

**BEFORE CONTROLLER OF PATENTS**  
**THE PATENT OFFICE, DELHI**  
**THE PATENTS ACT, 1970 (AS AMENDED)**

**SECTION 15**

IN THE MATTER OF AN APPLICATION FOR PATENT,

Application No. 201817040811

**D E C I S I O N**

The application was examined under Section 12 and 13 of Patents Act and First Examination Report (henceforth referred to as FER) containing a statement of objections was forwarded and the applicant's agent filed response to FER within stipulated time period.

As per the provisions under Section 13 (3) of Patents Act, the said amended case after reply to FER was examined and investigated in like manner as the original specification and the applicant was offered a hearing on 23/11/2021 vide official communication dated 25/10/2021, containing statement of objection.

The applicant's representative appeared for hearing on the above scheduled date and the said above objections were discussed. The applicant submitted his submission on 07/12/2021 highlighting on the same points as discussed during hearing.

In view of the objections, the Applicant has amended claims.

Claim 1 has been amended to introduce weight percentage from specification page 16 and 17, and features related to method of treatment are deleted without prejudice by way of correction/explanation.

Claim 3 has been amended to introduce weight percentage from specification page 17 by way of correction/explanation.

Claims 4 and 5 have been deleted without prejudice.

In response to objection under head Clarity and Conciseness of the hearing notice, the applicant submits that the objected terms have been deleted without prejudice in the interests of expediency of prosecution. A marked-up as well as clean copy of amended claims is submitted with the response.

In response to objection under head Clarity and Conciseness of the hearing notice: 1. the applicant submits that priority document and PCT application are filed in English language. Copy of the same is

attached for quick reference of the Ld. Controller. The Ld. Controller is requested to take the same on record and withdraw the objection.

**2.** 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.

In response to objection under head Invention u/s 2(1)(j) of the hearing notice following submission made by applicant:

The applicant submits to the Ld. Controller that the present invention relates to 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%.

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, 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%.

The technical effects of the present invention are shown in examples 1-3 as below:

1. **Example 1** shows that the composition as claimed in the 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 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.

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

In response to objection under head Non-Patentability u/s 3 of the hearing notice following submission made by applicant:

### **1. 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.

## **2. Section 3 (e):**

The applicant submits to the Ld. Controller that the presently amended claims relate to a compositions comprising DGLA with omega-3 polyunsaturated fatty acids 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%. The 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 that the composition as claimed in the 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 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.

Thus, based on the examples it is clear that the presently amended claims are not directed towards mere admixture but synergistic composition. Thus, the presently amended claim 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.

In response to objection under head Other Requirement(s) of the hearing notice, the applicant submits that the dependent claims have been suitably amended for antecedent basis. A marked-up as well as clean copy of amended claims has been submitted with the response.

The oral argument and the written hearing submission filed by the applicant's attorney have been carefully considered. Controller is of opinion that the subject matter as described and claimed in the instant applicant does not meet the requirements of 2(1)(ja) section 3 and section 59 of the Patents Act, 1970.

The applicant argument and submission is not considered convincing for the reasons indicated below.

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).*
3. Controller is of opinion that the data given for claimed composition does not found synergistic. The data given for claimed composition are not sufficient to stabilized synergism. Applicant fails to provide data comparing individual effects of each drug/active ingredients with combination of them as required to proof synergy. Synergy defines as "An interaction between two or more drugs that causes the total effect of the drugs to be greater than the sum of the individual effects of each drug". Therefore, in view of the aforesaid, it is concluded that the subject matter as described and claimed in the instant applicant does not meet the requirements of 2(1)(ja) section 3(e) of the Patents Act, 1970.

Thus, in view of the aforesaid and unsatisfactory submissions made by the Agents in respect of the pertinent requirement as raised in the said hearing notice, this instant application no. 201817040811 does not comply with the requirements of the Act. I, therefore, hereby order that the grant of a patent is refused under the provisions of Section 15 of the Patents Act.

Dated: 29-12-2021

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(Dr. Rajesh Patel)  
Assistant Controller of Patents & Designs