

INTTL ADVOCARE
HEAD OFFICE:
EXPRESS TRADE TOWER
B-36, SECTOR-132
NOIDA EXPRESSWAY, NOIDA-201303
NATIONAL CAPITAL REGION OF DELHI
INDIA
PH: + 91-120-2470200 - 298
FAX: + 91-120-2470299
Email: ipcare@intladvocare.com

MUMBAI OFFICE:
803, 8th FLOOR, "ARCADIA", 195 NARIMAN
POINT, MUMBAI-400021, INDIA
Ph: - +91-22-61239000
Fax +91-22-61239090
Email: mohan@intladvocare.com

DELHI OFFICE:
F-252, WESTERN AVENUE,
SAINIK FARMS,
NEW DELHI - 110 062.
PH: +91 11 29552930, 29552836
FAX: +91 11 29555679
CHAMBER:
386, NEW CHAMBER BLOCK
DELHI HIGH COURT
NEW DELHI - 110 003.

REPLY TO THE FIRST EXAMINATION REPORT
REPLY DEADLINE: JULY 29, 2021

Our Ref: PO/14/1396/RA/SP/11
July 28, 2021

The Controller of Patents,
The Patent Office,
New Delhi,

Kind Attn: Dr. Rajesh Patel, Controller of Patents

Re.: Société des Produits Nestlé SA,

Application No.: 201817040811

Filed on: October 29, 2018

Title: COMPOSITION FOR USE IN THE PROPHYLAXIS
OF ALLERGIC DISEASE

Dear Sir,

We write with respect to the First Examination Report dated January 29, 2021 issued on the above mentioned patent application and submit herewith the under mentioned documents and present the following reply.

Before replying to the objections raised in the First Examination Report, we would like to place an amended claim set to replace the claims presently on file.

CLAIM AMENDMENTS:

Original claim 4 is new claim 1 having features from claims 5, 7 and 9.

Original Claims 1 to 3, 6, 7, 9 and 11 to 14 are deleted without prejudice.

Remaining claims have been renumbered and dependences have been changed accordingly.

A marked-up as well as clean copy of amended claims is enclosed herewith.

The claim amendments carried out fall within the scope of the original specification and no new matter has been added. The claim amendments meet the requirements of section 57 and 59 of the Patents Act, 1970 and The Patents Rules, 2003 (as amended in 2016), the Applicant reserves the opportunity to further amend the claims at a later point of time.

We now present our reply to the objections raised in the First Examination Report *in seriatim*:

Part II (B)(1) - NOVELTY: AND Part II (B)(2) - INVENTIVE STEP: *Claim(s) (1-14) lack(s) novelty and inventive step, being anticipated in view of disclosure in the document cited above under reference D1-D2 for the following reasons:*

D1: US 5591446 A

D2: US 6150411 A

Reply: The Applicant respectfully submits that the Ld. Controller that the presently amended claims are novel and inventive in view of cited documents D1: **US 5591446 A** and D2: **US 6150411 A**.

Present Invention:

The subject matter of presently amended claim 1 relates to 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.

The technical effects of the present invention are shown in examples 1-3.

1. **Example 1** shows the composition of present invention results in: (a) total IgE and specific IgG1 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 when DGLA and NIF (DHA and EPA) were given together, a synergistic reduction of IL4 production was observed.
3. **Example 3** shows IL-10 was significantly increased in pups from fish oil+DGLA.

The problem at the hand is to identify a composition for therapy, especially prophylactic therapy for allergic diseases. In particular, it would be desirable to prevent or reduce the risk of development of allergies.

The solution for the above problem is provided by a composition of present invention comprising composition enriched in DGLA and an omega-3 polyunsaturated fatty acid, selected from the group consisting of DHA and EPA or a combination of DHA and EPA. 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. The concentration of DGLA is greater than the concentration of DHA or EPA.

Now, the Applicant will discuss the difference between the cited prior arts D1 and D2 along with claims of the present invention.

D1: US 5591446 A

The applicant submits to the Ld. Controller that cited document D1 discloses atopy-prophylaxis dietary supplement comprising at least one substance selected from the group consisting of γ -linolenic acid, dihomo- γ -linolenic acid. Cited document D1 discloses two compositions under table 2 and 3 (for pregnant or nursing mothers a composition comprising GLA or DGLA or GLA+DGLA).

However, cited document D1 nowhere teaches and is silent about composition with omega-3 polyunsaturated fatty acids and DGLA. D1 also does not teach or suggest concentration of DGLA to be at least 3wt% relative to the total fatty acid content; and the concentration of DGLA is greater than the concentration of DHA or EPA. Thus, it is evident that the presently amended claims are novel and inventive over cited document D1.

D2: US 6150411A

The applicant submits to the Ld. Controller that cited document D2 is of entirely different field relating to combating dyslexia or inadequate night vision or dark adaptation in dyslexics or normal individuals, by administering OHA or a precursor n-3 EFA. Cited document D2 discloses one formulation of granules or powder for use as above, made with gum acacia, gelatin, starch or other appropriate material containing by weight in each gram, 50 mg DHA, optionally with 50 mg of DGLA, 50 mg AA and/or 50 mg SA.

Cited document D2 does not add to the teachings of cited document D1. Thus, a person skilled in art would not combining D1 with D2 as it would not result in a composition comprising DGLA and an omega-3 polyunsaturated fatty acid, selected from the group consisting of DHA and EPA or a combination of DHA and EPA. Further, it would also not lead to specific amounts of the each components of composition as claimed in present invention and wherein the concentration of DGLA is greater than the concentration of DHA or EPA.

Based on the above, the applicant submits that the prior arts fail to disclose the following key aspects of the present invention:

- (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.

The applicant thus, submits that presently amended claims are not disclosed or suggested by D1 and D2 alone or in combination nor does it motivate a person skilled

in art to arrive at the present invention. Therefore, the subject-matter of the amended claims is inventive over the cited prior arts.

In the view of detailed submission above, applicant requests the Ld. Controller to waive of the present objection.

Part II (B)(3)- NON PATENTABILITY: *Claim(s) (2, 4-10, 13) are statutorily non-patentable under the provision of clause (e, i) of Section 3 for the following reasons:*

- 1. Claim 4-10, 13 attract Sec 3(e) of the Patents Act 1970 as amended by Patents (Amendment) Act 2005 as it is a case of compositions whose components are already known in prior art and in the case of instant application no synergistic effect exemplified by the specification with the same composition. It is case of mere admixture. Therefore, claims 4-10, 13 are objected.*
- 2. Claim 2 is related to method of treatment and hence not allowable under section 3(i) of The Patents (Amendment) Act, 2005.*

Reply:

1. Section 3(e):

The applicant submits to the Ld. Controller Claims 13 is deleted without prejudice. In view of deletion of claim 13 the objection stands moot for them.

Regarding presently amended claims 1 to 5, the applicant submits to the Ld. Controller that the claims relate to a compositions and technical effect is clearly shown through examples in specification. The technical effect of the present invention are shown in examples 1-3 is as below:

- 1. Example 1** shows the composition of present invention results in: (a) total IgE and specific IgG1 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 when DGLA and NIF (DHA and EPA) were given together, a synergistic reduction of IL4 production was observed.
- 3. Example 3** shows IL-10 was significantly increased in pups from fish oil+DGLA.

Thus, presently amended claims does not fall under the purview of section 3 (e).

In view of the detailed submission, the Applicant requests the Ld. Controller to withdraw the present objection.

2. Section 3(i): The applicant submits to the Ld. Controller that claim 2 has been deleted without prejudice. In view of deletion of claim 2 the objection stands moot for them. The Ld. Controller is requested to take the same on record and withdraw the present objection.

Part II (B)(5)- OTHERS REQUIREMENTS:

- 1. Independent claims should be prefaced with the term "A" and Dependent claims should be prefaced with the term "The".*
- 2. The term "according to" should be replaced with the term "as claimed in" in the respective claims.*
- 3. The Terms "long term", "preferably", "greater than" and "at least" to define ranges in the claims introduces uncertainty and thus results in lack of clarity of the claims. Thus the respective claims of the present application are not allowable u/s 10(4)(C) of The Patents (Amendment) Act,*
- 4. The subject matter of claim 1-3, 11, 13 is related to use claims and hence not allowable under section 2(1) (j) of The Patents (Amendment) Act, 2005.*
- 5. There is not technical features in the claims 1-3, 11, 13 and 14. Hence the claims 1-3, 11, 13 and 14 are objected u/s 2(1) j.*
- 6. State the novelty and inventive step of the alleged invention.*

Reply:

1. The applicant submits to the Ld. Controller that claims have been amended for antecedent basis.
2. The applicant submits to the Ld. Controller that the term "according to" has been suitably replaced with "as claimed in claims" in dependent claims.
3. The applicant submits to the Ld. Controller that terms "long term", "preferably", "greater than" and "at least" have a well-defined English meaning and has been used for the same meaning. Further, the term is clear to person skilled in art when claims are read with specification. Thus, applicant has retained the term in claims.
4. The applicant submits to the Ld. Controller that claims 1 to 3, 11 and 13 have been deleted without prejudice. In view of deletion of claims 1 to 3, 11 and 13 the objection

stands moot for them. The Ld. Controller is requested to take the same on record and withdraw the present objection.

5. The applicant submits to the Ld. Controller that claims 1 to 3, 11, 13 and 14 have been deleted without prejudice. In view of deletion of claims 1 to 3, 11, 13 and 14 the objection stands moot for them. The Ld. Controller is requested to take the same on record and withdraw the present objection.

6. The applicant submits to the Ld. Controller that novelty and inventive step of the present invention has been discussed in detail above. The Ld. Controller is requested to take the same on record and withdraw the present objection.

PART-III: FORMAL REQUIREMENTS:

TRANSLATION OF PR. DOCUMENT (CERTIFIED COPY ETC.): *As per Rule 20(3)b, verified English translation of the Priority documents and the International application shall be filed.*

Reply: The Applicant submits to the Ld. Controller that priority document and International application submitted with the patent office on 29th October 2018 is in English language. Further, priority document and International application filed with International Bureau is also in English language. Thus, translation of the same and its verification is not required.

The Ld. Controller is requested to take the same on record and withdraw the present objection.

OTHER DEFICIENCIES: *1. Details regarding application for patents which may be filed outside India from time to time for the same or substantially the same invention should be furnished within six months from the date of filing of the said application under clause (b) of sub section (1) of section 8 and rule 12(1) of Indian Patent Act.*

2. Details regarding the search and/or examination report including claims of the application allowed, as referred to in Rule 12(3) of the Patent Rule, 2003, in respect of same or substantially the same invention filed in all the major patent office's such as USPTO, EPO and JPO etc., along with appropriate translation where applicable should be submitted within period of six months from the date of receipt of this communication as provided under section 8(2) of the Indian Patents Act.

3. *Signatory assignment (signed by both applicant) should be given for the change in the applicant.*

4. *All essential forms should be filed by the new applicant.*

Reply:

1. **Section 8(1):** The Applicant herewith submits an updated Form 3 to meet the requirement of section 8(1) of the Patents Act, 1970.

2. **Section 8(2):** The Applicant submits that search and examination reports along with granted claims are being filed with this response.

3. The Applicant respectfully submits that the original notarized assignment from Nestec S.A. to Societe des Produits Nestle S.A. and its verified translation has been submitted with the patent office with application number 5574/DELNP/2012. Further, agent of the applicant and person authorized by the applicant has attested the assignment document. A copy of the same is uploaded along with the response for quick reference of the Ld. Controller. The Ld. Controller is requested to take the same on record and withdraw the present objection.

4. The applicant submits to the Ld. Controller that revised form 1, 2, 3, 5, and 18 has been submitted with patent office along with form 6 mentioning the name of the new applicant. Copy of the same has been submitted with this response for quick reference of the Ld. Controller. The Ld. Controller is requested to take the same on record and withdraw the present objection.

In view of the aforementioned detailed submission, we request the Ld. Controller to withdraw the present objection.

The learned Controller is requested to take the same on record and withdraw the present objection.

All the objections have been addressed and formal requirements have been met. We now respectfully request the Learned Controller to waive the objections.

It is requested to the Learned Controller to kindly allow the application for grant.

In any event, before taking any adverse decision, the Controller is respectfully requested to give an opportunity to the Applicant to be officially heard in the matter.

Thanking you,



(RAHUL ADEY)

IN/PA-3343

Agent for applicant

Encl.:

1. Amended claims Clean and Marked up Copy
2. As Filed Form-1, Form-2, Form-5 and Form-18
3. As filed proof of right
4. As Filed notarized assignment from Nestec S.A. to Societe des Produits Nestle SA.