment and inventive step.

28. Counsel for the respondent submitted that it was not permissible for the appellant to resort to the previously filed Claims at this stage. In the additional written submissions filed on behalf of the respondent on 11th January, 2023, it is claimed that there is no provision in the Act that permits the courts to allow any amendment at the stage of appellate proceedings.

29. Therefore, it would have to be considered whether an amendment can be allowed at the stage of appeal or not.

30. There is no provision in the Act, which specifically bars the amendment of a patent specification at the appellate stage. Amendment of patent applications and specifications are covered in Chapter X of the Act. Sections 57 to 59 of the Act are the provisions that govern the same.

31. A reference to Sub-Section 3 of Section 57 of the Act would show that an amendment application can be made even after the grant of patent.

The said provision reads as under:

> *57. **Amendment of application and specification or any document relating thereto before Controller**.—*
> *(1) Subject to the provisions of section 59, the Controller may, upon application made under this section in the prescribed manner by an applicant for a patent or by a patentee, allow the application for the patent or the complete specification or any document relating thereto to be amended subject to such conditions, if any, as the Controller thinks fit:*
> *Provided that the Controller shall not pass any order allowing or refusing an application to amend an application for a patent or a specification or any document relating thereto under this section while any suit before a court for the infringement of the patent or any proceeding before the High Court for the revocation of the patent is pending, whether the suit or proceeding commenced before or after the filing of the application to amend.*
>
> *(2) Every application for leave to amend an application for a patent or a complete specification or any document relating thereto under this section shall state the nature of the proposed amendment, and shall give full particulars of the reasons for which the application is made.*
>
> *(3) **Any application for leave to amend an application for a patent or a complete specification or a document related thereto under this section made after the grant of patent and the nature of the proposed amendment may be published**.*

32. Further, a reference to Sub-Section (1) of Section 58 of the Act would show that an amendment to the specification can be allowed in the proceedings before the High Court at the stage of revocation of a patent. The relevant provision reads as under:

> *58.* ***Amendment of specification before Appellate Board or High Court****.— (1) In any proceeding before the High Court for the revocation of a patent, the High Court, as the case may be, may, subject to the provisions contained in section 59, allow the patentee to amend his complete specification in such manner and subject to such terms as to costs, advertisement or otherwise, as the High Court may think fit, and if, in any proceedings for revocation the High Court decides that the patent is invalid, it may allow the specification to be amended under this section instead of revoking the patent.*

33. In view of the above, there is no specific bar for the amendment even at a subsequent stage. Only requirement under the Act is that the amendment has to fulfil the requirements under Section 59 of the Act and the consideration that has to be kept in mind is that the amended Claims are not inconsistent with the earlier Claims in the original specification.

34. Now, a reference may also be made to Section 15 of the Act, i.e., where a Controller has been given the power to require an application to be amended to his satisfaction. The said provision reads as under:

> *" [**15. Power of Controller to refuse or require amended applications, etc., in certain cases.**-Where the Controller is satisfied that the application or any specification or any other document filed in pursuance thereof does not comply with the requirements of this Act or of any rules made thereunder, the Controller may refuse the application **or may require the application, specification or the other documents, as the case may be, to be amended to his satisfaction before he proceeds with the application and refuse the application on failure to do so.**]"*

35. It is axiomatic that if the Controller has been given the power to direct an amendment to the patent application, the High Court, which is sitting in

appeal over the decision of the Controller, should also have similar powers to direct the patent applicant to amend Claims to its satisfaction.

36. Further, it is a settled position of law that an appeal is a continuation of the proceedings of the original court. The appellate jurisdiction involves a re-hearing on law as well as on facts. Reference in this regard may be made to a recent judgement of the Supreme Court in ***Ramnath Exports Pvt. Ltd. v. Vinita Mehta & Anr***, (2022) 7 SCC 678.

37. Vide order dated 10th September, 2009, in CS(OS) 593/2007 titled ***AGC Flat Glass Europe SA* v. *Anand Mahajan and Ors.***, a Single Judge of this Court had allowed amendments to Claims of a patent specification when an interim injunction application was being considered, so long as the amendment was in conformity with Section 58 and 59 of the Act. The operative portion of the said order reads as under:

> *25. In view of the aforementioned discussion and well settled position of law and bearing the facts of the present case in mind, I find that the present amendment is merely a clarificatory/ elaborative one and does not alter the scope of the invention. At best, even if the defendants" objections are accepted, the said amendment appears to be a disclaimer which also cannot come in the way of permitting the amendment and in fact, the same rather support the amendment. The merits of the controversy as to whether it is disclaimer or clarification will be decided at a later stage. The amendment is thus allowed as being a clarificatory one and the same does not attract the proviso of Section 58 and 59 of the Patent Act, 1970.*

38. In OA/12/2020/PT/MUM titled ***Adrenomed A.G.* v. *The Deputy Controller of Patents and Designs***, the IPAB while dealing with an appeal pertaining to objections under Section 3(i) of the Act, had ordered the

amendment of Claims. The relevant portion of the said order reads as under:

> *"18. Hence, looking at the provisions of the law and explanations provided in the guidelines both Nationally and Internationally in respect of 'use' claims and applicability of section 3(i) as well as considering the appellant's own admission, when they amended the claims to overcome such objections initially without countering the objection itself, we have no hesitation to accept the findings of the respondent.*
>
> *19. We, therefore, **direct the appellant to file amended set of claims deleting claims 12- 14 from the body of the claims** and submit existing claim 1-11 within 3 weeks from the issuance of this order, as there is no objection on to these claims in the impugned order of the respondent.*
>
> *20. Considering the above facts, we set aside the order of the Respondent dated 17/12/2019 and direct the respondent to grant the patent on the amended set of claims 1-11, within 3 weeks from the date of filing the amended set of claims."*

39. Thus, in conclusion, I observe that if the High Court, in appeal is considering the issue of grant of patent, it should necessarily have the same powers as given to the Controller under Section 15 of the Act, which includes power to require amendment. Further, the appellate proceedings challenging the refusal of grant of a patent, questions of facts need to be re-examined comprehensively and therefore, a liberal view has to be taken with regard to amendment of Claims.

40. In the present case, since the appellant is resorting back to the previously filed Claim, the same is fully covered under Section 59 of the Act. Taking into account the fact that the objection due to which the

amendment was pursued has itself been set aside, it would be in the interest of justice to allow the amendment at the appellate stage.

41. The appellant was given liberty to place on record the final set of Claims to be considered. Pursuant thereto, the appellants have filed the following set of Claims:

> *"1. A composition comprising DGLA for use in the prophylaxis of allergic disease in an offspring of a mammalian subject, comprising administration of the composition to said subject pre-pregnancy and/or during pregnancy and/or during lactation ad preferably wherein said composition is a composition enriched in DGLA wherein said composition also contains an omega-3 polyunsaturated fatty acid, selected from the group consisting of DHA and EPA or a combination of DHA and EPA, wherein said DGLA is comprised in said composition in a concentration of at least 3wt% relative to the total fatty acid content of the composition and more preferably in a concentration of at least 5wt%, at least 10wt%, at least 20wt%, at least 30 wt%, at least 35wt%, or at least 40wt% relative to the total fatty acid content of the composition, and wherein the concentration of DGLA is greater than the concentration of DHA or EPA. [**Supported by originally filed claims 4, 5, 6 – same as amended claim 1 filed on 28.7.2011**]*
>
> *2. The composition comprising DGLA as claimed in claim 1, wherein the composition further comprises omega-6 polyunsaturated fatty acid, selected from the group consisting of LA and GLA or a combination of LA and GLA. [**Supported by originally filed claim 5 – same as amended claim 2 filed on 7.12.2021**]*
>
> *3. The composition comprising DGLA as claimed in claim 2, wherein the concentration of GLA is 2.6wt% and the concentration of LA is 6.4wt%. [**Supported by originally filed claim 8 and pg. 17 of originally filed specification – same as amended claim 3 filed on***

7.12.2021]"

42. As can be seen from the above, in respect of Claim 1, the appellants have resorted back to the composition being a purpose-limited claim. As noted above, in my considered view, the aforesaid Claim is not covered under Section 3(i) of the Act as it does not bar patentability of compositions being used in the treatment or prophylaxis of a disease.

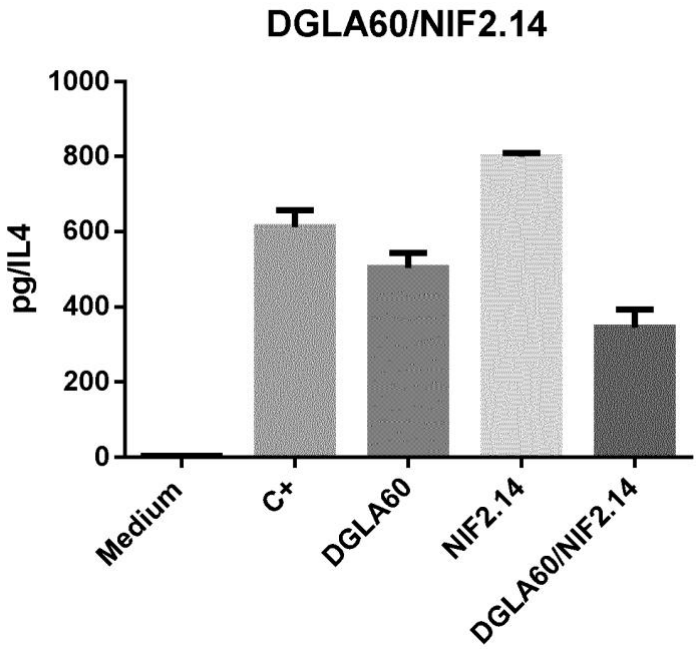
43. Now, I shall proceed to examine the amended Claims in light of the objections raised by the Assistant Controller of Patents and Design under Section 3(e) and 2(1)(ja) of the Act.

Objection with respect to Section 3(e)

44. The Patent Office has rejected the subject Patent Application under the provisions of Section 3(e) of the Act on the ground that insufficient data of synergy has been provided by the appellant. A perusal of the material on record would show that the appellant has provided extensive experimental data in the specification supported by examples as well as drawings showing the synergistic effect when compared to the individual. A reference in this regard may be made to pages 25 to 29 and pages 32 to 37 of the appeal paper book.

45. In the present patent application, Figure 5 is giving out a comparison between the IL 4 values of the Control Group, DGLA 60 group, NIF 2.14 group and the composition of the subject Patent Application. The said figure is extracted as under:

FIGURE 5



46. In the above figure, the IL4 values corresponding to DGLA alone, i.e., an individual component, has also been given. Additionally, the IL4 values of the composition have been represented, and the same are significantly lower than that of DGLA60 alone. Similarly, in other figures given in the complete specification, other parameters including IgE values, Mast Cells, and IL 10 secretion in brachial lymph nodes have been given.

47. The interleukin 4 (IL4) is an anti-inflammatory cytokine, which plays a pivotal role in regulating antibody production and inflammation. Excess production of IL4 is not advisable especially considering it can even cause tumours. The reduction of IL4 is a synergistic effect of the present composition.

48. In ***Lallubhai Chakubhai Jarivala v. Shamaldas Sankalchand Shah,*** (1934) 36 BOMLR 881, the Bombay High Court had given clarity on the

aspect of grant of patents with respect to new combinations. The relevant extract from the said judgement reads as:

> *19. The point of a combination patent is that the elements of which the combination consists is to produce one result. The merit depends upon the result produced. Frost in Vol. 1 of his Patent Law and Practice, Edn. 4 observes as follows (P. 74):*
>
> > *The merit, of a new combination very much depends on the result produced. When a very slight alteration turns that which was practically useless into what is useful and important, the Courts consider that, though the invention was apparently small, yet the result being the difference between failure and success, it is a fit subject-matter. Thus, the mere placing of two flat wicks parallel to each other in an oil lamp, two concentric round wicks having been previously combined, and flat wicks being perfectly well-known, has been held sufficient to merit a patent.*
>
> *20. The authority cited is Hinks & Son v. Safely Lighting Co., (1876) 4 Ch. D 607. In that case Jessel, M.R., makes the following observation*
>
> > *where a slight alteration in a combination turns that which was practically useless before into that which is very useful and very important, Judges have considered that, though the invention was small, yet the result was so great as fairly to be the subject of a patent; and as far as a rough test goes, I know of no better.*
>
> *21. In patent case the Courts attach great importance*

> *to the fact the alleged invention was only arrived at by a series of experiments. The learned Judge at p. 64 of the paper hook has referred to this principle and has cited an authority in support of it. It is beyond dispute that the plaintiff carried on numerous experiments from 1924 to 1930.*

49. A reference may be made to the IPAB order in ***Tata Global Beverages Limited*** (supra). The relevant observations in paragraph 94 are set out below:

> *"94. So far as the ground of insufficiency is concerned the applicant must prove that information given in the specification is insufficient to work the claimed invention. The sufficiency requirement is met if at least one way of working the invention is clearly indicated enabling the skilled person to carry out the invention. The applicant only submitted that in the absence of any control data of the colour of the starting material, the specification lack in establishment of any "improvement" related thereto. The expert also argued that condition of turbidity has not been taken into consideration while arriving at the results of Table 1 in the specification.* ***It is not necessary for the purpose of section 10(4) that the disclosure of a patent be adequate to enable the skilled person to carry out all conceivable ways of operating the invention. If the best method known to the patentee is disclosed it satisfies the requirement of sufficiency. Since the appellant has not contested the reproducibility of the example of the patent in question we find it sufficient for the purpose of section 10. We find that the appellant has not provided any substantiation for casting reasonable doubts on sufficiency of disclosure and the technical opinion submitted by the appellant do not point to a lack of reproducibility or feasibility of the claimed "invention". Therefore this ground also fails****."*

50. In view of the above, in my considered view, sufficient data has been

provided by the appellant comparing the individual components namely, DGLA-60, NIF 2.14 and control group and their efficacy with that of the claimed composition. Therefore, the objection taken by the Patent Office under Section 3(e) of the Act is not sustainable and the same is set aside.

The Subject Invention

51. In order to make an assessment if the patent application of the appellant satisfies the requirements of inventive step under Section 2(1)(ja) of the Act, I shall first summarise the invention and then proceed with the application of the test for determining inventive step.

52. The patent application of the appellant is directed towards a composition. This composition is a mixture comprising DGLA and certain omega-3 polyunsaturated fatty acids. The complete specification states that these omega-3 polyunsaturated fatty acids, which are to be used in combination with DGLA in the composition, could be either DHA (Docosahexaenoic acid) or EPA (Eicosapentaenoic acid) or even a combination of DHA and EPA. It has also been specified that the concentration of DGLA will be more than the concentration of DHA, EPA or the mixture of DHA and EPA.

53. The appellant has claimed that the administration of this composition yields the technical advancement/effect of reduction of allergies in the offspring of a mammalian subject. Needless to state, the mammalian subject would include humans. This effect according to the appellant, occurs when this composition is administered at the stage of pre-pregnancy, pregnancy or during lactation. The technical effect has also been illustrated in the patent specification as well as the written submissions of the appellant. The relevant portion of the submissions reads as:

> *1. Example 1 shows that the composition as claimed in the present invention results in: (a) total lgE and specific lgG1 to be significantly lower (figures 1 and 2); (b) skin symptoms were significantly milder (figure 3); and (c) significant lower number of mast cells in the jejunum.*
> *2. Example 2 shows that the composition as claimed in the present invention when DGLA and NIF (DHA and EPA) were given together, a synergistic reduction of IL4 production was observed.*
> *3. Example 3 shows that the composition as claimed in the present invention where IL-10 was significantly increased in pups from fish oil+DGLA.*

Finding on Inventive Step

54. The Division Bench of this Court in ***F. Hoffmann-La Roche Ltd. and Ors.*** **v.** ***Cipla Ltd., 2016(65) PTC 1 (Del)*** has laid down the seminal test to be followed for determining inventive step and lack of obviousness. The steps involved in the said test are as follows:

> "*Step No.1 To identify an ordinary person skilled in the art,*
> *Step No.2 To identify the inventive concept embodied in the patent*
> *Step No.3 To impute to a normal skilled but unimaginative ordinary person skilled in the art what was common general knowledge in the art at the priority date*
> *Step No.4* ***To identify the differences, if any, between the matter cited and the alleged invention and ascertain whether the differences are ordinary application of law or involve various different steps requiring multiple, theoretical and practical applications,***
> ***Step No.5*** ***To decide whether those differences, viewed in the knowledge of alleged invention, constituted steps which would have been obvious to***

***the ordinary person skilled in the art and rule out a hindside approach*"**

55. In line with the steps listed above, at the appellate stage, for determining inventive step, I shall start at Step 4 and identify the differences between the prior arts identified by the Controller.

56. The Assistant Controller of Patents and Designs has identified 2 prior arts:

i. **D1**- US5591446A titled '*Methods and agents for the prophylaxis of atopy*' with priority date of 11th April, 1995 and publication date of 7th January, 1997

ii. **D2**- US6150411A titled '*Use of DHA as a pharmaceutical composition*' with priority date of 25th May, 1995 and publication date of 21st November, 2000

57. The document D1 relates to a atopy prophylaxis dietary supplement comprising at least one substance selected from the group consisting of γ-linolenic acid (GLA), dihomo-γ-linolinic acid (DGLA) and the physiologically compatible salts, esters, amides, phospholipids, glycolipids thereof. The composition in D1, comprises GLA, DGLA or a mixture of GLA+DGLA, which maybe administered to pregnant or nursing mothers. However, D1 is silent about use of omega-3 polyunsaturated fatty acids, as both GLA and DGLA are omega-6 fatty acids. Thus, the prior art does not completely cover the subject matter of the appellant's Patent Application.

58. The document D2 relates to combating dyslexia or inadequate night vision or dark adaptation in dyslexics or normal individuals, and is not related to prophylaxis allergies. D2 discloses the use of administering DHA with n-3 and n-6 essential fatty acids which may include EPA. However, the examples of D2 do not give any disclosure of examples where the

concentration of DGLA is more than DHA. Crucially, D2 does not give any disclosure on the concentration range of DGLA and fatty acids. The appellant's invention however, is giving a specific range i.e., 3-35wt% relative to the total fatty acid content of the composition and is also specifying that the concentration of DGLA is greater than that of DHA or EPA or the mixture of DHA and EPA.

59. An important factor in considering prior art D2 is however, the technical advancement/effect that D2 is achieving. Given that D2 is aimed towards an entirely different purpose i.e., for combating dyslexia and inadequate night vision, I observe that D2 actually teaches away from the invention.

60. Therefore, D1 is the closest prior art and given that D2 is actually teaching away from the invention, there would not be any benefit in combining the teachings of both the prior arts.

61. The prior arts fail to disclose any of the following inventive concepts, which are essential for the subject patent application:

(1) Combination of DGLA and an omega-3 polyunsaturated fatty acid;

(2) Concentration of DGLA to be at least 3wt% relative to the total fatty acid content; and

(3) The concentration of DGLA is greater than the concentration of DHA or EPA.

62. Step 5 as per ***F. Hoffmann-La Roche Ltd.*** (Supra) is to analyse if these differences could be obvious to a person skilled in the art. If the differences were '*obvious to try*', then the same would have been attempted by now, especially considering that the prior art cited has been published in

the year 1995.

63. In terms of the decision of a Coordinate Bench of this Court in ***Avery Dennison Corporation v. Controller of Patents and Designs,*** 202/DHC/004697**,** the age of the prior art cited is a relevant consideration for determining if the subject matter of the Patent Application would be obvious to a person skilled in the art or not. The relevant portion of the said judgement is as follows:

> *36. One of the sure tests in analysing the existence of inventive step would also be the time gap between the prior art document and the invention under consideration. If a long time has passed since the prior art was published and a simple change resulted in unpredictable advantages which no one had thought of for a long time, the Court would tilt in favour of holding that the invention is not obvious.*
>
> *37. Terrel on Law of Patents (16th Edition) opines that the age of the prior art and why it was not done before is one of the factors to be considered while deciding on obviousness. The observations made in the judgement Brugger v. Medic-Aid Ltd, [1996] R.P.C. 635 delivered by the UK Patents Court has been cited to substantiate the consideration of this factor. The relevant portion reads:*
>
> > *"The fact that a piece of prior art has been available for a long time may indicate, contrary to first impressions, that it was not obvious to make the patented development from it. It is useful to bear in mind in this regard the concept of long felt want. This is a particularly efficient expression. An apparently minor development which meets a long felt want may be shown to be non-obvious because, although the prior art has long been available, the development was*

> *not hit upon by others notwithstanding that there was a need for improvement (the 'want') and an appreciation of that need (the 'felt'). In other words the age of prior art may be an indication that a development from it is not obvious if it can be shown that the circumstances in the relevant trade were such that a failure of the development to appear earlier is surprising."*

64. In the present case, the prior arts cited are having priority dates in the year 1995 whereas the present patent application has been filed with a priority date of 1st June, 2016. Thus, the prior arts cited are more than 20 years older than the subject Patent Application. Therefore, in my view, when the subject matter of the patent application is showing technical advancement over the cited prior arts, and when the cited prior arts are considerably old, it is a clear indicator of non-obviousness.

65. It is pertinent to note that the prior arts cited by the Indian Patent Office are the same as that were cited by the European Patent Office (EPO) when the corresponding European (EU) patent application was being prosecuted. The said EP patent application was granted vide publication EP3463332B1, dated 21st April, 2021. This, in my view, would also be a persuasive argument in support of the grant of the Indian Patent Application, especially when the same prior art has been cited.

66. Accordingly, the subject Patent Application satisfies the criteria of inventive step as the inventive concept of the subject patent application is a technical advancement over the prior art and is not obvious to a person skilled in the art.

Directions

67. The subject Patent Application shall accordingly proceed for grant. The appeal is allowed, with no order as to costs.

68. List the matter before the Patent Office on 20th February, 2023 for completion of formalities, including filing of necessary forms for amendment of specifications.

69. The Registry is directed to supply a copy of the present order to the office of the Controller General of Patents, Designs & Trademarks of India on the e- mail- llc-ipo@gov.in for compliance.

70. Pending applications also stand disposed of.

AMIT BANSAL, J.

FEBRUARY 03, 2023
dk