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BY EMAIL

Petition to the Administrative Council of the European Patent Organization

Cc:

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Re: European patent application 09735962.4; and European divisional application 17182663.9; Applicant: Asha Nutrition Sciences, Inc.

Dear Delegates in the Administrative Council,

We have been prosecuting the referenced patent applications directed to critical innovations for public health at EPO for last 10 years. However, rather than advancing the innovations EPO has been obstructing them. EPO statements in the prosecution history evidence that rejections have been applied to oblige us to reduce the claimed scope, even though as per provisions of European Patent Convention, the subject claims are perfectly patentable.

A narrow patent is not synonymous with a quality patent. The metric of quality disregarded by EPO is genuine innovation, *measured by betterment of life achieved*, though that is the very purpose of patents and is built into the law. For example, solutions to critical unmet needs are inventive even if claims are otherwise obvious (GL¹, G-VII, 10.3). Narrow patents in the nutrition arts have already caused great harm to public health and created *patent-practice-made humanitarian crises* by creating misinformation and taken us farther away from solving nutritional problems, preventative solutions, and sustainability. Narrow patent would defeat the very purpose of the subject innovations, conceived to overcome the misinformation in the art and the resulting public suffering and to set humanity on course to long-term solution to the lipid problem sparking downstream advancements in public health. Without sufficient patent scope and term, it is impracticable to effectively implement the claimed solutions.

EPO's unchecked dominance over European Patents results in *obstruction of innovation and fosters stagnation*. The dominance creates perverse incentives, such as EPO colluding with patent lawyers to defraud public, inventors, and applicants. As supervisory body of the EPO, we request your review of the matter detailed below and provide requested relief.

¹ Guidelines for Examination in the European Patent Office, November 2018

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I. Background of the Applications

The parent application has a filing date of 20 April 2009, it entered European phase on November 19, 2010. After the Examining Division (hereinafter “ED-1”) failed to render justice, the case was appealed to the Boards of Appeal (hereinafter “BoA”). At the oral proceedings held in July 2017, BoA colluded with the Applicant’s own representative (Representative 1) to undermine the application. Request for Correction of Minutes dated 3 August 2017 was submitted on 20 December 2017 (Attachments B and C). Formal Complaint was filed with EPO on January 30, 2018 (Attachment A with Exhibits A-E), which was dismissed by Directorate Quality Management. A Petition under Article 112a for review by the Enlarged Board of Appeal (hereinafter “EBoA”) was filed on March 26, 2018 (Attachment D), with the Complaint and copy of email communications between the Applicant and Representative 1 (Exhibit C) and declaration from Applicant’s CEO evidencing improper conduct at the oral proceedings (Exhibit D). The response to EBoA communication was filed on July 22, 2018 (Attachments E and F). The Enlarged Board disregarded the evidence of wrongdoings (Exhibits C-D) and refused to grant a review on October 10, 2018 (Attachment G). The Applicant documented in the Formal Complaint filed on November 12, 2018 (Attachment H) that it was improper for EBoA to disregard the evidence Exhibits C-D, which are the only mechanisms available to Applicant to report wrongdoings at EPO oral proceedings.

The divisional application filed in 2017 is now under examination by new Examining Division (hereinafter “ED-2”). ED-2 appears to take BoA and EBoA improprieties in the parent case as license for more improprieties in the divisional case (discussed below).

II. Background of the Inventions

The innovations pertain to tailored delivery of lipids. The independent claims pending in the divisional application are as follows (similar claims were presented in the parent case).

Claim 1:

- A lipid-containing formulation for a subject, comprising a mixture of lipids from different sources and a dosage of omega-6 fatty acids, wherein the formulation further comprises:
- a) a dosage of omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater, wherein:
 - (i) omega-6 fatty acids are 4-75% by weight of total lipids and omega-3 fatty acids are 0.1-30% by weight of total lipids; or
 - (ii) dosage of omega-6 fatty acids is not more than 40 grams; or
 - b) polyunsaturated, monounsaturated, and saturated fatty acids, wherein the omega-6 fatty acids are greater than 20% by weight of the total lipids and nutrients comprising one or more polyphenols, or one or more phytochemicals selected from: phytosterols, organosulfides, melatonin, saponins, coumarins, lycopene, lutein, zeaxanthin, and monophenols.

Claim 14:

Use of one or more factors of a subject selected from: age of the subject, sex of the subject, diet of the subject, the body weight of the subject, physical activity level of the subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and ambient temperature range of the subject's living area as an indicator for selecting a lipid-containing formulation for administration to the subject,

wherein the formulation comprises one or more mutually complementing daily dosages of fatty acids comprising omega-6 and omega-3 fatty acids, wherein the ratio of omega-6 to omega-3 fatty acids and their amounts are based on the one or more factors; wherein the omega-6 to omega-3 ratio is:

- 4:1 or greater, wherein the dosage of omega-6 is not more than 40 grams; or
- 1:1 to 50:1 based on amount of antioxidants, phytochemicals, and seafood in the subject's diet and/or the formulation; or
- wherein increase of omega-6 is gradual and/or withdrawal of omega-3 is gradual and the dosage of omega-6 is not more than 40 grams; or
- wherein the fatty acid content is matched to Table 6.

The inventions were conceived because of the following reasons:

- A. There is mass information and vilification of omega-6 in the prior art;
- B. the inventor arrived at an insight into peculiar dose-effect of omega-6 fatty acids, finding health benefits at higher dosages of omega-6 than taught in the prior art combined with higher ratios of omega-6 to other lipids (other fatty acids, antioxidants, and phytochemicals);
- C. dietary lipids are associated with health at fundamental level and incorrect lipid intake is associated with many diseases and medical conditions;
- D. natural sources of lipids are unpredictable in lipid content;
- E. less than 1% of the public understands lipids;
- F. it is too complex for the public to prepare lipid dosages for different members of the family; and because
- G. the innovations will set humanity on course to long-term solution to 100-year old lipid problem sparking downstream advancements in public health.

Prior art overwhelmingly teaches to reduce omega-6 and increase omega-3 intake, there is a widespread misconception in prior art that omega-6 is harmful to health², and dosage of omega-6 is poorly understood—stepwise increase in omega-6 was held to be harmful to health³ whereas the Inventor finds beneficial effects at higher dosages of omega-6. Prior art overwhelmingly teaches omega-6 less than 1-3% of calories, and omega-6 to omega-3 ratio less than 3:1 and closer to 1:1 and even less than 1:1; prior art fails to teach dosage of total omega-6 fatty acids or teaches extremely low dosage of omega-6 such as 1g/day; and prior art fails to teach

² Simopoulos, *Ann Nutr Metab* 1999;43:127–130; Hamazaki et al. *World Rev Nutr Diet*. Basel, Karger, 2003;92:109–132; Lands, *Ann. N.Y. Acad. Sci.* 1055: 179–192 (2005)

³ Ip et al., *Cancer Research* 45,1997-2001, May 1985; Lands, *Nutrition Reviews* 1986:44-6:189-95

formulations of omega-6 and omega-3 in consideration of total lipids (lipids include other fatty acids and lipid vitamins and lipid phytochemicals), typical teaching of omega-6 and omega-3 is in relation to total fatty acids or composition.

The scale of the problem is very large. According to WHO statistics, 33% of Europeans above the age of 15 have a chronic disease (e.g., heart disease, diabetes, cancer, asthma, ADHD), a large part of which is associated with mismanaged lipid consumption including omega-6 and omega-3 (also see Specification, publications⁴, and declarations on record). Premature deaths of 550,000 working-age people across European Union countries from chronic diseases cost EU economies EUR 115 billion or 0.8% of GDP annually. This figure does not include the additional loss in terms of lower employment rates and productivity of people living with chronic health problems. (See <http://www.oecd.org/health/europe-paying-a-heavy-price-for-chronic-diseases-finds-new-oecd-ec-report.htm>).

For further details and evidence, see Attachment A, p. 4-6, Exhibit D, paragraphs [002]-[004], Exhibit E (Wikipedia pages one omega-6), and the case history on EP Register. Over 40 references are on record as evidence of above. Evidence submitted to EPO includes nine declarations from esteemed scientists, evidencing that there is mass confusion in the art (also evident from EPO citations) and that claimed inventions are extremely important for public health. For example, see Patents for Humanity application, Attachment A, Exhibit A, prepared for US Patent and Trademark Office for corresponding cases (e.g., US Patent 1029295 B2).

All the evidence demonstrates the misinformation is widespread and continues to date. **The misinformation is in part because piecemeal patents in the nutrition field create an environment in which misinformation flourishes and perpetuates.** For example, 100s of patents have been issued, each directed to a narrow application of low ratios of omega-6 to omega-3, which were then marketed with advertisements hyping omega-3 out of context.

Whereas the *unexpected* correct solution taught in the subject patent applications is higher ratio of omega-6 to omega-3 with restricted dosage of omega-6, *not* smothering omega-6 with omega-3, and consideration of other lipids in the formulation.

In other words, prior art failed to understand the unexpected synergistic effects of higher ratios of omega-6 to other lipids and the dosage of omega-6 and the direction in which to proceed. The Prior art as a whole taught reduced intake of omega-6 and sought to suppress its actions with other lipids because the near-term effect of increase in omega-6 produced adverse symptoms.

Therefore, the subject innovation solves a long-felt critical need in humanity and has immense and real potential to enhance and protect public health, but for such innovation to take hold a significant patent as claimed is necessary, which will allow clear teaching, facilitate partnerships for implementation of innovation, and eradicate misinformation.

⁴ E.g., Bhagat U. Das UN. "Potential role of dietary lipids in the prophylaxis of some clinical conditions" Arch Med Sci 2015; 11, 4: 807–818.

III. Improprieties in Examination And Appeal Review

A. EPO Rejected the Parent Case Under the Pretext of Article 123(2) Because EPO Could Not Reject the Claimed Inventions Under Articles 54 and/or 56 EPC

First, we discuss the premise of Articles 54 and 56, because inability to reject the claims under Articles 54 and 56 in the current case has led EPO to overreach and improperly apply other rejections such as “added matter” under Article 123(2) and Unity of Invention under Article 82 EPC. The real reason for the objections, evident from prosecution history, is to restrict the scope of the claims, which has compromised the innovation and will further compromise the innovation.

In 10 years of worldwide prosecution no prior art has surfaced that could legitimately be said to destroy the novelty of the subject claims in accordance with Article 54 EPC, and lack of inventive step objection in accordance with Article 56 EPC could not be legitimately maintained upon the claims due to new insights presented, disadvantages predicted in the prior art, unexpected results, continuing opposite teachings and misinformation in the art, and critical unmet public health need. (GL, G-VII, 9 and 10.1-3).

The legal requirements for novelty rejection under Article 54 EPC are very strict and rightly so. In order to destroy novelty, the applicable prior art must disclose and enable the exact same invention with every single element as recited in the claims. The underlying principle of novelty rejection is that public—skilled persons including competitors—has been fully informed of the exact solutions and how to practice them and there can be no doubt about this. There are a series of EPO case laws that have held:

1. Lack of novelty is a question of inevitability and not a question of probability (T12/81, T270/97, T583/01).
2. Subject-matter described in a document can only be regarded as having been made available to the public, and therefore as comprised in the state of the art pursuant to Art. 54(1), if the information given to the skilled person is sufficient to enable him, at the relevant date, to practice the technical teaching which is the subject of the disclosure, taking into account also the general knowledge at that time in the field to be expected of him (T 26/85, T 206/83 and T 491/99)(GL, G-VI, 4).
3. Disclosure can only be considered "implicit" if it is immediately apparent to the skilled person that nothing other than the alleged implicit feature forms part of the subject matter disclosed (T 95/97).
4. The teaching of a document, independent of its nature, is not to be interpreted as embracing equivalents not disclosed in that document (T 167/84, T 517/90, T 536/95).

"[w]hen considering novelty, it is not correct to interpret the teaching of a document as embracing well-known equivalents which are not disclosed in the document; this is a matter of obviousness" (GL, G-VI, 2).

5. A sub-range selected from a broader numerical range of the prior art is considered novel (see T 198/84 and T 279/89; and GL, G-VI, 8).
6. Generic disclosure does not take away the novelty of a specific disclosure (rivets are considered novel over generic fasteners) (GL, G-IV, 5).
7. Patenting is also not excluded where a dosage regime is the only feature claimed which is not comprised in the state of the art (G 2/08).

Thus, there is clear and *purposeful* distinction between lack of novelty and lack of inventive step, in that the law recognizes that in order to destroy novelty a prior art document must disclose and teach how to practice the *exact same* invention then only it can be said that this is in possession of the public. Furthermore, a selected range from a broader numerical range is considered novel.

For instance, if there were a reference that exactly described and enabled a formulation to cure common cold permanently, then common cold would be cured. It would defy every conceivable logic if there is a reference that exactly describes and enables the formulation to cure common cold (e.g., dosage of compound A above X g/day), yet billions of humans repeatedly suffer the misery of common cold. Therefore, it is flawless if a reference *exactly* describes and enables claimed limitations, then such claims are not novel.

However, if exact same formulation is *not* described in the prior art, it is *not* clear what aspect of the prior formulation is problematic (e.g., how much compound A in absolute and relative to compound B), and there are *opposite teachings* to the claimed formulation (e.g., dosage of compound A below X g/day) and the public continues to suffer from the misery (like common cold), then the claimed formulation (ratio of compound A to compound B Y:1 and compound A above X g/day) can neither lack novelty nor inventiveness.

However, ED-1 extremely improperly disregarded the *principles built into the law* in Articles 54 versus 56 EPC in examining the parent application. ED-1 improperly alleged that the subject claims are anticipated by *individual* oils, even though a mixture from different sources was inherent in the "formulation" claims presented to ED-1. Subsequently upon appeal Applicant explicitly recited "mixture of lipids from different sources" in the claims presented to BoA; to which BoA responded by alleging "added matter" in all claim requests including where ED-1 had conceded to no added matter, because BoA had no excuse left to sustain rejections under Article 54.

Thus, EPO rejected all claim requests under the pretext of "added matter" under Article 123(2) EPC because rejections under Articles 54 and/or 56 EPC could not be sustained.

(i). ED-1 Conceded That Article 123(2) EPC was Satisfied in AR9-10 but Applied Article 56-type Rejections Under the Heading of Article 54 EPC to AR9-10

ED-1 applied improper “added matter” objections under Article 123(2) EPC to Main Request and Auxiliary Requests 1-8 but conceded there was no added matter in Auxiliary Requests 9 and 10⁵ (“AR9” and “AR10”), to which it applied improper “novelty” objection under Article 54 EPC.

Despite strict anticipation requirements (and evidence of public suffering) ED-1 rejected the parent application, AR9 and AR10, over alleged anticipation by each, D7 (reconstructing example 5 in hind sight) and D10 (fatty acid content of individual oils, alleged for the first time at the Oral Proceedings⁶), disregarding the terms “formulation”, “dosage of omega-6 and omega-3”, and “by weight of total lipids” recited in Claim 1, but neither recited nor enabled in D7 or D10⁷. Alleged anticipation by both D7 and D10 by ED-1 is astoundingly improper. Further, AR10 was solely rejected over alleged anticipation by mere recital of fatty acids in each of soybean oil, walnut oil, and wheat germ oils, in a table in D10 (see cited table below) and other phytochemicals possibly present in such oils based on food composition tables (D16).

EFA PARENT OMEGA 6 AND PARENT OMEGA 3 COMPOSITIONS OF SEEDS

Seeds		fatty acid percentage in oil						
		Polyunsaturated			Monounsaturated	Saturated		
Name	Fat Content in seed (%)	LNA 18:3w3 (%)	LA 18:2w6 (%)	LNA+LA w3+w6 (%)	18:1w9 (%)	18:0 (%)	16:0 (%)	Total (%)
hemp	35	20	60*	80	12	2	6	8
chia	30	30	40	70	-	-	-	-
kukui	30	29	40	69	-	-	-	-
flax	35	58	14	72	19	4	5	9
pumpkin	46.7	0-15	42-57	57	34	0	9	9
soybean	17.7	7	50	57	26	6	9	15
walnut	60	5	51	56	28	5	11	16
Wheat germ	10.9	5	50	55	25	18	0	18
evening primrose	17	-	81**	81	11	2	6	8

⁵ Decision March 3, 2015, p. 14-15.

⁶ Copying improprieties of the USPTO, see enclosed Letter to the Congress of the United States, Attachment J.

⁷ Decision March 3, 2015, p. 14-16.

As noted above in Section II, at least dosage of omega-6 and relevance of omega-6 to total lipids is not well understood in the art. Then how did ED-1 decide that the *skeletal* disclosure of the composition of individual oils describes and enables the subject “formulation” claims drawn to “dosage” of omega-6 and omega-3 and their concentrations in relation to “total lipids”, which tables are in public domain, but popular media, international scientists, various governments, and industry overwhelmingly teach to mix these oils to achieve low absolute and relative intake of omega-6 fatty acids⁸? *In other words, the individual oils in the prior art have neither disclosed the lipid dosages, the focus of the present invention, nor enabled the solutions to public suffering.*

Specificity in patent law has always been held as not anticipated by general prior art disclosure, and ***neither the EPO nor the courts have had any difficulty in examining and upholding specific disclosure and enablement as not anticipated by general prior art***, as noted above in Section III.A, points 1-7. Neither would an individual oil composition enable a skilled person to inevitably practice omega-6 dosages as taught in the subject disclosure (T12/81, T270/97, T583/01) based on state of the art at the time of the disclosure (T 26/85, T 206/83 and T 491/99), nor would it be immediately apparent to skilled person to practice the dosages as taught and consider omega-6 concentration in relation to total lipids from individual oils (T 95/97), nor is it proper to interpret equivalents not disclosed in the document (D10), that is a matter of obviousness (T 167/84, T 517/90, T 536/95). Furthermore, as evident from Attachment A, Exhibit D, paragraphs [002]-[004] and Exhibit E, there is still debate in the art on the claimed subject matter. Therefore, at least lack of enablement by D7 and D10 and that D10’s individual oil is not even a “formulation” was a dispositive point to ruling non-anticipation by D7 and D10, which ED-1 failed to do.

ED-1 applied “novelty” objection under Article 54 EPC because “lack of inventiveness” objection under Article 56 EPC could not be sustained because of opposite teachings, and long-felt critical unmet need. **Thus, ED-1 threw out the public interests, the very purpose why there is a distinction between lack of novelty and lack of inventiveness, and *unilaterally* decided that public suffering was unimportant and *overruled* the EPC** (see discussion above in Section III.A).

Many of the additional objections ED-1 raised are also so far-fetched that they make EPO unworthy of respect. Such as alleging lack of clarity in “age of the subject”⁹ which appears in 100s of dietary guidelines in every country, or alleging that fatty acid profiles of tissue samples in experiments in cited references anticipate the claimed formulations for ingestion¹⁰, or alleging lack of unity in a perfectly unified claim set.

Only the most egregious aspects are presented here to not overwhelm the delegates with detail. However, further details can be seen in Attachment A (e.g., pages 6-10) and at EPO Register.

⁸ Ip et al., Cancer Research 45,1997-2001, May 1985; Lands WEM Nutrition Reviews Vol 44. NO 6. June 1986; Simopoulos et al., Ann Nutr Metab 1999;43:127–130; Lands WEM. Ann. N.Y. Acad. Sci. 1055: 179–192 (2005)

⁹ Decision March 3, 2015, p. 5.

¹⁰ Summary of call with Chairman submitted to EPO on February 3, 2015, p. 2 #3.3.

(ii). BoA Applied Article 123(2) EPC Rejections to ALL Claim Requests Even Where ED-1 Skilled Persons Conceded Article 123(2) Was Satisfied
AND
BoA Colluded with Applicant's Own Representative to Undermine the Applicant

In order to overcome the ED-1 improper anticipation rejections over individual oils, the claims presented to BoA were amended to recite,

“A lipid-containing formulation comprising a mixture of lipids from different sources...”

Additionally, despite disagreeing with all objections Applicant made good faith serious efforts to overcome all objections, submitting on 09 July 2015, 21 alternate claim requests (Main Request and 20 Auxiliary Requests) successively overcoming all Articles 123(2), 82, 84, 54 and 56 EPC objections with 63-page Grounds of Appeal thoroughly rebutting the objections.

Two years later, on 18 April 2017 BoA issued a communication reraising some points rebutted in the Grounds of Appeal, without a word about the rebuttals. This was shocking because then what is the point of submitting Grounds of Appeal? Even if additional grounds were raised, counter argument should have been given to the rebuttals or the objections that have been rebutted should have been withdrawn. For detailed discussion see Attachment A, p. 17-21.

Nonetheless, Applicant responded to BoA communication on 28 June 2017 in a conciliatory tone with arguments and two additional Auxiliary Requests. However, BoA disregarded these arguments also, as discussed below. Again, then what is the point of submitting a response to BoA communications?

At the oral proceedings held in July 2017, BoA stated at the outset that it was minded of rejecting the application because of “possible” in other words, perceived anticipation by prior art. See Attachments A p. 25-26 and B p. 2. In other words, only for this case, BoA had overruled the law discussed above in Section III.A that to be anticipatory the prior art must inform public—skilled persons including competitors—of the exact solutions and how to practice them with specificity and without ambiguity and disregarded overwhelming evidence that a competitor could not obtain the claimed subject matter because competitors were teaching and claiming the opposite subject matter even after the filing of the subject application. See Grounds of Appeal submitted on 09 July 2015, p. 32-61; also see US Patent 7759507 issued on 20 July 2010 claiming, “the ratio of said omega-6 fatty acids to said alpha-linolenic acid (C18:3n-3) [one of the omega-3 fatty acids] is from about 0.25:1 to about 3:1”; and Attachment A Exhibit E accessed on 29 January 2018.

Because no legitimate anticipatory prior art could be cited BoA applied the allegation of “added matter” under Article 123(2) EPC to ALL the claim requests.

BoA zeroed in on the combination of features recited below alleging “added matter” because the combination was recited in Claim 1 of all claim requests; in this way BoA could reject all requests in one stroke.

“a dosage of omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1...”
and
“omega-6 fatty acids are 4-75% by weight of total lipids and omega-3 fatty acids are 0.1-30% by weight of total lipids.”

This was improper because:

- a) Applicant had already rebutted this objection in the response to BoA communication (points 7.3.1-7.3.5) submitted on 28 June 2017, asserting Tables 14-19 and original Claim 8 explicitly teach that formulations comprising ratios of omega-6 to omega-3 fatty acids are combined with their concentrations in reference to total lipids; and even if it was not explicitly taught it is permissible to combine separate items belonging to different embodiments described in one and the same document, if such combination has specifically been suggested (see T 305/87), which is suggested in Example 1 for instance.
- b) ED-1 had not objected to the *combination* in any of the requests. AR9-10 submitted to ED-1 reciting this combination were not held to “add matter” by ED-1. ED-2 has also not objected to the combination in the divisional case (Written Opinion March 14, 2018, p. 21) (though ED-2 is otherwise improper, see Section III.C below). Examiners are skilled persons, evidencing claimed *combination* is easily obtainable by skilled persons.
- c) Applicant had provided declarations from five different scientists (Pan and Shen declarations submitted on 9 May 2014, and Erickson, Rustagi, and Rucker declarations submitted on 5 December 2014) that the claimed subject matter is directly and unambiguously obtained from the Specification.

Additionally, BoA improperly alleged that omega-9 fatty acids were an essential feature of the claimed subject matter. It should be noted that omega-9 fatty acids are not recited in original claim 1.

For further detail see Attachment A, p. 19-21, 25-26, 27-28 and response submitted to BoA communication on 28 June 2017, p. 12-15.

Most disturbingly, BoA colluded with applicant’s own representative to undermine the applicant.

The representative, Mr. Michael Alt initiated the behavior by objecting to the Applicant’s CEO, Ms. Urvashi Bhagat (the undersigned) from arguing at the oral proceedings and repeatedly obstructing Ms. Bhagat. Although at first instance BoA said that there was no issue with the Ms. Bhagat making the arguments because the proceedings were ex-parte, but subsequently by laughing at such occurrences, BoA encouraged Mr. Alt and undermined the Applicant.

The Board’s minutes do not record this pivotal occurrence. Therefore, it is very important that there should be exact account of all BoA hearings, independent from the Board’s minutes.

Applicant requested on 20 December 2017, that page 2 of minutes be corrected as follows to reflect this occurrence.

“Ms. Bhagat attempted to make arguments before the Board when Mr. Alt interrupted her. Chairman said that there was no issue with Ms. Bhagat making the arguments, because the proceedings were ex-parte. However, when Ms. Bhagat attempted to speak again, Mr. Alt threw his pen making it uncomfortable for Ms. Bhagat to speak subsequently. The Board laughed at the lack of support from the counsel.” See Attachment B, p. 2.

Detailed account of this behaviour is described in Attachment A, p. 23-26; and evidenced in Exhibit C, Applicant’s Correspondence with Mr. Alt of Bird and Bird, 16 August 2017 to 18 September 2017, and Exhibit D.

Ms. Bhagat testified in Exhibit D paragraphs [0012]-[0015] of this humiliating experience. Specifically, see following testimony in paragraph [0014]-[0015]:

“From this point on the discussion in oral proceedings deteriorated. Mr. Alt was making feeble arguments, not citing what I wanted him to cite, and obstructing me from speaking, and the Board was an accomplice. There was an apparent collusion between Mr. Alt and the Board to undermine the subject application. Although I sporadically tried to argue again during the rest of oral proceedings, it was difficult for me to do so, because of objections and lackluster support from Mr. Alt, and the undercurrent of collusion among the Board and Mr. Alt. Each time I spoke, I spoke worriedly and hurriedly to avoid being cut off and the Board ridiculing and subverting the arguments.”

Furthermore, BoA dispatched the Minutes of Oral Proceedings on 03 August 2017 stating,

“[t]he Chairman gave the Board’s conclusion that claim 1 [of Main Request] did not meet the requirements of Article 123(2) EPC.” (Bottom of page 2).
“[t]he Chairman gave the Board’s conclusion that claim 1 of none of Auxiliary Requests 1 to 22 complied with Article 123(2) EPC.” (Bottom of page 3).

Applicant objected to “the Board’s conclusion” and requested that the minutes be corrected because the appeal was withdrawn when the BoA Chairman had said, “I have only given Board’s preliminary views, not conclusions.” See Exhibit D, paragraph [0020] and Attachment B, p. 2-3.

BoA refused to correct the minutes on 17 January 2018, denying the incidences obstructing Ms. Bhagat from presenting Applicant’s case at the oral proceedings and insisting “the Chairman did explicitly give conclusions (not just preliminary views) on the allowability of the main request and the auxiliary requests 1 to 22 under Article 123(2) EPC. See Attachments B and C.

If BoA did give “conclusions” and insisted that those were not “not just preliminary views”, then why did BoA allow withdrawal of the appeal? The only logical explanation is that BoA wanted its minutes to be treated as “decision” in examination of the divisional application, without having to affect the case law, singling out the subject case for maltreatment¹¹.

This is injustice! BoA and the representative made mockery out of the oral proceedings compromising the credibility of the legal profession and EPO.

¹¹ Applicant and its later legal representatives have searched the EPO database for minutes of oral proceedings where the appeal was withdrawn and such minutes recite any “conclusions” given at the oral proceedings, no such case was found.

B. The Enlarged Board Turned a Blind Eye to Evidence of Malfeasance in Its Review

Applicant filed a Petition for Review by Enlarged Board of Appeal under Article 112a EPC on 26 March 2018, in view of the following:

- Violation of right to be heard, since Applicant was obstructed from submitting its case at the Oral Proceedings held on 27 July 2017;
- BoA's refusal to correct the minutes on 17 January 2018, insisting that it gave "conclusions (not just preliminary views)" synonymous with "decision"; and
- The adverse effect on Applicant's divisional application, i.e., ED-2 treated BoA's minutes as a "Decision"—Written Opinion issued in the Divisional case on March 14, 2018, p. 2., states, "the earlier (Parent) application has been refused for deficiencies under Article 123(2) EPC." (As noted in Section III.A(i) above, ED-1 refused the parent application (AR9-10) for alleged deficiencies under Article 54 EPC, not Article 123(2) EPC. Thus, ED-2 treated BoA's "minutes" as a "Decision" and gave similar objections as BoA.)

Applicant asserted that in accordance with Article 112a (2) lit. (c), (d), and (e) EPC the Petition is based on the grounds that,

(c) a fundamental violation of Article 113 occurred in that Petitioner's right to be heard was violated;

(d) a fundamental procedural defect defined in the Implementing Regulations Rule 142 and Article 133(2) occurred in the oral proceedings held on 27 July 2017 in that the Petitioner was unrepresented (as noted in Section III.A(ii) Mr. Alt in effect represented the BoA not the Applicant); and

(e) a criminal act established under the conditions laid down in the Implementing Regulations had an impact on the oral proceedings and the "conclusions" imposed by the Board, in that there was a collusion between the Board and Mr. Michael Alt of Bird and Bird (Representative 1), at the oral proceedings held on 27 July 2017, to undermine the Petitioner.

Among evidence, Applicant submitted Exhibit C, Applicant's Correspondence with Mr. Michael Alt of Bird and Bird, 16 August 2017 to 18 September 2017, and Exhibit D, Declaration of Ms. Urvashi Bhagat dated January 30, 2018. For example, Mr. Alt admitted that he obstructed Ms. Bhagat from speaking, stating, "I... aimed at controlling your submission" (see Ms. Bhagat's email of 16 August 2017 and Mr. Alt's response of 31 August 2017).

Among relief, Applicant requested that the oral proceedings of 27 July 2017 be invalidated, and the appeal proceedings be reopened.

For further details, see Attachment D, Petition for Review by the Enlarged Board of Appeal under Article 112(a) EPC submitted on 26 March 2018.

The Enlarged Board of Appeal (EBoA) issued a communication on 12 June 2018. **Applicant was surprised to find that EBoA too had acted improperly disregarding the evidence cited in and submitted with the Petition.**

In its response to EBoA communication on 22 July 2018 (see Attachment F) Applicant pointed out the following:

- (i) EBoA had not acknowledged key evidence Exhibit C and Exhibit D submitted with the Petition, and Applicant corrected EBoA's enumeration of "Facts."
- (ii) BoA minutes were a "Decision" because of
 - a. the substance of the contents e.g., "conclusions" (synonymous with "decision") versus "preliminary views" in the paper titled "Minutes of the oral proceedings" and the BoA itself had insisted in its refusal (Attachment C) that the "conclusions" are "not just preliminary views",
 - b. the finality of the "minutes" on the case,
 - c. BoA made reasoned choices in arriving at "conclusions",
 - d. the procedural context, where Representative 1 was in collusion with BoA, and
 - e. that EPO itself had held the minutes to be decision in the divisional case.
- (iii) Applicant's right to be heard was violated because Applicant was obstructed in submitting its case.
- (iv) There was criminality in the act where Representative 1 was in collusion with BoA.
- (v) The withdrawal of the appeal was induced by BoA.

Applicant also asserted that the objections could only be raised when the Board refused to correct the minutes on 17 January 2018 to state "preliminary views" instead of "conclusion" (synonymous with "decision") and when BoA confirmed that it was in collusion with Representative 1 by declining to correct the minutes (see Attachment C).

See Attachment F for detailed response.

On 10 October 2018, EBoA issued its Decision again disregarding glaring evidence repeatedly called to attention. Annotated copy of the Decision R4/18 of the Enlarged Board of Appeal of 10 October 2018 is attached here as Attachment G.

Additionally, Applicant made of record the reasons why EBoA decision was improper in a Formal Complaint submitted on 12 November 2018 (Attachment H), where the Applicant's contentions included the following:

1. EBoA has disregarded evidence Exhibits C and D repeatedly cited in the Petition (see page 5 (points 7.a, 7.d), page 6 (points 7.f-g), page 7 (points 7.h-i), and page 8 (points 7.k and 9)), and throughout in the response to EBoA communication. The statements of employees of one of the parties were regarded as sufficient evidence in a series of appeal cases, e.g. T 162/87 and T 627/88, T 124/88, T 482/89 (OJ 1992, 646), T 363/90, T 830/90 (OJ 1994, 713), T 838/92 and T 327/91, T 190/05, J 10/04. Accordingly, EBoA should have honorably considered the Exhibit C and D.
2. What other evidence does the EBoA expect? Only five people were present in the oral proceedings. Four of them (Representative 1 and BoA) were in collusion against the Petitioner. Partners in crime do not implicate other partners. The fifth, the Applicant's

CEO gave testimony, Exhibit D, supported with Exhibit C. Besides the Applicant's CEO, does EBoA expect the walls to testify? It is noted that EPO ensures that there is no evidence of its wrongdoings at the oral proceedings by generally not allowing any cameras and sound recordings¹².

3. When the BoA expressly stated in its refusal to correct the minutes “the Chairman did explicitly give conclusions (not just preliminary views) on the allowability of the main request and auxiliary requests 1 to 22 under Article 123(2) EPC,” (emphasis added) it confirmed that “conclusion” is different from “preliminary views”. BoA made it clear that it did not use “views” or “conclusions” as alternates, or synonyms. In other words, BoA insisted that it gave a “decision.” Further, in the submission of 22 July 2018 (pp. 11) it was evidenced “conclusion” and “decision” are synonyms in the English language. EPO cannot distort the language per its convenience.
4. BoA wanted its minutes to be treated as a “decision” without having to formally issue a decision, that is why it insisted it gave “conclusions” and therein lays a major wrongdoing.

C. ED-2 in the Divisional Case Takes License for More Improprieties from BoA and EBoA Improprieties in the Parent Case

As called to attention in Section III.B above ED-2 treated BoA “minutes” as a decision, and took license for improprieties from BoA as evidenced by the following:

- a) ED-2 explicitly stated in the Written Opinion issued on March 14, 2018, p. 2., “the earlier (Parent) application has been refused for deficiencies under Article 123(2) EPC.” However, as noted in Section III.A(i) above, ED-1 refused the parent application (AR9-10) for alleged deficiencies under Article 54 EPC, not Article 123(2) EPC. Thus, ED-2 treated BoA’s “minutes” as a “Decision”.
- b) ED-2 took cues from BoA. For example, ED-2 alleges that omega-9 fatty acids are an essential feature of the invention in Written Opinion issued on March 14, 2018, p. 3-4, #1.2, similar to BoA allegation (Attachment B p.2.), but ED-1 skilled persons could obtain from the disclosure that omega-9 fatty acids are not an essential feature and held AR9-10 (which do not recite omega-9 fatty acids in claim 1) to comply with Article 123(2) EPC.

Further, when EBoA condoned BoA improprieties, then it was clear to ED-2 that they were free to disregard the law and evidence because the entire chain of command at EPO will condone their malfeasance.

Furthermore, taking their cues from BoA and EBoA ED-2 goes a step further in improprieties, and alleges that the recitation in claim 1 in terms of “by weight of total lipids” also “adds matter” and therefore violates Article 123 (2)/76(1) EPC (see Written Opinion p. 1.2.1), which neither ED-1 nor BoA had alleged.

¹² GL E-III, 8.2.1 and 10.1; and Notice of the Vice-Presidents Directorates-General 2 and 3 dated 25 February 1986, OJ EPO 1986, 63

It should be noted that original claim 1 does not recite omega-9 fatty acids, and the terms “by weight of total lipids” are the preferred embodiments throughout the original disclosure, e.g., claims 35, 36, and 38.

For detailed arguments, see responses of 02 November 2018 and 25 June 2019 (Attachment I) thoroughly rebutting all objections raised in the Written Opinion and Exam report dispatched on 25 February 2019.

Therefore, Applicant is justified in being filled with indignation from the poor treatment it has received for the last 10 years from EPO, especially for such an important invention for public health, which EPO should have advanced out of turn and allowed quickly.

IV. EPO Has Disregarded Numerous Complaints Submitted and Issues Brought Up by the Applicant

Applicant has submitted numerous complaints to EPO in the Parent and Divisional cases including the ones listed below. Almost all of which were addressed to Mr. Piotr Wierzejewski, Administrator Quality Management, the President, Secretary of the Administrative Council, Karin Seegert (Chief Operating Officer Healthcare, Biotechnology & Chemistry), Titia Kanbier (Examiner of the Divisional Application), and Reinoud Hesper (Patent Law). Some of the complaints were also addressed to EBoA. The appeals to BoA and EBoA are also technically complaints, but they are not listed below, as they have been separately addressed above.

1. 25 September 2017 Email – Issues brought up: Substantially similar claims were submitted to dozens of other jurisdictions, which do not find “added matter.” Is EP skilled person particularly inept? (There is no difference in scientific training in European countries and other countries, neighboring Israel, for example. Then why does EPO allege “added matter” as a rule, rather than exception as in other jurisdictions? Intellectual Property High Court of Japan and Intellectual Property Trial and Appeal Board of South Korea overturned the respective patent office’s lack of support, clarity, and enablement objections in the corresponding Applications. See the respective translated decisions with the claims in Attachments K and L.)
2. 11 December 2017 Email – Issues brought up: Same as above and that mindlessly restricted patents are harming the health of millions of Europeans and obstructing innovations.
3. 30 January 2018 Formal Complaint — See discussion under Section III.A above and Attachment A with Exhibits A-E.
4. 12 February 2018 Email – Issues brought up: Response to Mr. Wierzejewski’s letter of 01-02-2018. ED-1 and BoA raised clarity objections on everyday terms and “added matter”

objection on matters that are easily derived by dozens of patents offices around the world, and that there were divergent holdings by ED-1 versus BoA. Then they are just raising objections as convenient, without justification. We understand that EPO is obliged to observe EPC together with Guidelines for Examination, as well as jurisprudence of the Boards of Appeals, but that is exactly the problem, that they were not observed by ED-1 and BoA as detailed in the Formal Complaint dated 30-01-2018. Further, you have also alluded that Patent Prosecution Highway is a hoax by saying that allowance at JPO has no bearing at EPO.

5. 26 February 2018 Email – Issues brought up: The manner in which EPO insists that applicants work through lawyers, combined with the manner in which EPO controls the lawyers practicing at EPO, essentially equates EPO exploiting small inventors in collusion with lawyers. See details with evidence in our Formal Complaint dated January 30, 2018. Lawyers are worried about their relationship with EPO, EPO is concerned about fees that it collects (EPO is one of the few jurisdictions that requires annuity payments before patent grant, and the highest annuity fees), and EPO is the most unreasonable in that EPO denies restatements as “added matter.” Then EPO is an unethical revenue focused business that induces disclosure and denies rights, heedless to innovation. There were five people in the room at the oral proceedings held on 27 July 2017. The Board (three men) with an agenda to deny patent because it would have solved many problems (unfavorable to EPO revenue), the lawyer (one man) concerned about maintaining his relationship with EPO/Board and uninterested in solving the problem because that might adversely affect his revenue streams from other clients. The inventor/applicant was alone, ganged upon, and violated. We hope EPO can understand why we are so upset. There should be impartial public representatives present at oral proceedings; minutes to oral proceedings should be taken by a public body via audio recording; self-representation should be made easier; and oral proceedings should not be held in cases where applicant is outnumbered, in favor of written communications.
6. 20 March 2018 (three Emails) – Issues brought up: ESR issued by EPO in the divisional case on March 14, 2018, alleged added matter mindlessly. If EPO thinks skilled persons, for example, MD/PhDs in this case, are so dumb, then EPO’s existence is futile. There is no justification for existence of an organization whose charter on one hand is innovation but on the other hand is so rigid that it suffocates innovation. Added matter has to be considered in context of the invention and disclosure. In this regard, every single person everyday consumes n-6 and n-3 through their diet. After reading our disclosure a biology major (a skilled person) can understand the invention and derive the claimed subject matter without any difficulty whatsoever. It is a separate matter that they likely won’t be able to practice the disclosure in daily life, because lipids are unpredictable in their sources. That’s why commercial structure that we are building is necessary.

Why don't the examiners honor that literal support is not required?

Why don't the Examiner's honor that support is similar to novelty question?

Everything we have claimed is not novel for subsequent filers. (see T 667/08, T 201/83, T 305/87, and T 190/99).

Moreover, the EPO applies different standards when reading the Applicant's disclosure, in that it alleges nothing is disclosed, but when reading prior art, it conveniently adds on to prior art to allege anticipation or obviousness.

Purpose of the emails is not to give arguments. We will properly respond to the substantive EPO examination reports through our EPA attorney. The point in these emails is to call attention to the improprieties and double standards at the EPO. EPO is willing to do anything to knock down inventions. We want to ensure that top management is aware of how EPO is abusing inventors. You are making public ill and you are abusing inventors, contrary to the interest of the public. This is crime. Plain and simple!

7. 21 March 2018 (two Emails) — Issues brought up: The the last few emails were written because the written opinion of 14.03.2018 is highly improper. When alleging “added matter” EPO is rigid, basically negating almost all of the disclosure, but when alleging anticipation and obviousness, EPO embellishes the prior art extensively. That is our objection. The alleged “added matter” comes from minds unwilling to understand. We have seen “allowable subject matter” at page 21 of the written opinion. **The issue is that the EPO is changing the essence of the invention.** If you limit us the way you are, then we can't effectively solve the problem. There is a lot of noise in this art. We have to overcome that, and we can do that by clear teaching and building collaborations. It takes several decades and resources to solve this kind of problem. **You have already reduced us to 10-year patent term and now you are compromising what we can do with that. This is the reason for our anguish.**
8. 09 October 2018 Email — Issues brought up: Response to the Written Opinion issued in divisional case on 14.03.2018 is submitted. The support table that was submitted with the claims was ignored. Such thoughtless objections were raised, that it is simply not possible to stay calm after almost 10 years of prosecution. The objections have been applied with eyes closed to the EPO Guidelines for Examination and case law. We are having to submit long arguments again, and again, and again. So far, we have submitted *fifteen* papers in the parent and divisional case and numerous evidence documents. This is a total abuse of process and obstruction of innovation, contrary to EPO charge. The purpose of examination is to earnestly ensure disclosure, clarity, enablement, novelty, and invention. It is not to delay, drag, and compromise innovation by making excuses and misapplying the law. It is clear from our experience with EPO that EPO uses “added matter” as an excuse to compromise innovations and inventors. For example, what part of “Literal support is not required” (see T 201/83, G 0001/93, T 667/08, G 0002/10, GL H-IV, 2.2) do the EPO personnel not understand? You must understand not all problems can be solved by mere disclosures. So just because we have disclosed it does not mean that public

has derived the full potential benefits of the innovation. For some problems to be solved a protected environment is necessary to nurture and implement the innovation. The current innovation such, which without adequate patent protection is extremely difficult to implement above the noise in the art.

9. 22 October 2018 Email to EBoA — Issues brought up: The decision R 04/18 is extremely improper. Applicant's testimony (Attachment A, Exhibit D) was ignored, which testified that Board was improper in laughing in concert with Mr. Alt (highly inappropriate) and made a mockery of the oral proceedings. Conduct at the oral proceedings is important as per EPO case law. If this is how EPO and those who are authorised to represent different clients before the EPO such as EPAs, behave at oral proceedings, then it is clear why attendance at oral proceedings has been dropping. It is beyond doubt that the EPO has created a system, where EPO in collaboration with the lawyers exploits inventors and sabotages innovation. EPO has set up ways of denying patents, prolonging prosecution, while increasing revenues (fees) to EPO. EPO chop off arms and legs of innovation, under pretext of "added matter" so meaningful advancement does not take place.
10. 12 November 2018 Formal Complaint Upon Enlarged Board — See discussion under Section III.B above and Attachment H.
11. 25 November 2018 Email — Issues brought up: Treatment of the subject applications is violation of human rights and obstruction of sustainable development. Applicant is inclined to file a complaint at the United Nations, the ECJ and ECHR, because,
 - a. Patent practice is skewing the marketplace in favour of drugs and devices.
 - b. When nutrition patents are granted, they are severely restricted which causes confusion and makes the problem worse, as EPO is doing under the pretext of "added matter" and "unity of invention".
 - c. Public has been paying for lipid patents since 1870s (<https://en.wikipedia.org/wiki/Margarine>) but the problem has not gone away.
 - d. The very issue is that they are not formulating lipid dosages by demographics, which is the necessary foundation, but they are inventing different oil mixtures, or structurally altering molecules.
 - e. It was a German patent of structurally altered fats (https://en.wikipedia.org/wiki/Wilhelm_Normann) that gave us hydrogenated fats and caused worldwide diseases for 100 years.
 - f. Thus, occasionally, some mixtures/molecules are promoted but then they realize it does not solve the problem or causes more problems and come back to square one. The result is lipid delivery to public has not substantially advanced in 6000 years.

Because lipids are associated with health at a fundamental level, and nature is unpredictable in lipid content, public suffers at a mass scale. It is a particular problem for impoverished populations. (Patents for Humanity application, Attachment A, Exhibit A was enclosed.) The lipid problem will not go away unless solved as we have proposed and

that is a massive undertaking requiring funds for implementing and teaching, and to be able fend off those who will try to undermine our efforts. The EPO has already compromised and sabotaged the innovation with 10 years of delay.

12. 03 December 2018 Email — Issues brought up: The European lawyers and the EPO collude to compromise innovation because lawyers and EPO find it lucrative to issue many restricted patents at the expense of innovation. This is why there is no material progress in many arts.
13. 11 March 2019 Two Emails — Issues brought up: Exam Report of 25 February 2019 is improper as evidenced by the following:
 - a. Written Opinion dated 14.03.18, cf Form 1507, sheet 24, #14.1; also communication dated February 25, 2019, sheet 6: Under what shameful logic did the Examiner allege that Claim 1 of D1 teaches O₆ to O₃ ratio of 5:1 to 10:1. The correct disclosure in D1 is "a lipid source having an omega **3** to **6** fatty acid ratio of approximately 5:1 to about 10:1." (See Claim 1 and Summary of Invention).
 - b. All the arguments that were submitted in supplemental response in November 2018 were ignored.
 - c. Table of support filed in October 2018 was ignored. We are the inventors, we know the Specification inside out, but it is the insistence of Examiners that they will construe the Specification in a way that allows them to compromise innovation.
 - d. Table of Support submitted with claim filing in October 2017 was ignored.
 - e. Examination Guidelines were ignored.

As evidenced by the above, EPO makes disclosure up or it negates disclosure as convenient. Reader at EPO doesn't understand because the reader is **not** inclined to understand. ED-2 can't even obtain from the disclosure what ED-1 in parent case could.

Patents are **not** charity. We did not ask for some "allowable subject matter." We set out to solve the problem. EPO is compromising the innovation and public health by improperly restricting us. It is unacceptable. It is no wonder that patents accomplish nothing, and public continues to suffer. In 100 years, the lipid problem has not been solved. It is because of such improprieties. EPO is focused on revenue from many small patents not on solving problems.

14. 13 March 2019 Email — Issues brought up: The purpose behind emailing EPO with copies to the President and Council Secretary is that EPO has abused the process for so long that at this time it is necessary for us to give it back unvarnished in plain words that EPO is committing crimes against inventors and public at large. We want this to be noticed in real time by the President and Council Secretary. Therefore, we email whenever we notice something atrocious. **Extraordinary measures are necessary because EPO has refused to give us just examination in past nine years.** Improprieties in discussions on 12 March 2019 with current representative Dr. Radkov were listed and it was said that formal substantial arguments will be submitted by Dr. Radkov. Such

extreme improper examination should never happen in the first place. Purpose of examination is to ensure that public is not already in possession of the claimed subject matter. It is not to harass applicants knowingly and compromise innovation. **EPO is aware that the objections applied are improper, but EPO does that anyway to restrict applicants.** EPO has not understood let alone fully appreciated that EPO through its actions is obstructing innovation and causing harm to the public at large. At this rate we could be 100s of years further and the lipid problem will never be solved, rather more mess would have been created from issuing many restricted patents (and patents like hydrogenated fats). **We hope to wake up seniors at EPO through these emails, as to the wrongs currently going on at EPO.**

15. 14 March 2019 Email — Issues brought up: In-part we are having so much difficulty with the case is that ridiculously improper Unity of Invention objections were applied in the parent case. In order to overcome the improper Unity of Invention objections we had to change the structure of the claims, which is still within our rights, but not the ideal way of writing the claims. Better way of writing the Claim 1 is as in the Main Request submitted in the parent case to ED-1 and the BoA. We will formally address this in due course in the divisional case. In the meantime, we request the responsible people on this list to counsel the Examiners not to apply improper Unity of Invention objection. Then claims can be written as they should be.

16. 27 March 2019 Email — Issues brought up: Additional contentions (in the divisional case), for the review and action of EPO personnel on the list after further review of exam report dated February 25, 2019 and the results of March 12, 2019 EPO consultation with Dr. Radkov mailed by EPO on March 20, 2019. **EPO demonstrates contempt for inventors and their time and financial means, innovations, and public at large by ignoring arguments and evidence submitted over and over and over again—over last nine years in these cases.** For example, on November 2, 2018, we submitted a 27-page long response rebutting each and every of points and sub-points 1-13 in the written opinion dated March 14, 2018, which the Examiner has entirely ignored. Examination Guidelines (GL) are a sham and by extension EPO is a sham, if the Examiners can ignore the Guidelines. For example, the Examiner has ignored the following in examination: GL H-IV, 2.2 (literal support is not required), 2.4 (a combination of the preferred disclosed narrower range and one of the part ranges lying within the disclosed overall range on either side of the narrower range may be derivable from the original disclosure), Article 69(1) EPC (claims determine the scope of disclosure), and G-VII, 5.4 (each feature has to be evaluated in examining novelty and inventiveness). It is clear from the communications that the quality of product in question does not meet the standards set by the President of the EPO. Accordingly, we also consider Director Quality Management's letters to us dated February 9, 2018 and November 22, 2018, to be improper because examination is **not** in accordance with the Guidelines or standards set by the President of the EPO. “Practice of the EPO” (raised in exam report dated Feb 25, 2019, p2) is ultra vires created by EPO Examiners. This has no place in patent examination. Either something is within the law or it is not. There is

no such thing as “this is our practice”, which implies “Yes, we know it is contrary to the law, but we can choose to do so.” That is absurd. It cannot be tolerated in the 21st century.

17. 28 March 2019 Email — Issues brought up in response to Mr. Wierzejewski’s email of 28 March 2019: So far EPO has failed to properly read and respond to over a dozen responses and complaints submitted in the parent and divisional cases, not to mention 20-40 evidence documents that have been submitted evidencing opposite teachings and long-felt critical unmet public health need. EPO is astoundingly improper, such that it cannot even read a plain and simple table—Table 20, listing ~80 nutrients and 40 lipids and their dosage ranges and three paragraphs above the table. You note Guidelines, GL E-VI, 4, but you conveniently ignore the other parts of the Guidelines, such as GL H-IV, 2.2, GL H-IV, 2.4, and GL-VII, 5.4. You want to see what helps you obstruct innovation; you ignore the rest. The purpose of EPO’s existence is not restriction of patents; the purpose is advancement of innovation for betterment of human condition. EPO should be regularly teaching its staff so that they don’t lose sight of the purpose of their existence.

Applicant has not received a meaningful response to the complaints. Thus far EPO has only given sparse and feeble responses to serious issues. This is completely unacceptable and contrary to the interests of the public.

For example, in his letter of 09 February 2018 in response to the Formal Complaint (Attachment A) Mr. Wierzejewski simply covered up EPO improprieties and suggested that Quality Management is essentially powerless. The entire lengthy Formal Complaint with five Exhibits was dismissed in one short sentence “*We have come to the conclusion that in this case the procedure was applied in an exemplary way.*”

Further, in his letter of 22 November 2018 Mr. Wierzejewski again covered up EPO improprieties, stating that the EPC and the Guidelines for Examination were observed during the procedure. However, as noted the discussions above the EPC and the Guidelines for Examination were **not** observed during the examination of the parent and the divisional applications. Mr. Wierzejewski also stated that “allowable and patentable subject matter” has been indicated in the Divisional case at page 28 (actually page 21) of the European search opinion. However, that is not the “allowable and patentable subject matter”, that is improperly restricted subject matter that will severely compromise the innovation, which has already been compromised by the EPO due the 9-yearlong prosecution of the application. For detailed rebuttals, see Applicant’s response of 25 June 2019. Also as stated above in Section IV.13 and Applicant’s email of 11 March 2019, patents are not charity. Applicant does not seek some “allowable subject matter,” Applicant rightfully seeks protected environment for proper implementation of the extremely important innovation for public health (further elaborated below).

V. EPO's Unchecked Dominance Over European Patent System Results in Obstruction of Innovation And Fosters Stagnation

—

EPO Has Monopoly Over Patent Grants In 38 EPC Countries, Giving EPO Seemingly Unchecked Dominance Over Inventors, Applicants, and Legal Representatives, Creating Perverse Incentives

A. EPO like any organization seeks to strengthen itself with more revenue at the expense of innovation and fosters stagnation

EPO is autocratic because of unchecked dominance and seeks to empower itself further with more revenue at the expense of innovation. EPO needlessly restricts patent scope and forces divisional applications because many restricted patents and more divisional applications mean more revenue for EPO. However, restricted patents and divisional applications stifle innovation for the following reasons:

- i. Extra prosecution costs and delays from unnecessary restrictions which then have to be challenged under appeal, and more divisional applications are particularly burdensome for small applicant companies that form majority of EPO customers.
- ii. The prosecution delays impede implementation of innovation because investors and strategic partners do not come forward until patent scope is clear. By the time the patent is granted so little patent term is left that the window to nurture the innovation in protected environment is gone (e.g., the subject case is still in prosecution 10-years after filing, during this time over \$100,000 in EPO fees and legal fees have been incurred). **It should be noted that disclosure or teaching is not always enough to solve a problem. In cases such the present one, the complex innovation will not take hold in the absence of a sufficient protected term. Just like a tree sapling needs a fence around it to protect from cattle to allow growth, similarly such inventions need the twenty-year patent term for proper implementation. Therefore, the view that the patent system's objective is to induce disclosure, would be misplaced.**
- iii. Many restricted patents are particularly problematic in nutrition. Thousands of patents are granted on very restricted formulations leading to advertising campaigns that cancel each other out and cause mass misinformation. This leads to total confusion and public stops believing everything.
- iv. The points i-iii above lead to stagnation. Meaningful scope and timely patents are not granted; therefore, foundational problems are never solved or properly implemented. For example, in the field of lipids we have known at least since the

invention of oils 5,000 years ago¹³ that lipids are important for health. In last 100 years, numerous patents have been granted either on extending shelf life (e.g. hydrogenated fats), or on structurally altering lipid molecules (e.g. hydrogenated fats), or on use of a fatty acid (e.g. omega-3) for prevention or treatment of X disease. Such solutions are often lost in the noise or cause great harm to the public (e.g. hydrogenated fats and out of context hype of omega-3). Consequently, decades later the art backtracks, for example, hydrogenated fats are now outlawed 100 years later.

Thus, by granting restricted patents and way too late, and by misplacing incentives, the EPO is making mini-solutions and creation of misinformation more financially rewarding fostering stagnation. At this rate we could stagnate for another 1000s of years without meaningful advancement in the field of nutrition.

An illustration of unnecessary restrictions in the present case is as follows: Because ED-1 improperly kept applying lack of Unity of Invention objection, on appeal to BoA the claim 1 recited above in Section II, was presented as follows in AR13.

1. A lipid-containing formulation comprising a mixture of lipids from different sources, wherein the formulation comprises a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 to 50:1, and wherein the amount of omega-3 fatty acids is between 0.1 to 30% by weight of total lipids.
2. A formulation according to claim 1, wherein the omega-6 fatty acids are 4-75% by weight of total lipids.
3. A formulation according to claim 1, wherein the dosage of omega-6 fatty acids is not more than 40 grams.
4. A formulation according to claim 1, which comprises polyunsaturated, monounsaturated, and saturated fatty acids, and the amount of omega-6 fatty acids is greater than 20% by weight of the total lipids.

However, BoA then relied upon the allegation of “added matter” to obstruct the innovation, and ED-2 copied BoA in the divisional application (discussed above).

B. Perverse Incentives Between EPO and European patent attorneys, such that rather than representing the client the attorneys represent EPO to the client

EPO holds monopoly to control patent grants in almost all European countries and with no apparent legal body above it, therefore, EPO wields unjust power and indirectly controls all European patent attorneys. The legal representatives appear more concerned about appeasing EPO officers than protecting the rights of a small company client. Moreover, both EPO and legal representatives gain in fees from prolonging the prosecution.

In the present case, Applicant’s legal representatives have told the Applicant that EPO keeps track of law firms’ dealings with EPO and punishes law firms unfavourable to EPO. For

¹³ https://en.wikipedia.org/wiki/Vegetable_oil#History

evidence see Ms. Bhagat's testimony (Attachment A, Exhibit D paragraph [007]). Therefore, when representing a small firm (as in the subject case), legal representatives have greater incentive in going along with EPO with whom they will do business for decades representing various clients, rather than the small company that they may only represent on few cases. For evidence see incidents detailed in the Formal Complaint (pages 11-12 and 23-26) and Exhibits B and C (email exchanges with the representatives), and Exhibit D paragraphs [008], [0010]-[0015], and [0021]-[0022]. Large companies on the other hand turn tables because they can bring consistent inflow of cases to legal representatives and their own legal teams into EPO proceedings.

Therefore, for a multitude of reasons EPO has perverse incentives in alignment with legal representatives, which in particular adversely affect small companies. In such cases, client is paying the lawyer, but the lawyer is working for EPO. That is unethical and illegal.

Applicant has not experienced this degree of abuse by legal representatives in alignment/collusion with PTO Officers in any other jurisdiction. There is something wrong about EPO practices that instill this behavior.

C. EPO Ensures That No Evidence of Its Wrongdoing is Preserved

EPO personnel take minutes of oral proceedings and rarely correct them upon requests from parties, as evidenced by Attachments B and C and evidence Exhibits C and D paragraphs [0014]-[0015] and [0020]-[0022]. Further, camera recording or sound recording are almost never allowed in the oral proceedings¹⁴, and if allowed on rare occasions are controlled by EPO personnel.

In other words, no evidence of EPO's wrongdoing at oral proceedings can ever be preserved.

Therefore, EPO has a conflict of interest with innovation, the more it restricts patent scope, i.e. innovation, the greater its revenue; and the more it colludes with applicants' legal representatives, the more its revenue. Therefore, EPO is not only obstructing innovation, but it is fostering stagnation, counter to its charge. Again, this is contrary to the interest of the public the EPO is expected to uphold

¹⁴ GL E-III, 8.2.1 and 10.1; and Notice of the Vice-Presidents Directorates-General 2 and 3 dated 25 February 1986, OJ EPO 1986, 63

VI. Patent-Practice-Made Humanitarian Crises

The dubious practices discussed above have created at least two kinds of humanitarian crises, first towards the public at large, and second towards independent inventors and small entities.

A. Humanitarian Rights Violations of Public at large

1. If Applicant's claims were directed to a drug candidate similarly differentiated over the prior art, the patent would have been granted many years ago (see G 2/08 holding, "patenting is also not excluded where a dosage regime is the only feature claimed which is not comprised in the state of the art"). Though EPC does not disfavour patent grant to nutrition, but EPO practice does, as evidenced above. When patents are favourably granted to drugs and devices it makes them more financially rewarding. Therefore, marketers and providers heavily tout them and make public dependent on drugs and devices. Thus, the patent practice is skewing the marketplace in favor of drugs and devices and taking public farther from prevention.
2. When nutrition patents are granted, they are severely restricted which causes confusion and makes the problem worse, as EPO is doing under the pretext of "added matter" and "unity of invention". As asserted above, piecemeal patents, particularly in the field of nutrition, do not solve problems and cannot advance nutritional arts. Rather, they create confusion by flooding the market with piecemeal product solutions that are then advertised with conflicting messages, leading to mass confusion, and canceling out of the teachings.
3. The misdirected patent policy is why public has been paying for lipid patents since 1870s (<https://en.wikipedia.org/wiki/Margarine>) but the problem has not gone away. The very issue is that patent protection is not provided to formulated lipid dosages for subjects, which is the necessary foundation, but patent protection is provided to different oil mixtures, or structurally altered molecules, or designing new oil varieties, which is of limited value because lipid content will still depend on where and how a species is cultivated.
4. Such missteps take us farther and farther from genuine solutions, in the meantime more harm is caused to public health. For example, it was a German patent of structurally altered fats (https://en.wikipedia.org/wiki/Wilhelm_Normann) that gave us hydrogenated fats and caused worldwide diseases for 100 years.
5. Thus, occasionally, some oils, mixtures, molecules are promoted but then they realize it does not solve the problem or causes more problems and come back to square one. The result is lipid delivery to public has not substantially advanced in 6000 years.

Because lipids are associated with health at a fundamental level, and nature is unpredictable, public suffers at a mass scale (see Section II above). It is a particular problem for impoverished populations. See Attachment A, Exhibit A.

This is a humanitarian crisis from which public has been suffering for at least 100 years, since industrialization of nutrition started to prevail. If patents were equitably granted to nutrition and drugs, then at least nutrition and prevention has a fair chance. However, in the current scenario, where EPO has compromised and sabotaged efforts such as ours with undue restrictions and 10 years of delay in patent grant, nutrition has little chance and the crisis may get more severe.

B. Humanitarian Violations of Independent inventors and Small Entities and Worldwide Effects of EPO Actions

It is extremely arduous for small entities and independent inventors to sustain such long prosecution (10 years in the present case), especially when they can get neither fair representation nor just treatment from any of the EPO's chain of command, Examining Divisions, Board of Appeal, or the Enlarged Board of Appeal, as demonstrated above.

Further, EPO's collusion with Applicant's legal representative is a *grave violation of human rights*, violating the confidence in the legal profession and justice to the very core.

Furthermore, in this case there is evidence of EPO copying USPTO's improprieties¹⁵, and many other jurisdictions in turn have copied EPO's and USPTO's improper actions. That is *the Governments are violating independent inventors/small entities (and the public) in collusion with each other*. Because of this collusion Applicant has had to file scores of extra responses to repeated improper objections and over dozen appeals and lawsuits in various jurisdictions. Imagine the burden all these actions have placed on the small company and its proprietors, and how this has obstructed innovation and reduced the time window to implement the critical innovation.

Thankfully, some governing bodies in some other jurisdictions have demonstrated greater sense of responsibility, duty, and justice than EPO and the United States of America, thus far. For example, Intellectual Property High Court of Japan (in case of Japanese Patent application 2014-099072) and Intellectual Property Trial and Appeal Board of South Korea (in case of Korean Patent Application 10-2010-7026029) have reversed the decisions of their respective patent offices. See the respective translated decisions with the claims in Attachments K and L.

The injustice in United States has been called to the attention of the President, the Speaker, and the Congress of the United States of America. See Attachment J.

Thus, EPO practices (in collusion with other jurisdictions) have put human rights and sustainable development in jeopardy.

¹⁵ Alleged anticipation by individual oils was brought up for the first time by ED-1 at the Oral Proceedings held on 11 February 2015, following USPTO's allegation of anticipation by individual oils as alleged "products of nature" in the Office action of 18 August 2014 p. 14-20, in case of corresponding US patent application number 12/426,034. Additionally, BoA had raised some far-fetched objections copying the USPTO Examiner, such as referring to "different sources" as "different producer" or "different supplier." See BoA Communication of 18 April 2017; also see Attachment A, p. 17-18, 26, 31, and 32. Exhibit D paragraph [0016]-[0017]-[0022].

VII. Conclusion and Remedy Requested

Since ED-1 actions in 2015, four years have been lost in appeal and divisional application processing at the expense of innovation and public health. ED-1 and BoA successfully obstructed innovation and public well-being! They defeated the very purpose of patents, innovation for betterment of the human condition, the very reason for EPO's existence!

To what gain?

EBoA should have shown grave concern upon such violations happening at EPO that are abusive to inventors, applicants, and are sabotaging implementation of innovation for public benefit. Under the circumstances EBoA should have invalidated the oral proceedings to discourage such behaviour. Instead EBoA emboldened the actions, and ED-2 now follows in the footsteps of BoA.

This is extremely detrimental to innovation, public benefit, and EPO's charter.

How can a supra-governmental body, such as EPO, whose very reason for existence is to support innovation for betterment of the human condition obstruct such an important innovation? How can such a body be so irresponsible?

We request the Delegates in the Administrative Council take action to stop this malfeasance and request the following remedies:

1. Maintain close oversight of ED-2 actions in the divisional case along with the President for prompt grant of the case.
2. Due to EPO's malfeasance, adjust the patent term such that the 20 years patent term is counted from the date of filing of the divisional application on 21 July 2017.
3. Contemporaneous record should be taken of all oral proceedings similar to national court proceedings to avoid collusion and misconduct. At least oral proceedings at EPO should be recorded by automated video, a copy of which should be handed to the Applicant immediately at the conclusion of the oral proceedings.
4. There should be closer scrutiny of mindless added matter objections applied at EPO.
5. Reconsider revenue and reward at EPO, removing incentives for unnecessary restrictions that compromise innovation.
6. Ensure that EPO is not influencing Applicant's representatives compromising justice.
7. Extend/adjust patent terms where there are unjust delays in EPO prosecution. Such remedies exist at least at the USPTO and the Brazilian Patent Office, and quite rightly so.


Urvashi Bhagat
Chief Executive Officer

Attachment A:

Formal Complaint, submitted on 30 January 2018 with following Exhibits:

- Exhibit A. US Patents for Humanity Application, 8 November 2015
- Exhibit B. Applicant's Correspondence with Mr. Nick Lee of Kilburn & Strode, 23 April 2015
- Exhibit C. Applicant's Correspondence with Mr. Michael Alt of Bird and Bird, 16 August 2017 to 18 September 2017
- Exhibit D. Declaration of Ms. Urvashi Bhagat, dated 30 January 2018
- Exhibit E. Wikipedia, "Omega-6 fatty acid" (accessed on 29 January 2018)



January 30, 2018

BY EPOONLINE

Directorate Quality Management (www.epo.org/complaints, akiller@epo.org)
<https://forms.epo.org/service-support/contact-us/contacto-form.html>

Christoph Ernst, Chairman, Administrative Council of the European Patent Organisation
Benoît Battistelli, President
Željko Topić, Vice-President Directorate-General Administration
Raimund Lutz, Vice-President Directorate-General Legal/ International Affairs
Karin Seegert, Director, Chief Operating Officer Healthcare, Biotechnology & Chemistry
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European Patent Office
80298 Munich

FORMAL COMPLAINT

European patent application 09 735 962.4 (EP 2 278 885)

Appeal no. T1712/15-3.3.09

Applicant: Asha Nutrition Sciences, Inc.

Dear Mr. Ernst, Mr. Battistelli, and Relevant EPO Officers,

This is to submit a formal complaint reporting abuse and unprofessionalism both by the Examining Division (ED) and the Board of Appeal (Board) in the subject case. Board is expected to be a just body protecting the integrity of European Patent Office (EPO) and applicants' rights, which the Board failed to demonstrate. Highlights of Applicant's experience in both instances are called to attention below. Strong remarks in this complaint are justified considering the Applicant, a small company, has suffered immensely due to this abuse for nearly 10 years, despite the fact that the inventions are directed to solving a ~100-year old problem in the lipid art due to which public health suffers immensely—millions of Europeans are affected costing 0.8% of GDP annually (evidence is cited below).

- (1) Applicant believes that ED and the Board held the scope of Applicant's invention against the Applicant for this reason they abused the Applicant. Ironically, the problem to be solved by the invention is in part due to the confusion created by piecemeal patents. EPO is causing great harm to the public by favoring piecemeal patents and denying inventions that solve foundational problems. It is particularly problematic in nutrition.
- (2) Applicant submits evidence that Applicant has been abused by EPO officers in collusion with Applicant's own authorized legal representatives. Specifically, at the oral proceedings held with the Board on 27 July 2017, Applicant's then-authorized legal representative colluded with the Board, effectively representing the Board, not the Applicant.

For these reasons, which are elaborated below, the oral proceedings held on 27 July 2017 should be invalidated, the subject patent application should be restored, and a new fair appeal board should be appointed to hear the case. A copy of this Formal Complaint is requested to be placed in the electronic file history of the application 09 735 962.4 in the European Patent Register.

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- (iv) Board's Minutes Fail to Record Mr. Alt's Objection to Ms. Bhagat Speaking During the Oral Proceedings and Board's Reaction to The Same and That Effectively Board Colluded With Mr. Alt Against The Applicant
- (v) Board's Minutes Fail to Record Board's Statement that it had to ensure patent was not issued on claims that were possibly anticipated by prior art
- (vi) Board's Minutes Fail to Record the Discussion About "omega-6 to omega-3 ratio of 4:1 or greater"
- (vii) Board's Minutes Misrepresent The Discussion on Combination Of Ranges of Omega-6 To Omega-3 Ratios With The Percentages Of The Fatty Acids and About Non-Essentiality of Omega-9 Fatty Acids in Claim 1 of All Requests; and Board's Actions Are Invalid
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ADDENDUM

- Exhibit A. US Patents for Humanity Application, 8 November 2015
- Exhibit B. Applicant's Correspondence with Mr. Nick Lee of Kilburn & Strode, 23 April 2015
- Exhibit C. Applicant's Correspondence with Mr. Michael Alt of Bird and Bird, 16 August 2017 to 18 September 2017
- Exhibit D. Declaration of Ms. Urvashi Bhagat

I.

PROCEDURAL HISTORY OF THE APPLICATION

The subject Applications has a filing date of 20 April 2009, it entered European phase on 19 November 2010. Supplementary European Search Report (SESR) was mailed on 30 July 2013. Oral proceedings with the Examining Division were held on 11 February 2015. Notice of Appeal was filed on 5 March 2015. Oral proceedings with the Boards of Appeal were held on 27 July 2017, during which the appeal was withdrawn.

II.

BACKGROUND OF THE INVENTION

Prior art overwhelmingly teaches to reduce omega-6 and increase omega-3 intake, there is a wide misconception in prior art that omega-6 is harmful to health, and dosage of omega-6 is poorly understood (Specification paragraphs [0006]-[0007] and rest of the disclosure). Abundant evidence has been submitted to EPO including several scientific publications and eight declarations from esteemed scientists, evidencing that there is mass confusion (also evident from EPO citations D1-D15 in the present case) in the art and that claimed inventions are extremely important for public health.

The claimed inventions were conceived mainly because the Inventor came to know of serious harm to public health caused by the erroneous omega-6 and omega-3 teachings coming out of US National Institutes of Health (USNIH) prior to April 2008, in particular the following,

"uncontrolled excessive production of omega-6 eicosanoids over prolonged periods of time is associated with heart attacks, thrombotic stroke, arrhythmia, arthritis, asthma, headaches, dysmenorrhea (menstrual cramps), inflammation, tumor metastases and osteoporosis. ... The distance-learning site for the Office of Dietary Supplements has a section on dietary reference intakes [<http://efaeducation.nih.gov/sig/dietary2.html>] with a graph and citations [<http://efaeducation.nih.gov/sig/dri.html>]. These show that most people are eating on the order of 20 times more of the essential vitamin-like n-6 linoleic acid than they need. As with vitamin A and vitamin D, from which the body makes potent hormone-like compounds, there is a probable risk in excessive intakes. The website notes evidence for requiring these substances in amounts on the order of **0.5% of calories or less**, but a day's menu in the United States far exceeds that." *WEM Lands* (in collaboration with USNIH) Ann. N.Y. Acad. Sci. 1055: 179–192 (2005), pp183. (Submitted to EPO on 5 December 2014).

Thus, *Lands* (and USNIH) taught less than 1.11g/day of omega-6 (0.5% of calories based on 2000 calories) and "to eat more fish and take an omega-3 supplement" (abstract, page 185 and 189). Several examples in subject Application describe public suffering caused by such teachings. For example, note Examples 12 and 22, where the subjects limited their daily omega-6 intake to ~1 g from EFA supplement and olive oil (which is also erroneously touted in prior art, see *Baum et al.*, Journal of Clinical Lipidology (2012) 6, 216–234, pages 221-223, "Olive Oil [] friend or foe?"; cited in submission to EPO dated 31 October 2013, page 5, and Grounds of Appeal submitted 9 July 2015, page 54), and in addition took 1 g/day fish oil (mostly long chain

omega-3) supplement, and as a result seriously compromised their health. However, in Examples 12 and 22 the Inventor found that at least 11g/day (5% of calories Example 11) omega-6 was needed to reverse adverse health and it took few weeks to nurture the subjects back to safe health. In addition, *Lands* 2005 directs readers to distance-learning websites (efaeducation.nih.gov), which teach public how to achieve *Lands* teachings in day-to-day living.

Additional teachings similar to *Lands* have been called to attention in various submissions to EPO. For example, in Grounds of Appeal at pages 9-10, it was called to attention that there have been concerted erroneous teachings by international scientists (*Simopoulos*. *Ann Nutr Metab* 1999; 43:127-130) on omega-6 and omega-3—opposite to Applicant’s claims.

Since the April 2008 priority date of the subject patent application, state of art has changed in support of the claimed inventions, but confusion in the art persists evidenced by publication on record (*Baum et al. supra*; *Calder*, *Biochimie* 91 (2009) 791–795; *Fritsche*, *Prostaglandins, Leukotrienes and Essential Fatty Acids* 2008:79:173– 175; *Johnson et al.*, *J Acad Nutr Diet.* 2012;112:1029-104) and declarations submitted to EPO (Erickson, Das, and Fritsche declarations submitted on 31 October 2013, and Erickson, Rustagi, and Rucker declarations submitted on 5 December 2014). There is a great continuing public health hazard due to such incorrect teachings and mass confusion in the art, which is also prevalent in mainstream media and products on market directed to the general public. See Exhibit D, paragraphs [003]-[004].

The scale of the problem is very large. According to WHO statistics, 33% of Europeans above the age of 15 have a chronic disease (e.g., heart disease, diabetes, cancer, asthma, ADHD), a large part of which is associated with mismanaged lipid consumption including omega-6 and omega-3 (see Specification, publications and declarations on record). Premature deaths of 550,000 working-age people across European Union countries from chronic diseases cost EU economies EUR 115 billion or 0.8% of GDP annually. This figure does not include the additional loss in terms of lower employment rates and productivity of people living with chronic health problems. (See <http://www.oecd.org/health/europe-paying-a-heavy-price-for-chronic-diseases-finds-new-oecd-ec-report.htm>). **Consider the public health implications for the eight years that this application has been pending at EPO.**

Furthermore, even after the disclosure of the present Application, although a skilled person can practice the solutions based on the disclosure of the application, but there is little chance that public by and large can practice the solutions because less than 1% of public can understand (even name) or measure lipids in lipid sources (see Exhibit A, US Patents for Humanity Application, November 8, 2015, page iii, 3rd paragraph) and the problem pertains to daily life. Therefore, the solutions have to be implemented at public level, rather than skilled person level. From public health perspective, solutions have to be pre-formulated for them and they have to be taught how to adapt the solutions in daily life, a very challenging and expensive feat.

The above backdrop lead the Inventor and the Applicant to pursue the subject patent application because in order to effectively solve the problem significant clear public teaching—overcoming the noise in the art—is required, which requires capital and a protected environment to nurture the solutions. See Ms. Bhagat’s testimony, Exhibit D paragraphs [002]-[005].

If the question is why should the Applicant have rights to the solution, the answer is because the for ~100 years prior art has failed to solve the claimed problem (see declarations submitted on 5

December 2014, paragraph [0026]), because piecemeal patents have already contributed to the problem (e.g., see confusion perpetrated by cited art D1-D15), because narrow patent will create further noise and confusion, and because Applicant has legal rights to the claims as has been repeatedly demonstrated on record.

III.

GROSS IMPROPRIETIES OF THE EXAMINING DIVISION

[Specification reference in this document is to WO2009/131939 A9 (A9) unless otherwise indicated because both International Search Authority and ED had accepted A9 and all communications with ED cited A9. A9 is restatement in better form of what is already in WO2009/131939 A2 (A2). No changes were made to claims in A9 and nothing from A9 affected subsequently filed claims. However, Board had relied upon A2, therefore when responding to the Board Applicant cited A2 (see Section V2-4).]

1.

ED communications of 26 March 2014 and of 31 July 2014 And Applicant's Response 9 May 2014 and 5 December 2014

There were too many grossly improper objections raised by the ED. Following is a just a small sample of the absurdity of the objections in written proceedings.

(i) **Article 123(2) EPC**

Almost all of the rejections in communications of 26 March 2014 and of 31 July 2014 were arbitrary and capricious. They were thoroughly and repeatedly rebutted in the responses submitted on 9 May 2014 pages 1-7, and on 5 December 2014 pages 6-10, citing T667/08, which held that teaching conveyed by the disclosure was relevant not explicit disclosure, and T201/83, which held that exemplified value could be extracted based on entirety of the disclosure. **The focus of the entire disclosure is that prior art misunderstood the importance of omega-6 for health and that it is a misconception that omega-6 is unhealthy, rather the risk is that of omega-3 and other lipids suppressing critical for health omega-6 activity. Therefore, omega-6 to omega-3 ratio should be high and total lipids should be considered, most importantly dosages of omega-6 and omega-3 should be controlled. This is established in the very beginning of the disclosure at paragraphs [006]-[007] and then at paragraphs [0021]-[0022].** In such a disclosure instant claims are perfectly supported. This discussion is intentionally kept brief because deeper discussion on the subject is provided under Section V - Proceedings Before The Board Of Appeal.

(ii) Article 84 EPC

Following terms in claims were objected (communications mailed on 30 and July 2013 and 31 July 2014), which are all extremely commonly used in the art. Almost in every country, every government and numerous private bodies publish annual dietary guidelines reciting and defining such terms, further these terms appear in various dictionaries and scientific papers, and furthermore instant Specification describes these terms. The following is part of the submissions as support.

- Phytochemicals: known to skilled artisans (Wikipedia: chemical compounds that occur naturally in plants), also see para 22-27, 30, 33, and para 72.
- Daily amounts: see tables 9, 10, 11, 12, 13, and 20, and example 7 and 8.
- Based on: known to skilled artisans (Dictionary: (be based on) derive from, spring from, stem from, originate in, have its origin in, issue from.) see tables 9, 10, 11, 12, 13, example 7 and 8
- Age of the Subject: see tables 9, 10, 11, 12, 13
- Sex of the subject: see tables 9, 10, 11, 12, 13
- Diet of the subject: see tables 9, 10, 11, 14-19, also see para 33
- Lipid tolerance: see table 12
- Lipid imbalance: see para 17, example 12 para 69
- Medical conditions: see para 14-20, table 13
- Climate of the subject's living area: tables 5,6,7,8
- Avoiding unfavorable dietary interactions: para 33

Thus, the terms appear in thousands of documents in the art. Objecting to such everyday terms that appear in thousands of prior art documents is an example of poor examination and reflects very poorly on EPO. If examiners do not know these terms then they are not qualified to examine patent applications in this art. Applicants should not have to waste any time responding to such arbitrary and capricious objections. In the subject case Applicant repeatedly rebutted these objections with evidence (on 31 October 2013, page 6; on 9 May 2014, page 7; and on 5 December 2014, page 10-12).

(iii) Article 54 EPC

In the communication dated 31 July 2014 ED cited 15 documents, out of which it alleged that D5, D6, D7, and D10 destroy the novelty of at least claim 1 (for brevity only claim 1 is discussed here), which recited,

- A lipid-containing formulation, comprising a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater, wherein:
- (i) omega-6 fatty acids are 4-75% by weight of total lipids and omega-3 fatty acids are 0.1-30% by weight of total lipids; or
 - (ii) omega-6 fatty acids are not more than 40 grams.

Applicant argued with evidence in the response filed on 31 October 2013 (page 3) and 5 December 2014 (page 16-18) that it is well known in the art that lipids include lipid vitamins (e.g. vitamin A, E, D, K) certain phytochemicals (e.g. polyphenols and sterols) and fatty acids, and that cited references teach omega-6/omega-3 by weight of total

fatty acids or dry matter, and that in a composition in which omega 6 is 15% of the total fatty acid content, omega 6 could be, for example, 1% of the total lipid content. Applicant also asserted that none of the cited documents including D5 taught and enabled dosage of total omega-6 fatty acids, which is not well understood in the art. Therefore, requirements of Article 54 EPC have been met.

(iv) Article 56 EPC

Applicant argued with evidence that the claimed subject matter is not well understood: prior art routinely teaches reduction in omega-6 fatty acids, low omega-6 to omega-3 ratios, and ignores dosage of omega-6 and presence of other lipids (vitamin A, E, D, K, and phytochemicals such as polyphenols and sterols) in formulations, which profoundly affect omega-6/omega-3 requirements and health. Applicant also cited opposite teachings and long-felt unmet need. See Section II-Background of the Invention, above. Therefore, for all these reasons, Applicant asserted that instant claims are inventive (31 October 2013 pages 3-5, 5 December 2014 pages 18-25), and requirements of Article 56 EPC have been met.

2.

20 January 2015 Call With Mr. François Leprêtre, ED Chairman

A telephone call was held with Mr. François Leprêtre, Chairman of ED on 20 January 2015 prior to the February 2015 oral proceedings in the hope that an agreement could be reached obviating the need for oral proceedings (see summary of call submitted on 3 February 2015). Applicant's then-authorized representative Mr. Nick Lee from Kilburn & Strode and Ms. Urvashi Bhagat, inventor of the subject matter underlying the referenced application also attended the call.

During the call Mr. Leprêtre conceded to the presence of inventive step, but he was still making excuses. For example, it was most disturbing and objectionable that Mr. Leprêtre alleged that Tables 5-6 of D7 disclosing fatty acid profiles of RBC membrane and plasma of tissue samples in an experiment results anticipated Applicant's Claim 1 recited above directed to dosages. In other words, ED was alleging subject matter not even remotely close to the claim as anticipatory. This is another appalling example of ED improprieties.

Applicant rebutted Mr. Leprêtre allegations as follows (documented at pages 2-5 of summary of the call submitted on 3 February 2015),

Example 5 of D7 discloses 4.2% n6 and 0.6% n3 by weight, but the identity of what underlies the weight for determining the foregoing relative weights is not disclosed. It is reasonably concluded that the concentrations disclosed are by weight of dry matter based on the disclosure in page 2 line 11 and claim 4. Furthermore, claims 2 and 3 disclose omega-6 and omega-3 fatty acids as percent of total fatty acids, not total lipids. Example 5 discloses fat to be 23% of the composition, but 'fat' is not 'lipids'. Towards rest of the composition, 36% protein is disclosed, but remaining 41% composition is not disclosed. Therefore, n6 and n3 'by weight of total lipids' cannot be computed.

Tables 5 and 6 disclose fatty acid profiles of RBC membrane and plasma, but not that of composition to be administered. Whereas the instant claim 1 is clearly directed to a formulation for administration, as it recites "dosage" and "nutrients".

Natural products may contain low amounts of non-fat or non-fatty acid lipids, although not always (e.g. beeswax), but the claimed man-made formulations can have high amounts of non-fat and non-fatty acid lipids. In a man-made lipid formulation, non-fat or non-fatty acid lipids (e.g. sterols and waxes) can be present in relatively large amounts, e.g. 10/20% of a composition. For example, a composition comprising 750mg n6 + 150mg n3 + 100mg phytosterols contains n6:n3 ratio 5:1, 75% n6, 15% n3, and 10% non-fat and non-fatty acid lipids by weight of total lipids...

Thus, as explained in points 3.3-3.7 above, D7 teachings will not inevitably result in products of instant claim 1a)(i), the descriptive “by weight of total lipids” is missing from D7, skilled persons have verified that D7 has “not disclosed concentrations of omega-6 and omega-3 fatty acids by weight of total lipids or principles of integrating non-fatty-acid lipids with omega-6 and omega-3 for effective formulations”, and D7 is not an enabling disclosure. Therefore, D7 cannot be considered anticipatory. [Citing T270/97, T12/81, T583/01, T 167/84, T 517/90, T 536/95, GL¹-G-VI-2, T 95/97].

On the subject of unity of invention, Mr. Leprêtre expressed openness to accepting new/revised claim requests even though it was past the deadline for such submissions. Applicant proposed alternate Claim 1 (see pages 5-6 of summary of call submitted on 3 February 2015) for Mr. Leprêtre’s reaction. However, Mr. Nick Lee of Kilburn & Strode abruptly ended the call. (Mr. Lee was not acting in the best interest of the Applicant discussed below in Section IV- Perverse Incentives Between EPO And Legal Representatives, which also explains that new/revised claim requests were not submitted prior to oral proceedings due to lawyer change).

3. **11 February 2015, Oral Proceedings**

Despite the skilled person’s testimony (Erickson, Rucker, and Rustagi Declarations submitted on 5 December 2014) and case law T667/08 and T201/83, ED maintained Article 123(2) EPC objections in Main Request (MR) and Auxiliary Requests (AR) 1-8. ED demonstrated a modicum of respectability in that AR9 and AR10 were not objected to under Article 123(2) EPC (minutes to oral proceedings pages 2-3 and communication dated 3 March 2015 pages 14-15).

ED also demonstrated some sensibility in that AR9 and AR10 (which contained the objected terms, see Section III-1.(ii) above, in Claims 5, 6, 7, and 9) were not objected to under Article 84 EPC (minutes to the oral proceedings pages 2-3 and communication dated 3 March 2015 pages 14-15).

ED held that AR9 did not meet the requirements of Art. 54 EPC based on D7 (example 5) or D10 (table at page 33). AR9 Claim 1 is recited below,

A lipid-containing formulation, comprising
a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 to 45:1,
wherein:
omega-6 fatty acids are 4-75% by weight of total lipids and omega-3 fatty acids are 0.1-30% by
weight of total lipids.

ED disregarded, smothered, and shoved aside abundant arguments, evidence, and case law (submission of 5 December 2014 pages 16-18, and summary of the call submitted on 3 February 2015, pages 2-5 (partially reproduced above), and oral

¹ Guidelines: Guidelines for Examination in the European Patent Office

arguments at the proceedings) that D7 or D10 do not disclose explicitly or inherently each limitation of Claim 1 and will not inevitably result in products of instant Claim 1. Note that not only do D7 and D10 not disclose and enable total omega-6 and omega-3 fatty acids “by weight of total lipids”, there is also no disclosure and enablement of “dosage of [total] omega-6 and omega-3 fatty acids” in D7 or D10, both of which are poorly understood features in the art as abundantly evidenced on record.

ED was highly improper. ED was out of excuses to deny the patent; therefore ED resorted to copying USPTO impropriety in citing individual oils. For the first time during oral proceedings, ED cited individual oils from D10 page 33, and despite the fact that Claim 1 is drawn to a “formulation” and individual oils are not “formulations” and individual oils neither provide (due to natural variability) nor enable “dosage of total omega-6 and omega-3”, the technical problem to be solved by the claimed inventions and essential feature of AR9.

Yet to be conciliatory reading that ED was making excuses to oblige the Applicant to reduce the scope of the claims, Applicant submitted AR10 at the oral proceedings. AR10 Claim 1 is recited below,

A lipid-containing formulation, comprising:
omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 to 45:1 and nutrients comprising one or more polyphenols, or one or more phytochemicals selected from phytosterols, organosulfides, melatonin, saponins, coumarins, lycopene, lutein, zeaxanthin, and monophenols, wherein omega-6 fatty acids are 4-75% by weight of total lipids and omega-3 fatty acids are 0.1-30% by weight of total lipids.

ED conceded that requirements of Art 123(2) EPC were met but that of Art 54 EPC were not met alleging that some phytochemicals recited in the AR10 Claim 1 are implicitly present in individual oils in view of D16 (introduced during oral proceedings). However, ED was improper because instant claim deals with selection of individual elements, sub-sets, and sub-ranges in addition to “formulation” and “dosage of total omega-6 and omega-3”. In determining the novelty of a selection, it has to be decided, whether the selected elements are disclosed in an individualized (concrete) form in the prior art (see T 12/81 T 198/84 and T 279/89).

ED refused the Application extremely improperly at oral proceedings despite that D10 only disclosed part of the claimed limitations and that AR10 was directed to selection of phytochemicals, and selection of individual elements, sub-sets, and sub-ranges.

4.

Summary Of Experience With ED

Some of **the objections raised by ED are so far-fetched that they make EPO unworthy of respect**, such as alleging lack of clarity in “age of the subject”, and alleging that fatty acid profiles of RBC membrane and plasma of tissue samples in experiment results anticipate a formulation for administration, or that individual oils, which are neither consistent in nutrient content nor a formulation to anticipate Applicant’s claims drawn to “formulations”, specific ranges, “dosages”, and specific phytochemicals.

IV.
**PERVERSE INCENTIVES BETWEEN EPO
AND LEGAL REPRESENTATIVES**

Applicant has been adversely affected by perverse incentives between EPO and applicants' legal representatives (patent lawyers) in proceedings with the EPO. Legal representatives have been more concerned about appeasing EPO officers than protecting the small company client's rights. Applicant's legal representatives have told the Applicant that EPO keeps track of law firms' dealings with them and punishes law firms unfavourable to EPO. See Ms. Bhagat's testimony (Exhibit D paragraph [007]). Therefore, when representing a small firm as in the subject case, legal representatives have greater incentive in going along with EPO with whom they will do business for decades representing various clients, rather than the small company that they may only represent on few cases. Large companies on the other hand turn tables because they can bring consistent inflow of cases to legal representatives and their own lawyers into EPO proceedings.

Furthermore, lawyers have incentives in not obtaining allowance promptly because by spending more time, requesting oral proceedings, and by filing more divisional applications, they can invoice more. Lawyers also may not be incentivized to obtain the best protection for a small company client because less protection for small company client may be in the interest of a higher paying large company client. EPO has similar conflict of interest in forcing unnecessary divisional applications and allowing lesser protection to applicants because EPO generates more revenue from such actions and piecemeal patents, which is harmful to public.

Therefore, for a multitude of reasons EPO has perverse incentives in alignment with legal representatives, which in particular adversely affect small companies. Applicant provides below evidence in dealings with legal representatives, Mr. Nick Lee of Kilburn & Strode, and Mr. Michael Alt of Bird and Bird, and how they worked against Applicant's interests in favour of EPO. Applicant has not experienced this degree of abuse by legal representatives in alignment/collusion with PTO Officers in any other jurisdiction. There is something wrong about EPO practice that instills this behavior.

1.
Improper Actions of Mr. Nick Lee of Kilburn and Strode

Mr. Lee abruptly ended the call held on 20 January 2015, and excused Mr. Leprêtre from the call stating that it was past 5pm his time and he did not need to stay on the call further. This was odd because if anything Mr. Leprêtre's time was wasted by not taking the time to work things out on the call. It had taken six weeks to arrange the call, and by not sorting things out on the call Mr. Leprêtre, his team, the Applicant, and Mr. Lee had to prepare for and attend the oral proceedings on 11 February 2015. And that is exactly why Mr. Lee did not want to sort out claims on the call because by doing so he can bill more in preparing for and attending the oral proceedings. Not only that, Mr. Lee wanted the Applicant to pay him in advance for the work for oral proceedings. As evidence, Applicant submits contemporaneous (dated April 23, 2015) email exchange with Kilburn and Strode (Exhibit B). Also see Ms. Bhagat's testimony (Exhibit D paragraph [008]).

No new claim requests were submitted prior to oral proceedings of 11 February 2015 because Applicant had to engage a new lawyer since Mr. Lee had not been acting in the best interest of the Applicant. The new law firm VO was engaged on 27 January 2015. It was difficult enough to bring the new lawyer up to speed for oral proceedings in the short time; there was no time to submit additional claim requests.

2.

Improper Actions of Mr. Michael Alt of Bird and Bird

In summary, during the oral proceedings of 27 July 2017, Mr. Alt obstructed Ms. Bhagat, Applicant's Chief Executive Officer from making submissions, he made feeble arguments, he failed to cite relevant case law, and he colluded with the Board in undermining the Applicant. Mr. Alt effectively represented the EPO Board, not the Applicant. This is discussed in detail in Section V-4, Gross Improprieties at Oral Proceedings of 27 July 2017, parts (iv)-(ix). Also see Exhibit C, Applicant's Correspondence with Mr. Michael Alt of Bird and Bird, 16 August 2017 to 18 September 2017, and Ms. Bhagat's testimony, Exhibit D paragraphs [0012]-[0015] and [0017]-[0021]).

V.

PROCEEDINGS BEFORE THE BOARD OF APPEAL

1.

Grounds of Appeal Submitted on 9 July 2015

Applicant submitted 63-page Grounds of Appeal on 9 July 2015 along with New Main Request and 20 New Auxiliary Claim Requests and various evidence papers. The new claim requests included varying amendments to previous 11 requests on file with serious attempts to overcome ED objections. One of the main reasons was to overcome the surprising objection raised by ED at the oral proceedings based on the individual oils of D10. Consequently, "a mixture of lipids from different sources" was added to almost all requests to emphasize the difference between the claims and the individual oils of D10. Although differences over individual oils were already present in previous requests at least because the claims were directed to a formulation, i.e. to a composition that was obtained by formulating i.e. putting together its components, and to dosage of omega-6 and omega-3 neither disclosed nor enabled by D10.

(i) Article 123(2) EPC

Submitting lengthy arguments with respect to Article 123(2) EPC Applicant cited evidence that skill level of a person in this art is extremely high, quite frequently they have both PhD and MD with decades of rigorous scientific training, and that the subject matter is vehemently and publically debated (not only in scientific journals but also in public media), such that similar or opposite teaching is **immediately derived** by skilled persons. **The features as such recited in instant claims are extremely well known in the art, but the ranges (as well as the reference (values) based on which they are calculated) and dosages taught in instant claims are opposite of those overwhelmingly taught by the prior**

art. Some of the arguments directed to Article 123(2) EPC are reproduced below from Grounds of Appeal (pages 8-20).

For the purposes of Section 123(2) EPC, it is emphasized that because the concepts are extremely well known in the art, skilled persons can at once envisage and derive the features/ranges recited in instant claims from instant specification. Five skilled persons have testified that the claimed limitations are directly and unambiguously obtained from the disclosure (see declarations submitted with letter dated December 4, 2014 and May 9, 2014).

Applicant would like to point to the GL-H-IV, 2.3 and T 667/08 which provide that: “It is ... essential, when deciding on issues of added subject-matter, to **identify the actual teaching conveyed by the original disclosure**, i.e. the technical information that the **skilled person** reading the original disclosure would have derived from its content (description, claims, drawings) considered in its entirety. This approach might lead to the identification of subject-matter which has not been explicitly revealed as such in the application as filed, but nevertheless derives directly and unambiguously from its content. **Literal support is not required by the wording of Art. 123(2) EPC... If this were not the case, the original disclosure would be deprived of a part of the information it actually contains, namely the technical teaching that the skilled person would retrieve from the application...**” [Emphasis added]

Under the present circumstances, the broadest message conveyed by the original application is that omega-6 is a critical nutrient and because omega-3 (and other lipids) can interfere with the activity of omega-6, the disclosure teaches omega-6 to omega-3 ratios significantly greater than 4:1 (e.g. 50:1) with the exception of certain dietary cohorts, in addition to teaching omega-6 and omega-3 concentrations based on total lipids and upper limit of omega-6 dosage...

(Page 10)

“Ratio of omega-6 to omega-3 of 4:1 or greater”

It is highlighted again that the upper limit “*or greater*” is clearly implicitly disclosed for a skilled person when reading the application as originally filed as a whole. As noted at the beginning of this section, level of skill in this art is very high. Since the direction of the ratio is taught and how to practice the dosage is taught (in claims and throughout the disclosure), skilled persons can obtain that when amount is managed as directed, the ratio can be any ratio greater than 4:1.

In this regard reference is made to paragraph [006] of the scientists’ Declarations filed with letter of December 4, 2014, where these scientists declare:

“The teaching omega-6 to omega-3 ratio of 4:1 or greater is directly and unambiguously obtained from the patent application.”

In addition it is highlighted that original claim 4 combined with statements such as in paragraph [0021]:

“The present disclosure incorporates relatively high ratio of omega-6 to omega-3 fatty acids”

and the majority of the examples where omega-6 to omega-3 ratios greater than 4:1 have been disclosed (see for example Table 3, 7, 9 and 14 to 19 as well as Examples 11, 12, 15.1, 17, 19, 26 and 27) give a skilled person a direct and unambiguous support for an omega-6 to omega-3 ratio of “*4:1 or greater*”. This is confirmed by the scientists’ Declaration submitted with letter of December 4, 2014.

In this context reference is also made to paragraphs [005] to [008] of the Declarations by Dr. Shengrong Shen and Dr. Wensheng Pan submitted with letter of May 9, 2014, confirming that the skilled person would derive “*4:1 or greater*” from the application as filed...

In T 201/83 (OJ 1984, 481), the board came to the conclusion that the amendment of the concentration range for a component of a claimed alloy was admissible on the basis of a value described in a specific example since the skilled person could have readily recognized that this value was not so closely associated with the other features of the example as to determine the effect of that embodiment of the invention to a significant degree. The limit could therefore be deduced from the original documents...

(Pages 13-15)

“A mixture of lipids from different sources”

Support for this feature can be found in the application as originally filed as a whole, especially in paragraph [0008] where it is stated that the present invention relates to the use of compositions and methods that use more advantageous sources of omega-6 fatty acids in the presence of nutritionally adequate omega-3 fatty acids. Paragraphs [0022] and [0029] recite lipid components to be used, for example. Further, paragraph [0028] discloses a variety of sources from which the lipid mixture can originate. Further, paragraph [0030] states that synergy among complementing nutrients from sources is incorporated.

Thus, for a skilled person when reading the application as a whole it becomes immediately apparent that the lipids contained in the claimed lipid formulation and comprising the omega-6 and omega-3 fatty acids originate from different sources. Thus, the application as originally filed discloses intermixtures of lipids from different sources.

(Page 17)

(ii) Article 84 EPC

Applicant submitted 10 pages of arguments (at pages 21-31) that Article 84 EPC requirements were met including that the term “dosage” is extremely well known in the art.

The Oxford Dictionary in their US version defines dosage as “The size or frequency of a dose of a medicine or drug: *a dosage of 450 milligrams a day there are recommendations about dosage for elderly patients,*” which is a specified amount delivered/or administered to a subject. The use of the word “dosage” in the current patent application is clearly directed to determination of amount to be administered and/or administration in prescribed amounts (see tables 9 to 13 and examples 11 to 27 of the application). Further, dosage is very well known to be distinct from concentration (see attached *Duffus JH, Risk Assessment Terminology, Chemistry International Vol. 23, No. 2 March 2001*).

(Pages 21-22)

(iii) Article 54 EPC

Applicant submitted 20 pages of arguments that Article 54 EPC requirements were met (pages 32-51) because the cited documents D1-D15 failed to take away the novelty of instant claims asserting the following.

In this context, it is worth emphasising that it is well known in the art that **fatty acids are a subset of lipids**, i.e., in a composition fat or fatty acids may constitute 50% or even less of total lipids. For example, beeswax is predominantly waxes, i.e. non-fatty acid lipids. For definition of lipids see Fahy et al... The reference further discloses that the term “*lipid*” encompasses fatty acyls (e.g. fatty acids, icosanoids, docosanoids, fatty alcohols, fatty aldehydes, fatty esters) glycerolipids (including triglycerides)) glycerophospholipids, sphingolipids, sterol lipids (e.g. cholesterol, phytosterols, marine sterols, fungal sterols, vitamin D) saccharolipids and polyketides. Further, **fats (triglycerides) are also a subset of lipids** (see *The Nomenclature of Lipids, J Lipid Res.*

1978 Jan;19(1):114-28, submitted with the letter of December 4, 2014). However, although the classification and terminology of lipids is very well-known in the art, but the significance of “total lipids” as a reference (value) for the calculation of omega-6 and omega-3 fatty acids is not well understood, therefore, prior art does not typically base omega-6 and omega-3 concentrations on “total lipids”. See paragraphs [0019] and [0025] of declarations submitted on December 4, 2014.

It is noted that natural products may contain low amounts of non-fat or non-fatty acid lipids, although not always (e.g. beeswax), but the claimed man-made formulations can have high amounts of non-fat and non-fatty acid lipids. In a man-made lipid formulation, non-fat or non-fatty acid lipids (e.g. sterols and waxes) can be present in relatively large amounts, e.g. 10 to 20% of total lipids. For example, a composition comprising 750mg n6 + 150mg n3 + 100mg phytosterols contains n6:n3 ratio 5:1, 75% n6, 15% n3, and 10% non-fat and non-fatty acid lipids by weight of total lipids. [Emphasis added].

(Pages 33-34)

The teachings of lipid interactions, therefore considering “total lipids” and “dosages” in omega-6 and omega-3 formulations are an important contribution to state of the art made by the subject patent application as confirmed by the scientists declarations submitted on December 5, 2014, paragraph [005], [0018]-[0025]. The subject matter can only be regarded as having been made available to the public, and therefore as comprised in the state of the art pursuant to Art. 54(1), if the information given to the skilled person is sufficient to enable him, at the relevant date (see G-VI, 3), to practice the technical teaching which is the subject of the disclosure, taking into account also the general knowledge at that time in the field to be expected of him (see T 26/85, T 206/83 and T 491/99). (GL G-VI, 4).

It is emphasized that the significance of “total lipids” as a category is not well understood in the art. Food labeling practices routinely separately group lipid vitamins from fats and fatty acids and ignore important lipid components. Various authoritative dietary guidelines also routinely ignore important lipids and do not recognize the importance of “total lipids” as a category (including Dietary Guidelines for Americans http://www.cnpp.usda.gov/sites/default/files/dietary_guidelines_for_americans/PolicyDoc.pdf). Typical disclosure is “total fat.” For example, see FDA Nutrition Facts Labeling requirements (<http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm274593.htm#see3>). The skilled person would not be motivated to obtain omega-6 and omega-3 as a ratio of “total lipids” as conventionally defined, from the disclosure of cited documents. The consideration of total lipids in formulating omega-6 and omega-3 is an important teaching of the subject patent application, that is not well understood in the prior art, and the cited documents fail to teach that as specified in instant claims. See paragraph [0019] and [0025] of Declarations submitted on December 5, 2014.

(Pages 49-50)

Applicant also cited the following case law,

Anticipation is question of **inevitability and not of probability**, in that the practitioner must reach the same solution every time using the teachings of the cited prior art document as in the claimed invention in order for the prior art document to be considered anticipatory (see T 270/97, T 12/81 (OJ 1982, 296), T 583/01).

In assessing novelty, the teaching of a document, independent of its nature, is not to be interpreted as embracing equivalents not disclosed in that document (see T 167/84, T 517/90, T 536/95). GL, G-VI, 2 expressly states that "when considering novelty, it is not correct to interpret the teaching of a document as embracing well-known equivalents which are not disclosed in the document; this is a matter of obviousness".

An alleged disclosure can only be considered "implicit" if it is immediately apparent to the skilled person that nothing other than the alleged implicit feature forms part of the subject matter disclosed (see T 95/97).

(Pages 50-51)

(iv) Article 56 EPC

Furthermore, Applicant submitted 10 pages of arguments that Article 56 EPC requirements were met (pages 51-61), ED acknowledged that an important invention has been disclosed, and that in the Decision of 3 March 2015 there was no inventive step rejection, additionally asserting the following,

First of all it must be highlighted that the prior art the prior art, including D1-D15, overwhelmingly teaches the opposite of the subject patent application, and that there are significant gaps in the technical knowledge of the prior art due to which technical solutions of the instant claims are not obvious to skilled persons.

Further, the scale of opposite teaching in the prior art is astounding. For example, *Simopoulos, 1999 supra*, speaks of "a workshop [held at US National Institutes of Health]... truly international in nature bringing together scientists from academia, government, international organizations, and industry, from Australia, Canada, Denmark, France, Italy, Japan, Norway, Switzerland, United Kingdom, and the United States." The international scientists at the workshop issued a statement teaching omega-6:omega-3 ratio <3:1, and omega-6 <3% of energy (i.e. less than 7.5% of dietary fat/lipids) (see Table 1), both of which are opposite of instant claims. Thirty prominent scientists listed in the reference ratified this statement.

Opposite and inconsistent teachings in the art are evidence that a prejudice existed in the prior art which has been overcome by the present invention. Hence, the present invention involves an inventive step. Main points are summarized below and subsequently elaborated:

- Prior art (including D1-D15) overwhelmingly teaches omega-6 is inflammatory and omega-3 is anti-inflammatory, therefore recommends extreme reduction in omega-6 and relatively high levels of omega-3.
- Prior art (including D1-D15) recommends nutrients including omega-3 and other lipids that suppress the activity and metabolism of omega-6 without any teaching that long-term suppression or deficiency of omega-6 can be harmful.
- Prior art (including D1-D15) does not disclose or consider the relevance of other lipids in delivery of omega-6 and omega-3. Typical disclosure is as % of fatty acids (D6-D7) or % of energy (D5).
- Prior art overwhelmingly teaches reduction of omega-6 consumption. For example, D5 teaches preferably 2-3% of energy (see e.g. lines 5 to 6 at page 11 of D5) and, *Lands WE, Ann. N.Y. Acad. Sci. 1055: 179-192 (2005)* teaches omega-6 less than 0.5% of calories.
- Prior art (including D1-D15) overwhelmingly teaches omega-6 to omega-3 ratios lower than 4:1.
- Prior art (including D1-D15) fails to teach the importance of total omega-6 or omega-3 dosage in conjunction with ratios.
- Prior art (including D2, D3, D5-D7, D12, D13) overwhelmingly teaches relatively high eicosapentaenoic acid and docosahexaenoic acid consumption.
- Prior art (including D2, D5, D15) overwhelmingly recommends high monounsaturated fatty acid (MUFA) consumption without any caution

...

Further it is well established case law that the question to be answered, when dealing with inventive step, is whether there is any teaching in the prior art as a whole that would (not simply could, but would) have prompted the skilled person, faced with the objective technical problem,

to modify or adapt the closest prior art while taking account of that teaching, thereby arriving at something falling within the terms of the claims, and thus achieving what the invention achieves. In other words, the point is not whether the skilled person could have arrived at the invention by adapting or modifying the closest prior art, but whether he would have done so because the prior art incited him to do so in the hope of solving the objective technical problem or in expectation of some improvement or advantage (see T 2/83). GL G-VII, 5.3

(Pages 52-53)

Opposite and inconsistent teachings in the prior art constitute evidence that the art does not understand the subject matter. In such a scenario case of obviousness or lack of inventive step cannot be made because no clear teaching is available to skilled persons from the prior art to arrive at the claimed invention.

Thus, the subject matter of the present application involves an inventive step in view of the disclosures of D1-D15 and common technical knowledge in the prior art.

(Page 61)

Applicant also pleaded that the claim scope is commensurate with the size of the problem to be solved. The claimed inventions have the potential of making very significant advancement in the art and enhancing public health. The claims should be granted.

2.

Board's Communication of 18 April 2017 and Applicant's Response of 28 June 2017

[Board referred to A2; therefore A2 was referenced in response to the communication.]

Two years later on 18 April 2017 Board of Appeal issued a communication. **Applicant was dismayed to receive this communication because the communication indicated that Board chose to disregard the Grounds of Appeal and the case history to make far-fetched excuses. Applicant did not expect this. Board of Appeal is expected to be honourable, uninfluenced by considerations other than justice, but Board's communication indicated otherwise.** Following is a sample of impropriety of the objections.

(i) Improper Clarity Objections (Board's Item 7.1):

The meaning of "different sources" appears to be vague and even unclear. Does this mean that, for example, three different vegetable oils, such as coconut oil, palm oil and sunflower oil, have to be used, or merely three sunflower oils from different producers. And where in the application as filed is the basis for any of these interpretations?

Claim 1 does not contain any feature defining the "dosage" in terms usually used in this field (see e.g. paragraphs [0036] to [0041] of the A2 publication [paragraphs [0034]-[0039 of A9]).

This is extremely objectionable because it indicates the Board disregarded Grounds of Appeal. For example, with respect to "different sources" at page 17 of Grounds of Appeal it was asserted,

Support for this feature can be found in the application as originally filed as a whole, especially in paragraph [0008] where it is stated that the present invention relates to the use of compositions and methods that use more advantageous sources of omega-6 fatty acids in the presence of nutritionally adequate omega-3 fatty acids. Paragraphs [0022] and [0029] recite lipid

components to be used, for example. Further, paragraph [0028] discloses a variety of sources from which the lipid mixture can originate. Further, paragraph [0030] states that synergy among complementing nutrients from sources is incorporated. [Same paragraph numbers in A2 and A9].

Applicant had to reassert in the response to Board's communication submitted on 28 June 2017 pages 4-5, "Each time the term "source" appears in the Specification... "source" refers to a type of food (dietary source) containing substantially same nutrients... Thus, the specification defined that "different sources" differ in nutrient profile rather than in the supplier. Nowhere does the Specification refer to "different producer" or "different supplier." Board's phraseology in this objection (and others discussed below) indicated that the Board had read USPTO prosecution history and felt compelled to raise some of the objections raised by USPTO examiner. Applicant believes that the Board was aware that USPTO examiner's objection was improper, despite that the Board applied the objection. But note that USPTO Appeal Board **did not** raise this far- far-fetched objection. **Again, a high standard of honour is expected at Board level, which the EPO Board failed to demonstrate by raising such an objection despite that Applicant had pre-emptively provided support from Specification in Grounds of Appeal.**

Similarly, Board's objection to the term "dosage" was an improper copy of the USPTO Examiner's objections and it indicated that Board chose to disregard Grounds of Appeal, which states at page 21-22, that the term "dosage" is extremely well known in the art, as follows,

The Oxford Dictionary in their US version defines dosage as "The size or frequency of a dose of a medicine or drug: *a dosage of 450 milligrams a day there are recommendations about dosage for elderly patients,*" which is a specified amount delivered/or administered to a subject. The use of the word "dosage" in the current patent application is clearly directed to determination of amount to be administered and/or administration in prescribed amounts (see tables 9 to 13 and examples 11 to 27 of the application). Further, dosage is very well known to be distinct from concentration (see attached *Duffus JH, Risk Assessment Terminology, Chemistry International Vol. 23, No. 2 March 2001*)...

Furthermore, the feature "dosage of omega-6 fatty acids is less than 40 grams" is present in claim 6.c)(iv) of Auxiliary Request 10 presented at Oral Proceedings which was confirmed to be in compliance by Examination Division's Decision of March 3, 2015 (see item 8.1).

Applicant had to reassert in the response to Board's communication submitted on 28 June 2017 pages 6-9, the term "dosage" is well known in the art as "*specified amount of substance for one time or regular ingestion,*" as evidenced by Specification, numerous dictionaries and references on record, and accompanying declarations from skilled persons (Das and Erickson declarations) and that the EPO routinely allows the terms "dose" or "dosage" in claims as illustrated by several granted EP patents (EP0689454B1, EP0404376B1, and EP1041987B1).

(ii) Improper Exclusions From Patentability Objection (Board's Item 7.2)

Board had to be aware (if it is competent) that the objected claims did not recite diagnostic or therapeutic method practiced on the human or animal body, yet the Board raised this objection. Applicant responded by asserting, the factors listed in the use claims subject to the Board's objection do not require any examination that is carried out on the subject's body. For example, the age and the other factors can be obtained by simply asking the individual; moreover

Applicant may not even ask the individual about the recited factors and may prepare the formulations predictively based on the recited factors (Applicant's response pages 10-11).

(iii) Improper Added Subject Matter Objection (Board's Item 7.3)

Finally, Board hurled the ultimate EPO weapon, "added matter."

- 7.3.1 Claim 1 of new MR and new AR1-3, "omega-6 to omega-3 ratio of 4:1 or greater" open upper limit is not disclosed in the application as filed.
- 7.3.2 Claim 1 of new AR4-7, combination of "omega-6 to omega-3 ratio of 4:1 to 50:1" with "omega-6 fatty acids are 4-75% by weight of total lipids and omega-3 fatty acids are 0.1-30% by weight of total lipids" is not disclosed in the application as filed.
- 7.3.3 Claim 1 of new AR8-12, 15-18, same combination objection as in 7.3.2.
- 7.3.4 Claim 1 of new AR13-14, same combination objection as in 7.3.2.
- 7.3.5 Claim 1 of new AR19-20, same combination objection as in 7.3.2, and that phytochemicals have been arbitrarily combined with other features of Claim 1.
- 7.3.6 Declarations of skilled persons cannot be used to support arguments regarding Article 123(2) EPC.

It is clear from the above that Board picked the features that were common to Claim 1 of all requests (MR and AR1-20) to attack ruthlessly, because then in one stroke Board could reject all requests. Board knew that novelty and inventive step rejections could not be made considering the prosecution record.

With respect to Board's allegation that "omega-6 to omega-3 ratio of 4:1 or greater" open upper limit is not disclosed in the application as filed, is extremely objectionable because it indicated that Board disregarded Grounds of Appeal, which states at pages 13-14,

In addition it is highlighted that original claim 4 combined with statements such as in paragraph [0021] [same paragraph number in A2 and A9]:

"The present disclosure incorporates relatively high ratio of omega-6 to omega-3 fatty acids"

and the majority of the examples where omega-6 to omega-3 ratios greater than 4:1 have been disclosed (see for example Table 3, 7, 9 and 14 to 19 as well as Examples 11, 12, 15.1, 17, 19, 26 and 27) give a skilled person a direct and unambiguous support for an omega-6 to omega-3 ratio of "4:1 or greater".

Board chose to disregard supporting case law citations in the Grounds of Appeal, for example, T 667/08 that "technical information that the **skilled person** reading the original disclosure would have derived from its content (description, claims, drawings) considered in its entirety" is considered, "**literal support is not required**" and T 201/83 that "claimed alloy was admissible on the basis of a value described in a specific example since the skilled person could have readily recognized that this value was not so closely associated with the other features of the example." None of this was mentioned in Board's Communication of 18 April 2017. Applicant had to reassert this in the response to Board's communication submitted on 28 June 2017 at pages 11-12.

With respect to combination of features that the Board objected to in items 7.3.1-7.3.5, the Board had raised that objection for the first time. **ED did not raise such an objection.** Applicant responded in the communication submitted on 28 June 2017 as follows,

[i]t has been stipulated in T 305/87 it is permissible to combine separate items belonging to different embodiments described in one and the same document, **if** such combination has specifically been suggested (see T 305/87)...

(Page 11)

Appellant asserts the allegation is completely groundless since the claimed combination is disclosed not only in tables 3 and 4 but also in numerous other examples as well as in the filed application as a whole:

1. Table 3 and 4 are part of one and the same example, i.e. Example 1. In consecutive paragraphs within Example 1, paragraph [0042] [paragraph 40 in A9] recites, “The formulations may include specific ratios of various lipid components as shown below in Table 3”, and paragraph [0043] [paragraph 41 in A9] recites, “In some embodiments, the lipid formulation calls for specific percentages of omega-9, omega-6, and omega-3 fatty acids, as shown in Table 4 below.” This evidences that the two features are by no means disclosed in the context of different aspects of the invention, but clearly relate to the same type of formulation.

2. Tables 14-19 also teach that formulations comprising ratios of omega-6 to omega-3 fatty acids are combined with their concentrations in reference to total lipids.

3. Original claim 8 also evidences that applicant intends to claim formulations comprising ratios of omega-6 to omega-3 fatty acids combined with their concentrations in reference to total lipids...

(Pages 12-13)

One and the same Example 1, paragraph [0042] [paragraph 40 in A9] recites, “In specific embodiments of the disclosure the formulations described herein have high antioxidant and phytochemical content [which are described in paragraph 22]... In specific embodiments sterols [phytosterols], sweeteners (such as honey), and herbs/spices (such as curcumin [a polyphenol]) [are] included in the compositions... The formulations may include specific ratios of various lipid components as shown below in Table 3,” and paragraph [0043] [paragraph 41 in A9] recites, “In some embodiments, the lipid formulation calls for specific percentages of omega-9, omega-6, and omega-3 fatty acids, as shown in Table 4 below.” Thus, the claimed combination is expressly recited in Example 1.

(Pages 14-15)

Board alleged “added matter” in all requests despite the fact that ED had conceded that at least AR9-10 presented to ED, substantially same as AR15-20 presented to the Board, met the requirements of Article 123(2) EPC (minutes to oral proceedings pages 2-3 and communication dated 3 March 2015 pages 14-15). **It must be kept in perspective that ED is comprised of skilled persons (if not then EPO examination is a sham). Therefore, if the matter that is obtainable from the Specification by ED, then at least that matter is obtainable by other skilled persons from the Specification, because if anything ED is taught to and has a motivation to raise objections.**

With respect to Board’s item 7.3.6, Applicant asserted at page 16, the declarations on file disprove arbitrary rejections/objections. Applicant had provided declarations from **five different scientists** (Pan and Shen declarations submitted on 9 May 2014, and Erickson, Rustagi, and Rucker declarations submitted on 5 December 2014) that the claimed subject

matter is directly and unambiguously obtained from the Specification. The statutory declarations were given under penalty for false statements (final paragraph of all declarations). Nowhere in Article 123(2) EPC does it say that skilled person's declarations are not acceptable. Rather, almost all of the case law (e.g. T 667/08, T 201/83) states that matter that a skilled person can obtain from disclosure is not "added matter" under Article 123(2) EPC. Board did not explain why despite skilled persons declaration that they can obtain the claimed matter from the disclosure, Board insisted on "there is no obvious reasons why skilled person would do so."

There are no gaps in the application as filed; there are explicit reasons for skilled persons to combine the features as claimed. Specification **explicitly** discloses omega-6 to omega-3 ratios in combination with omega-6/omega-3 concentrations by weight of total lipids in Tables 14, 15, 16, 17, 18, and 19, and in Claims 4, 6-8, and **implicitly** in Table 20, where total lipids along with omega-6/omega-3 fatty acids are recited.

EPO is known to ruthlessly apply "added matter" objections, but generally such actions happen at examining division level not at Board level. Again, Boards are known and expected to be more honourable. Board's "added matter" rejections are extremely improper this is further elaborated in the context of Oral Proceedings with the Board below.

(iv) Odd Inventive Step Remark (Board's Item 8)

The Board made an odd inventive step remark (item no. 8) because ED had not raised an inventive step objection in its communication of 3 March 2015 (which ED raised in previous communications and Applicant had amply rebutted), all of the cited documents had already been discussed with respect to inventive step at pages 51-61 of Grounds of Appeal, and Board had made no mention of why arguments submitted in Grounds of Appeal were insufficient. It is noted that if ED communication of 3 March 2015 is interpreted as not having addressed inventive step rather than having withdrawn inventive step objection, then an **illegality in procedure arises** that ED's actions are expected to be complete; otherwise prosecution could go on forever.

(v) Board Disregarded Grounds of Appeal

As has been noted above Board consistently failed to acknowledge, consider, and rebut arguments, evidence, and case law cited in Grounds of Appeal and on record. What is the purpose of submitting Grounds of Appeal then? Are Applicants simply to incur 10s of thousands of euros in paying attorneys for writing grounds of appeal and EPO fees, wait for years for appeal proceedings to commence, only for the Board to disregard all submissions. The whole concept of appeals at EPO then is a sham. It is just a revenue stream for lawyers and EPO. Are we in the 1920s that governmental bodies can exercise such mindless oppression?

3.

Request For Postponement of Oral Hearing of 19 May 2017

On 19 May 2017, Applicant submitted a request to the Board that due to the circumstances of Ms. Urvashi Bhagat, the Applicant's Chief Executive Officer, who intends to argue before the Board, it is requested that the date of oral proceedings be changed to not earlier than September 2017. The Board denied the request on 26 May 2017.

4.

Gross Improprieties at Oral Proceedings of 27 July 2017

[Specification reference in the following is to A2 version, per Board's preference.]

At the oral proceedings, in attendance were by W. Sieber (Chairman), N. Perakis, and F. Blumer comprising the Board, and Mr. M. Alt of Bird and Bird, Applicant's then-authorized professional representative, and Ms. Urvashi Bhagat, the Inventor and Applicant's Chief Executive Officer. The proceedings commenced at 9:00 hours and ended at 12:30 hours, i.e. the proceedings had been in progress for three-and-a-half hours, when the appeal was withdrawn and the proceedings were closed.

Oral proceedings almost exclusively focused on alleged non-compliance with Article 123(2) EPC of Claim 1 of all requests.

(i) Board's Minutes of the Oral Proceedings Are Grossly Misstated

The minutes of oral proceedings mailed by EPO on 3 August 2017 are grossly misstated. On 20 December 2017, Applicant submitted a request for correction of some of the gross misstatements in the minutes, but the request was denied on 17 January 2018, stating that Board does not see any reason to correct the minutes more than four months after the minutes were sent. Note that due to improprieties at oral proceedings explained throughout this submission, a new legal representative to replace Mr. Alt had to be engaged, which took time. Further, subsequent to engagement of the new representative, Adrian Tombling of Withers & Rogers, Applicant was tied-up in meeting the deadlines relating to EP17182663.9 (divisional of the subject patent application had been filed due to EPO improprieties in the parent case) and EP11833527, which were both due in November 2017. Subsequently, Applicant submitted the request for correction of minutes in December. Applicant is a small company with limited staff, which affects response time. There **is** a reason for correction of minutes because those reviewing the case history can refer to the minutes, which can have bearing on Applicant's corresponding pending applications.

With regard to erroneousess of the minutes, firstly, it is noted that the minutes are too short even as a summary to correctly reflect three-and-a-half hours of discussion, clearly sections of the discussion are left out. Secondly, in denying to correct the minutes of the oral proceedings Board provided self-incriminated evidence confirming that it was in collusion with Mr. Alt, Applicant's then-authorized Professional Representative, against the Applicant. This is demonstrated in the following.

(ii) Board's Minutes Fail To Record That The Board Decided to Discuss Claim 1(a)(i) of Main Request First

The minutes are wrong in stating, "The appellant agreed to discuss the invention identified as a)(i) in claim 1 first." Board did not ask the Applicant, which invention it wanted to discuss first, Board announced that it was going to discuss claim 1(a)(i) of the MR first. Clearly, it was Board's plan to deny the patent under pretense of "added matter" because features claimed in Claim 1(a)(i) of the MR were common to claim 1 of all requests. It is evidenced by Board's communication of 18 April 2017 (see V-2.(iii) above).

(iii) Board's Minutes Fail To Record The Technical Problem Solved By The Claimed Inventions Asserted By The Applicant At The Oral Proceedings

Ms. Bhagat said that this invention was conceived because I became aware that there is mass confusion and incorrect teachings in the art with respect to omega-6 intake/dosage. Prior art has overwhelmingly taught to reduce omega-6 intake/dosage, which in fact is the most important fatty acid we consume. Reference was made to paragraphs [0006] to [0008] of A2, which state,

Numerous studies provide evidence for the prophylaxis and treatment of medical conditions using supplementation with omega-3 fatty acids and recommendations to reduce omega-6 consumption... The omega-3 content in these lipid formulations was several-fold higher than that of omega-6... a recently published U.S. patent application, US2008/0039525, disclosed lipid compositions used for diabetic patients, which contained omega-3, omega-6, and omega-9 fatty acids, with the specific ratio of omega-6 to omega-3 being between 0.25:1 to 3:1.

...In fact, on January 26, 2009, for the first time the American Heart Association issued an advisory to correct the perception that omega-6 are unhealthy... The current methodologies are confusing for the consumer, hence lead to over consumption or under consumption of critical nutrients with major health consequences.

...the present disclosure relates to the use of compositions and methods that use more advantageous sources of omega-6 fatty acids, in the presence of nutritionally adequate omega-3 fatty acids... The disclosure also relates to methods and compositions that deliver omega-6 and omega-3 fatty acids along with other nutrients that optimize the daily delivery [dosage]... of omega-6 and omega-3...

All of the Examples 11-27 are focused on omega-6 fatty acids and secondly on omega-3 fatty acids (in Example 14.1 only omega-6 administration is disclosed). Ms. Bhagat said that the subject matter is highly debated in public and scientific journals, for this reason skilled persons can easily obtain the claimed subject matter from the disclosure.

Board's minutes do not record this discussion. Applicant requested on 20 December 2017, that minutes be corrected to reflect this, which was denied. Board's lack of record in the minutes indicates Board's refusal to acknowledge the technical purpose of the invention and a mind unwilling to understand (T 190/99).

(iv) Board's Minutes Fail to Record Mr. Alt's Objection to Ms. Bhagat Speaking During the Oral Proceedings and Board's Reaction to The Same and That Effectively Board Colluded With Mr. Alt Against The Applicant

As Ms. Bhagat was making the arguments above (Section V-4.(iii)), Mr. Alt objected to Ms. Bhagat making the arguments. Mr. Sieber said that there was no issue with Ms. Bhagat making

the arguments because the proceedings were ex-parte. However, even after that when Ms. Bhagat attempted to speak again, Mr. Alt created he a huff throwing his pen on the table (see below). Board laughed at the lack of support from the counsel, and this was repeated during the proceedings. Subsequently, it became uncomfortable for Ms. Bhagat to speak again, and this undermined Applicant's position. See Ms. Bhagat's testimony (Exhibit D paragraphs [0013]-[0015]).

Board's minutes do not record this pivotal occurrence. Applicant requested on 20 December 2017, that page 2 of minutes be corrected as follows to reflect this occurrence.

"Ms. Bhagat attempted to make arguments before the Board when Mr. Alt interrupted her. Chairman said that there was no issue with Ms. Bhagat making the arguments, because the proceedings were ex-parte. However, when Ms. Bhagat attempted to speak again, Mr. Alt threw his pen making it uncomfortable for Ms. Bhagat to speak subsequently. The Board laughed at the lack of support from the counsel."

Board denied correcting the minutes in its communication dated 17 January 2018, stating,

"Concerning the substance of the proposed correction in the paragraph drafted by the appellant on page 2 of the minutes, the Board notes that none of its members can remember any of the alleged facts. The Board further notes that the Chairman did explicitly give conclusions (not just preliminary views) on the allowability of the main request and auxiliary requests 1 to 22 under Article 123(2) EPC."

[The second sentence of Board's statement above pertaining to "conclusions" versus "preliminary views" pertains to page 3 last paragraph of the minutes. Whether the Board gave "conclusions" versus "preliminary views" is discussed below.]

It is interesting to note that Board has selective memory, it remembers what it wants to remember "conclusions (not just preliminary views)", but not that it was colluding with the Applicant's then-authorized representative to undermine the Applicant in the oral proceedings. Although Mr. Sieber first said that there was no issue with Ms. Bhagat making the arguments because the proceedings were ex-parte, but subsequently by laughing at such occurrences, which were repeated, Board encouraged Mr. Alt and undermined the Applicant. See Ms. Bhagat's testimony (Exhibit D paragraphs [0014]-[0015]).

As evidence of the above, Applicant submits the enclosed Exhibit C, contemporaneous email communications with Mr. Alt shortly after the oral proceedings (dated 16 August 2017 to 18 September 2017), in which he admits that there was an issue at the oral proceedings where he obstructed Ms. Bhagat from speaking, stating, "I... aimed at controlling your submission" (Ms. Bhagat's email of 16 August 2017 and Mr. Alt's response on 31 August 2017). Also see Ms. Bhagat's email of 18 September 2017, 10:13 AM (Pacific), where she states,

"Why did I fly all the way over to Munich, if you were to shut me up? We filed a request with the EPO to postpone the oral proceedings so I could argue at the oral proceedings. You even knew that I am prosecuting pro se in US. So you knew I am not uninformed in patent prosecution. I have been prosecuting this case for 10 years in multiple jurisdictions. I know the case inside out. You also knew that it was difficult for me to come to Europe at that time, but I made the time, which you wasted..."

The Board had said there was no issue in my speaking. Even after that you threw your pen when I tried to speak, making it uncomfortable for me to speak. Oral proceedings are very

time sensitive, you have to rebut allegations without loss of a moment. You couldn't rebut and you made it difficult for me to do so because later the moment was lost."

Ms. Bhagat also testifies (Exhibit D paragraphs [0015]),

"Although I sporadically tried to argue again during the rest of oral proceedings, it was difficult for me to do so, because of objections and lackluster support from Mr. Alt, and the undercurrent of collusion among the Board and Mr. Alt. Each time I spoke, I spoke worriedly and hurriedly to avoid being cut off and the Board ridiculing and subverting the arguments."

Applicant takes a strong objection to Board's denial of Mr. Alt obstructing Ms. Bhagat from speaking during the oral proceedings because the denial in view of Mr. Alt's admission that he obstructed Ms. Bhagat from speaking is evidence that Board is guilty of undermining the Applicant in collusion with Applicant's own representative. Effectively Mr. Alt represented the Board and not the Applicant. This is a strong reason why the oral proceedings of 27 July 2017 should be invalidated.

(v) Board's Minutes Fail to Record Board's Statement that it had to ensure patent was not issued on claims that were possibly anticipated by prior art

Board stated during oral proceedings that the Board was focused on Article 123(2) EPC because it had to ensure that patent was not issued on claims that were possibly anticipated by prior art (partly because amount of non-fatty acid lipids in compositions may be very small). The fact that the Board made this statement is evidenced in Ms. Bhagat's enclosed email to Mr. Alt of September 18, 2017, 11:01 AM (Exhibit C), and Ms. Bhagat's testimony (Exhibit D paragraph [0016]). There are two problems with Board's statement.

- a. Anticipation objection cannot be given based on possibilities and probabilities, prior art cannot be interpreted as embracing well-known equivalents not disclosed in prior art, and anticipation is question of **inevitability and not of probability**.
- b. Board admitted that it was denying the patent under the pretense of non-compliance with Article 123(2) EPC.

Although Mr. Alt did not rebut Board's statement during the oral proceedings, but Applicant had submitted in Grounds of Appeal that anticipation objection cannot be given based on possibilities and probabilities citing T 270/97, T 12/81 (OJ 1982, 296), T 583/01 (and that non-fatty acid lipids in a formulation can be present in relatively large amounts e.g. 10-20%). Further, for anticipation objection to be applied the prior art has to be **specific** and **enabled** with respect to each limitation (e.g. dosage in instant claims). Furthermore, any prior use has to sufficiently inform the public. In this case there is overwhelming evidence that public was **not** sufficiently informed and a skilled person could **not** practice the technical teaching which is the subject of the disclosure; therefore claimed subject matter **cannot** be said as comprised in the prior art pursuant to Art. 54(1) (T 26/85, T 206/83 and T 491/99, GL G-VI, 4). Also see discussion above under V-1.(iii).

Thus, Board's minutes fail to record this significant point that it was concerned about imagined anticipatory "prior art", despite arguments and case law citations in the Grounds of Appeal, and the Board improperly relied upon Article 123(2) EPC to deny the patent.

Applicant is also reasonably certain that Board imagined "prior art" because Board had consulted prosecution history of corresponding US divisional application no 13/332,251, where such imaginary prior art was raised in interviews, but not formally applied—obviously because legally USPTO could not apply such an objection just like EPO cannot. (Exhibit D paragraph [0016])

(vi) Board's Minutes Fail to Record the Discussion About "omega-6 to omega-3 ratio of 4:1 or greater"

As evident from Board's communication of 18 April 2017, item 7.3.1, it was on Board's agenda to discuss the feature "omega-6 to omega-3 ratio of 4:1 or greater" in Claim 1 of new MR and new AR1-3, support basis for which under Article 123(2) EPC was discussed but not recorded in Board's minutes.

Ms. Bhagat argued citing Grounds of Appeal (see Section V-1.(i) above) pointing to paragraph [0021] which states,

"The present disclosure incorporates relatively high ratio of omega-6 to omega-3 fatty acids while maintaining optimal daily delivery [dosage] of both omega-6 and omega-3." and that majority of the examples disclose omega-6 to omega-3 ratios greater than 4:1 (Table 3, 7, 9 and 14 to 19 as well as Examples 11, 12, 15.1, 17, 19, 26 and 27), which give a skilled person a direct and unambiguous support for an omega-6 to omega-3 ratio of "4:1 or greater". Ms. Bhagat also cited T201/83 and asserted that it was permissible to extract the exemplified value of at least 4:1 to combine with "*high ratio of omega-6 to omega-3 fatty acids*".

Ms. Bhagat also reiterated the following from the Grounds of Appeal,

"It is highlighted again that the upper limit "or greater" is clearly implicitly disclosed for a skilled person when reading the application as originally filed as a whole. As noted at the beginning of this section, level of skill in this art is very high. Since the direction of the ratio is taught and how to practice the dosage is taught (in claims and throughout the disclosure), skilled persons can obtain that when amount is managed as directed, the ratio can be any ratio greater than 4:1."

At this point Mr. Alt interrupted, creating a huff by throwing his pen on the table, and the Board laughed. To save the situation, Ms. Bhagat said, "I will let the counsel argue this." Mr. Alt cited paragraph [0042], which discloses formulations that "render extra omega-3 unnecessary." Board did not accept the argument stating that there was no basis for "omega-6 to omega-3 ratio of 400:1," for example.

From this point on the discussion in oral proceedings deteriorated. Mr. Alt was making feeble arguments and not allowing Ms. Bhagat to speak, and the Board was an accomplice. (Exhibit D paragraph [0014])

Board was wrong. All of the Tables 9 to 13 disclose dosages of omega-6 under the column titled "Range O6-g" and dosages of omega-3 under the column titled "Range O3-g", wherein ranges as high as 400:1 are evident, for example in Table 13 under Obesity (40/0.1=400:1). Omega-6 dosages in Tables 9-13 vary from 1-40 g and omega-3 dosages vary from 0.1-6 g to provide for

supplements and entire diet (paragraphs [0019], [0032]) by demographics (e.g. age and gender). Note the high dosages of omega-6 divided by high dosages of omega-3 yield a ratio of 4:1 (e.g. $25/6=4.17$). It is also clear from the entirety of the disclosure that low ratios are discouraged (paragraphs [0006]-[0007]; for example, there is nothing in the disclosure that would support a ratio of less than 1:1. In view of totality of the disclosure, the claimed range is fully supported. Claimed features recite “dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater”, which dosage can be for entire diet or to supplement a base diet that may contain omega-6/omega-3 (paragraphs [0036]-[0037]). To suggest that a skilled person (MD/PhD in this art) cannot obtain from the disclosure that when the base diet has high omega-3 the supplement may have lower omega-3 and that this may further increase omega-6 to omega-3 ratio in the supplement, is an insult to skilled persons who frequently have both MD and PhD. Therefore, neither is the claimed ratio range not disclosed, nor is it too high. Skilled persons have testified that they can obtain the claimed subject matter from the disclosure. It was improper for the Board to disregard that (see Sections V.2.(iii) above and Section V-4.(viii) below).

Board’s minutes fail to record the discussion on this significant point and Board failed to acknowledge and rebut arguments and case law citations (e.g. T 667/08 and T 201/83) in the Grounds of Appeal and during oral proceedings. For example, in Mr. Alt’s enclosed email of 31 August 2017, in Exhibit C, he states, “The most relevant case law was cited in the submissions and also in the hearing. I referred to, e.g. T 667/08”. Board’s minutes do not explain why Board disregards T 667/08 and T 201/83.

(vii) Board’s Minutes Misrepresent The Discussion on Combination Of Ranges of Omega-6 To Omega-3 Ratios With The Percentages Of The Fatty Acids and About Non-Essentiality of Omega-9 Fatty Acids in Claim 1 of All Requests; and Board’s Actions Are Invalid

Board alleged that the combination of the features “omega-6 to omega-3 ratio of 4:1...” with “omega-6 fatty acids are 4-75% by weight of total lipids” and/or “omega-3 fatty acids are 0.1-30% by weight of total lipids”, which is present in Claim 1 of all of the claim requests, is not disclosed in the application as filed.

Mr. Alt said that the combination is disclosed in Example 1 (paragraphs [0042]-[0043]), which includes Tables 3 and 4, and in original claims 4 and 6-8.

Board said that Example 1 is not an example because it is written as general description. Board also stated that original claims 4 and 6-8 were written in US dependency form and not in EPO dependency form, stating, “Why should we follow US, US does not follow us?” (It has been discussed above that Board followed US in mutilating “different sources” and “dosage”, and in imagined prior art, but here conveniently Board did not want to follow US.) See Ms. Bhagat’s testimony (Exhibit D paragraph [0017]).

Though concerned about Mr. Alt creating another huff, Ms. Bhagat managed to squeeze in the assertion that Tables 14-19 also teach that formulations comprising ratios of omega-6 to omega-3 fatty acids combined with their concentrations in reference to total lipids. Board said that Tables 14-19 include other features. Ms. Bhagat wrote on paper asking Mr. Alt to argue citing

T201/83 that in view of totality of the disclosure omega-6 to omega-3 ratios combined with their percentages in relation to total lipids are features that could be isolated and effectively manipulated separately. Mr. Alt declined to argue. As evidence Ms. Bhagat's email dated September 18, 2017 in Exhibit C, and Ms. Bhagat's testimony (Exhibit D paragraph [0018]).

Board was wrong on many counts. First, in view of totality of the disclosure omega-6 to omega-3 ratios combined with their percentages in relation to total lipids are features that could be isolated and effectively manipulated separately (T201/83). Second, the test for allowability corresponds to the test for novelty given (T 201/83). In view of Example 1, Tables 14-19, Claims 4, 6-8, Example 11, and rest of the disclosure, Applicant's Claim 1 in MR and ARs 1-22 would be anticipated for any claimants subsequent to priority date of the subject patent application.

Further, Board had no answer to Applicant's submission on 28 June 2017 that it is permissible to combine separate items belonging to different embodiments described in one and the same document, if such combination has specifically been suggested (see T 305/87).

Stating that Example 1 is not an example because it is written as general description makes the claimed subject matter all the more allowable, because then subject matter in Example 1 is part of the main disclosure. Paragraph [0042] specifically states, "The formulations may include specific ratios of various lipid components as shown below in Table 3." Further, paragraph [0043] specifically states, "In some embodiments, the lipid formulation calls for specific percentages of omega-9, omega-6, and omega-3 fatty acids, as shown in Table 4 below," which include, "omega-6 4-75% by weight of total lipids" and "omega-3 0.1-30% by weight of total lipids." Note that the end ranges of the fatty acids in Table 4 add up to 195% (omega-9 90%, omega-6 75% and omega-3 30%), therefore the ranges disclosed in Table 4 are definitely not ranges for one composition, but ranges to choose from, to form a composition.

Regarding essentiality of omega-9 fatty acids, Board is fully aware that, "Essential features of a claim are those necessary for achieving a technical effect underlying the solution of the technical problem with which the application is concerned (the problem usually being derived from the description)." GL F-IV-4.5.2.

Ms. Bhagat asserted, main problem that the claimed inventions are solving is that of correct intake of omega-6 fatty acids relative to omega-3 fatty acids and total lipids, which the prior art has failed to understand (Specification paragraphs [0006]-[0007]). Examples 12, 15, 17, 19, 26, and 27 only recite omega-6 and omega-3 amounts wherein their ratios are evident. Furthermore, descriptions of all the examples 11-27 are concerned about omega-6/omega-3. Mr. Alt said the Tables 9-13 disclose dosage of omega-6 and omega-3 fatty acids, but not that of omega-9. (Note that Example 14.2 and original claim 40 do not even mention amounts of omega-3. They are merely concerned about correct omega-6 delivery.)

Board makes vague statements at page 2 and page 3 of the minutes, "Chairman gave the Board's conclusion that claim 1 [of MR and AR1-22] did not meet the requirements of Article 123(2) EPC." The minutes neither say that Board has concluded that combination of ranges of omega-6 to omega-3 ratios with the percentages of the fatty acids is not disclosed, nor that omega-9 is an essential feature, nor statements crucial to the conclusion. Minutes just say Board

concluded, “Claim 1 [of MR and AR1-22] did not meet the requirements of Article 123(2) EPC.” On what basis was the “conclusion” given is not stated.

GL E-II-10.3, specifically states, “Vague or general statements are to be avoided. Also, care must be taken to ensure that statements crucial to the decision are correctly recorded.” If Board maintains, as it did in its communication dated, 17 January 2018, that it gave “conclusions (not just preliminary views)”, then that is a decision. Then the statements crucial to the decision must be correctly recorded, which the Board did not do. Then because Board did not explain the reasons for its “conclusion”, the “conclusion” is invalid.

Therefore, Boards actions are not only improper; they are also invalid.

(viii) Board’s Minutes Fail To Record The Discussion About Statutory Declarations Submitted By The Applicant

Ms. Bhagat asserted citing T 667/08, “technical information that the skilled person reading the original disclosure would have derived from its content (description, claims, drawings) considered in its entirety” is considered, “literal support is not required”. Ms. Bhagat said that we have submitted declarations from skilled persons, wherein they have testified that they can obtain the claimed subject matter from the disclosure.

Mr. Sieber dismissed the declarations stating they are the same. (This allegation was misplaced copy of US prosecution history). **Board was wrong. Declarations are not the same; Pan and Shen declaration submitted on 9 May 2014 are entirely different from Erickson, Rustagi, and Rucker declarations submitted on 5 December 2014. All declarants testified under penalty of false statements that the claimed subject is directly an unambiguously obtained from the disclosure.**

Ms. Bhagat asked Mr. Alt during the oral proceedings to argue that as per case law, there was no issue with declarations being the same, but Mr. Alt did not cite case law, e.g. T558/95, wherein the board held that the fact that the statutory declarations produced by the opponent partly used the same wording and had been drawn up by employees of the opponent did not necessarily mean they should be excluded as inadmissible. See Ms. Bhagat’s testimony (Exhibit D paragraph [0019]). Even if Mr. Alt did not cite case law, the Board is aware of it. Board is expected to be honorable, which the Board failed to demonstrate. **Board should not make such below par objections.**

Mr. Sieber said that I am looking for support, but I am not finding. First, Applicant had cited support in Example 1, original Claim 4, original Claims 6-8, and rest of the disclosure. Second what part of “literal support is not required” does the Board not understand? “Literal” means “word-for-word” (thefreedictionary.com/literal), which is not required by Article 123(2) EPC (T 667/08). Also what part of “suggested” does the Board not understand? “Suggested” means “to express indirectly” (thefreedictionary.com/suggest). It is permissible to combine separate items belonging to different embodiments described in one and the same document, **if** such combination has specifically been **suggested** (see T 305/87).

Five esteemed scientists (skilled persons) have testified that they understand the disclosure and that they can obtain the features in all of the claims of all of the requests from the disclosure.

There have been a series of decisions at EPO (e.g. T 667/08, T 305/87, T201/83), which have held that the underlying considerations under Article 123(2) EPC are always based on the skilled person's understanding of the disclosure. **It is unclear why Board disregarded the declarations. Board's minutes do not explain this crucial point, without which Board's alleged "conclusions" have no meaning.**

Furthermore, ED held that AR9-10 presented to ED, which also contain combination of ranges of omega-6 to omega-3 ratios with the percentages of the fatty acids and no omega-9 fatty acids in Claim 1, met the requirements of article 123(2) EPC (minutes to oral proceedings pages 2-3 and communication dated 3 march 2015 pages 14-15). Therefore, ED—skilled persons—can clearly obtain the combination and the non-essentiality of omega-9 fatty acids from the disclosure.

Furthermore, several other patent office examiners—skilled persons—such as Japan (Application No. 2011-506377), Australia (Patent No. 2009239499), Israel (Application No. 208858), New Zealand (Patent No. 589357), Singapore (Patent No. 165822), and Malaysia (Patent No. MY-157040-A) have either granted substantially similar claims as instant appealed claims or held them allowable. Additionally, there is no added matter objection in case of corresponding US applications 12/426,034 and 13/332,251.

For example, Japan Patent office holds the following claim allowable in corresponding Japanese Application No. 2011-506377,

A lipid-containing formulation comprising a mixture of lipids from different sources, wherein the formulation comprises a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater, wherein:

- (i) omega-3 fatty acids are 0.1-20% by weight of total lipids; or
- (ii) dosage of omega-6 fatty acids is not more than 40 grams.

See Ms. Bhagat's testimony (Exhibit D paragraph [006]).

Why is it that all these examiners—skilled persons—at all these patent offices, of which US and Japan are trilateral offices that mutually honor the claims held allowable in respective offices, can obtain the claimed subject matter from the disclosure, but Board cannot? At the very least all of these patent examiners are not biased in favor of the Applicant, rather they have a bias to raise objections by the very nature of their jobs. **Whether or not the Board of Appeal at EPO can overrule ED decisions, is a separate matter from ED examiners and other patent offices' examiners being skilled persons. If all these skilled persons can obtain the subject matter from the disclosure, then the Board must be incompetent or improper that it cannot.**

In view of the fact that so many patent examiners—skilled persons—including ED, find the combination of ranges of omega-6 to omega-3 ratios with the percentages of the fatty acids and non-essentiality of omega-9 fatty acids supported by the Specification but Board does not, Board demonstrated a mind unwilling to understand (T 190/99), and that Board was overreaching for excuses to deny the patent. And Board did not explain why it disregards T 667/08 and T 305/87 crucial to the "conclusion."

Therefore, Board's actions are improper and invalid.

(ix) Board's Minutes Misrepresent "Conclusions" versus "preliminary views"

Board communication of 17 January 2018, is incorrect in stating,

"The Board further notes that the Chairman did explicitly give conclusions (not just preliminary views) on the allowability of the main request and auxiliary requests 1 to 22 under Article 123(2) EPC."

Accurate statements made near the end of oral proceedings are as follows,

- (1) After Mr. Sieber announced that AR23 would not be admitted into proceedings, Mr. Alt asked if the Board would allow the Applicant to withdraw the appeal at this point?
- (2) Mr. Sieber said, "I have only given Board's preliminary views, not conclusions. Therefore, the Applicant can withdraw the appeal."
- (3) Mr. Alt then said, "Applicant withdraws the appeal."
- (4) Subsequently, Mr. Sieber said, "I will now give Board's conclusion that Claim 1 of main request and auxiliary requests 1 to 22 do not comply with Article 123(2) EPC."

The above is testified in Ms. Bhagat's enclosed testimony (Exhibit D paragraph [0020]).

Therefore, Applicant correctly asserted in the request for correction of the minutes of the oral proceedings at bottom of pages 2 and 3, that when Applicant withdrew the appeal, at that point Mr. Sieber had given Board's preliminary views. It is improper for the Board to lure the Applicant towards withdrawal of appeal and then impose "conclusions".

Further, as asserted above, Board only made vague statements. No statements crucial to the "conclusion" were given or are recorded in the minutes, as per GL E-II-10.3. There is no mention in Board's minutes as to why the Board T 667/08, T 201/83, T 305/87, and T 190/99. If indeed Board gave "conclusions" then in view of T 667/08, T 201/83, T 305/87, and T 190/99, the case should have been referred to Enlarged Board of Appeals.

Therefore, Board's actions are improper and invalid.

(x) Board Did Not Follow Any Principle or Law It Shifted As Convenient

As evidenced throughout this submission the Board was not following any principle or law in the oral proceedings. The Board shifted as convenient, undermining the Applicant in collusion with Applicant's representative, following USPTO when convenient and not following USPTO when not convenient, misquoting and misapplying Article 123(2) EPC, disregarding case law, and improperly shifting from "preliminary views" to "conclusions". **Applicant felt defrauded by the Board. It was a major let down to wait for two years for the hearing with the Board and then to be met with such impropriety.**

Board gave arbitrary "conclusions" in order to oblige the Applicant to reduce the scope of the claims. Board's actions are unprofessional and dishonorable.

VI.
27 JULY 2017 ORAL PROCEEDINGS ARE INVALID

As evidenced above and in the attached Exhibits, there was a sinister conclusion between the Board and Mr. Michael Alt of Bird and Bird at the oral proceedings held on 27 July 2017. Mr. Michael Alt effectively represented the Board not the Applicant. Further, not only did Mr. Michael Alt not represent the Applicant, he obstructed Ms. Bhagat from arguing on behalf of the Applicant. Thus,

- (1) The Applicant was unrepresented at the oral proceedings;
- (2) The Applicant was obstructed from speaking at the oral proceedings; and
- (3) The Board and Mr. Alt colluded against the Applicant, and Mr. Alt effectively represented the Board not the Applicant.

Therefore, the oral proceedings held on 27 July 2017, are invalid.

Board insists that it gave “conclusions,” but it has not given statements crucial to the “conclusions”. In particular, why did the Board disregard T 667/08, T 201/83, T 305/87, and T 190/99, and skilled persons testimony—including ED, dozens of patent offices including US and Japan, five declarations from scientists. Therefore, Board’s “conclusions” are invalid.

VII.
CONCLUSION AND REMEDY REQUESTED

Applicant has demonstrated consummate professionalism having patiently prosecuted this application for almost 10 years, rebutting blatantly improper rejections, such as clarity objection over “age of the subject,” “RBC fatty acids profile” as anticipating Applicant’s claims drawn to “formulations” comprising “dosages” for administration to subjects, and Article 56 EPC-type objections applied as Article 54 EPC objections (copying USPTO), and finally Board’s far-far fetched “added matter” objections, even though ED—skilled persons—had conceded to no added matter in combining omega-6 to omega-3 ratios with their concentrations relative to total lipids and to non-essentiality of omega-9 fatty acids, and even though dozens of patent offices do not find any added matter in the similar claims and five skilled persons have testified that they can obtain the claimed subject matter directly and unambiguously from the disclosure.

ED and Board made blatant excuses in denying the patent because scope of the invention is large, which is a shame, because main point of patents is to solve critical (large) problems. The claimed inventions solve the lipid problem that has been a source of immense pain and suffering for millions of Europeans for ~100 years. See Section II-Background Of The Invention above.

EPO is requested to stop and think—Where is this improper patent policy taking us as a society?

Patent system is asking for too much from the public. Public has been paying for lipid patents at least since 1902 hydrogenated fats patent (https://en.wikipedia.org/wiki/Wilhelm_Normann), i.e. for ~100 years, but the problem of healthy lipids for public benefit is still not solved. In part,

the problem is the way patent system favors piecemeal patents. For example, 100s of patents on omega-3 have been issued, each directed to a particular aspect, evident from cited documents D1-D15 in this case. It does not help to address the lipid problem on a piecemeal basis it only complicates matters. Each patent holder then tailors its marketing message to fit its product and how it is superior over the competition. The result is that public is thoroughly confused and true solutions and clear message is never given to the public. This keeps snowballing and complicating matters further. We should have learnt something from the hydrogenated fats patents, which compromised the health of millions of people worldwide.

The patent system is organized to not solve or lessen the fundamental problems as best as it can. It is a perpetual problem for the society. Lipid metabolism is affected by many factors described in the subject patent applications. Further, food sources are highly variable and unpredictable in lipid content. Furthermore, 99% of public cannot even name lipids and is ill-equipped to decipher lipid content and formulate lipids. The only way to solve this problem and set humanity on the right course is to pre-formulate lipids for public in predefined omega-6/omega-3 dosages and ratios as in instant claims. There are numerous downstream beneficial actions by third parties stemming from the Applicant's contributions, which will further advance humanitarian causes and make a lasting impact on humanity (see Exhibit A, US Patents for Humanity Application, November 8, 2015, page vi-vii).

Despite EPO obstructions and despite being a small company, Applicant has demonstrated unwavering commitment to solving the problem incurring enormous costs in prosecuting the case and paying EPO fees for nearly 10 years. Significant window of opportunity has been lost from being able to effectively solve the problem. That is extremely harmful to the Applicant and the public. This kind of platform takes a long time to nurture and protected environment is necessary to nurture the solutions. Therefore, the delay is a loss to the public.

It has also been called to attention above that there are perverse incentives for applicants' professional representatives in alignment with EPO, and that this is particularly detrimental to small companies, such as the Applicant in current case. Applicant has also reported above that this went to the point of collusion between Applicant's then-authorized legal representative, Mr. Michael Alt, and the Board at the oral proceedings held on 27 July 2017. Applicant has not noticed this degree of alignment/collusion in any of the other jurisdictions. There is something wrong about EPO practice that instills this behavior.

EPO should make self-representation easier to accommodate cases where law firms may not fully support solutions to a problem that eats into their business by solving a problem that is a source of multiple revenue streams to them. In such cases, Applicant may be better off self-prosecuting. Again main purpose of patents is to solve problems. If a small company sets out to solve a problem, and the professional representative and EPO work against the Applicant because it eats into their revenue by solving the problem in one step or fewer steps, then patent system is not working to solve the large problems in the best interest of the public.

The Applicant has also lost confidence in EPO oral proceedings. The proceedings before ED and the proceedings before the Board, were marred with the legal representatives using oral proceedings as means to invoice more and badger the Applicant for advance payments, and the

EPO (ED and Board) surprising the Applicant with new citations, disregarding arguments, evidence and case law on record, and undermining the Applicant—in case of the Board in collusion with the Applicant’s counsel.

Irreparable harm has been caused to the Applicant. There is no remedy at law to make up for the harm caused. Applicant requests the EPO to at least redress the case as following and consider additional possible remedies.

- (i) Oral proceedings of 27 July 2017 be invalidated, considering Applicant was not represented at all. The legal representative, Mr. Michael Alt, who was supposed to represent the Applicant, in fact represented the EPO and harmed the Applicant.
- (ii) The application status be restored for new proper hearing by the Boards of Appeal.
- (iii) A new fair Board of Appeal be assigned to the case.
- (iv) The new Board be instructed to promptly render a written decision on entirety of record including this Formal Complaint, properly addressing Applicant’s arguments, evidence, and case law.
- (v) If the new Board of Appeal maintains the refusal, then the case be immediately referred to Enlarged Board of Appeal under accelerated proceedings.
- (vi) A copy of this Formal Complaint be placed in the electronic file history of the subject patent application (EP09 735 962.4) in the European Patent Register.


Urvashi Bhagat
Chief Executive Officer

Enclosures:

- Exhibit A. US Patents for Humanity Application, 8 November 2015
- Exhibit B. Applicant’s Correspondence with Mr. Nick Lee of Kilburn & Strode, 23 April 2015
- Exhibit C. Applicant’s Correspondence with Mr. Michael Al of Bird and Bird, 16 August 2017 to 18 September 2017
- Exhibit D. Declaration of Ms. Urvashi Bhagat dated January 30, 2018
- Exhibit E. “Omega-6 fatty acid” Wikipedia, accessed January 29, 2018



OMB 0651-0066 Approved for use through 8/31/15.
U.S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE
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Humanitarian Use Application

Application Title: **Pre-formulated lipids, tailored lipids, and balanced lipids and micronutrients.**



Application Date: November 8, 2015

Category: Nutrition

Organization Applying:



Primary Location of the applicants:

City: Palo Alto State: CA Country: USA

Public Contact Info:

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Address: PO Box 1000, Palo Alto, CA 94302
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Preferred contact method: admin@asha-nutrition.com
Press contact: admin@asha-nutrition.com

If you wish to provide private contact info to be notified about your application status, please email it to patentsforhumanity@uspto.gov. Otherwise we will use any contact info associated with your submission.

It is estimated that the Humanitarian Award Application will take 4 hours to complete. Applying for the Award is voluntary; however, if you apply you must provide the information requested. Failure to provide this information may delay or prevent processing of your application. Please send any comments on the amount of time required to complete this form and/or suggestions for reducing the time burden to the Chief Information Officer, USPTO, PO Box 1450, Alexandria, VA 22313-1450. DO NOT SEND APPLICATIONS TO THIS ADDRESS

Qualifying Patents

1. List the relevant U.S. utility patents or patent applications you own or license that you wish to apply under. These patents must relate to the technology described in this submission. Add more rows if needed. Only one patent or patent application is required for eligibility. If any patents or applications are found ineligible, the remaining items will be considered. If no eligible items remain, the PTO may contact the applicants to determine if eligible material can be identified.

U.S. Patent Application Number (PCT Number) (PCT Publication number)	Title	Filing Date
12/426,034 (PCT/US2009/041114) (WO2009/131939 A9)	Lipid-Containing Compositions And Methods Of Use Thereof	April 17, 2009
13/332,251 (PCT/US2009/041114) (WO2009/131939 A9)	Lipid-Containing Compositions And Methods Of Use Thereof	December 20, 2011
13/877,847 (PCT/US2011/056463) (WO 2012/051591 A2)	Optimized Nutritional Formulations, Methods For Selection Of Tailored Diets Therefrom, And Methods Of Use Thereof	April 4, 2013

2. Are any of these patents or patent applications licensed from an entity not listed as an applicant on this form?
 NO

In no more than five pages, please address the following questions.

Eligibility Questions

3. What humanitarian issue(s) does this application cover? If not widely recognized, provide enough information to determine whether the issues significantly affect the health or quality of life of an impoverished population.

This application covers, pre-formulated lipids, tailored lipids, and balanced lipids and micronutrients, a game-changing solution for protecting and advancing public health at foundational level, whereby millions of people worldwide can benefit particularly the impoverished populations.

The foundation to health is nutrition. The most important and difficult to manage nutrients consumed are lipids, which include omega-6, omega-3, and several antioxidants and phytochemicals. Micronutrients include antioxidants, phytochemicals, and minerals, which affect metabolism of omega-6, omega-3, and other fatty acids. Most of the chronic diseases are associated with mismanaged lipid consumption, further immunity and daily well being is affected by lipid consumption, furthermore lipid requirements are different for different members of the family (by body size, hormones...)(See *Bhagat et al. 2015, Arch Med Sci 2015; 11, 4: 807–818*). In 2012, in the US chronic diseases affected 117 million people costing ~\$2 trillion (<http://www.cdc.gov/chronicdisease/overview/index.htm>); worldwide chronic and infectious diseases affected ~2 billion people (http://www.who.int/healthinfo/global_burden_disease/estimates/en/index2.html).

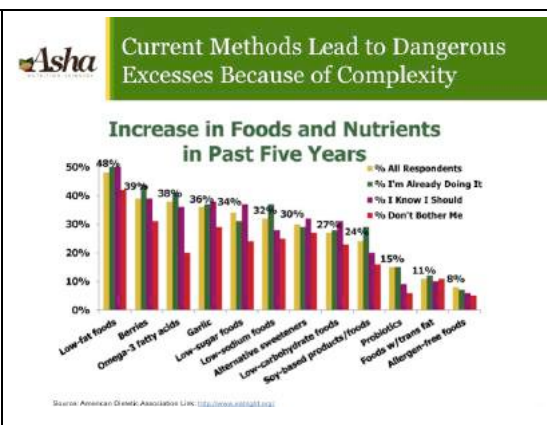
Natural lipid sources, oils, nuts and seeds etc, are variable and unreliable in lipid content and composition, and they contain many components that materially affect lipid metabolism. Important lipids such as polyphenols and several phytochemicals are poorly understood and absent from available dietary guidance, see Dietary Guidelines for Americans (http://www.cnpp.usda.gov/sites/default/files/dietary_guidelines_for_americans/PolicyDoc.pdf). Adding to the complexity is mass confusion in the field with many spins on what is desirable and what is not. For example, many bodies and publications have disparaged omega-6 or taught low amounts of omega-6 and low omega-6 to omega-3 ratios (*Lands, Nutrition Reviews 1986:44-6:189-95; Lands, Ann. N.Y. Acad. Sci. 1055: 179–192 (2005); Simopoulos, Ann Nutr Metab 1999;43:127–130; Hamazaki et al. World Rev Nutr Diet. Basel, Karger, 2003:92:109–132*), even though omega-6 is the most critical fatty acid for health. Further, too many supplements are sold without regard for interactions. For example, it is a misconception that omega-3, antioxidants, and phytochemicals are always good for health. Such issues have increased the risk of some diseases. It is extremely complex for public to solve this problem. For example, **less than 1%** of Americans can correctly name types of fats (see surveys at <http://www.foodinsight.org>), let alone lipids. Unless corrected, the chaotic out-of-context touting of nutrients will create further problems in the field of nutrition and consequently health.

Fatty acid composition of some common edible fats and oils.

Percent by weight of total fatty acids.

Oil or Fat	Unsat./Sat ratio	Saturated						Mono unsaturated		Poly unsaturated	
		Capric Acid C10:0	Lauric Acid C12:0	Myristic Acid C14:0	Palmitic Acid C16:0	Stearic Acid C18:0	Oleic Acid C18:1	Linoleic Acid (ω6) C18:2	Alpha Linolenic Acid (ω3) C18:3		
Almond Oil	9.7	-	-	-	7	2	69	17	-	-	
Beef Tallow	0.9	-	-	3	24	19	43	3	1	-	
Butterfat (cow)	0.5	3	3	11	27	12	29	2	1	-	
Butterfat (goat)	0.5	7	3	9	25	12	27	3	1	-	
Butterfat (human)	1.0	2	5	8	25	8	35	9	1	-	
Canola Oil	15.7	-	-	-	4	2	62	22	10	-	
Cocoa Butter	0.6	-	-	-	25	38	32	3	-	-	
Cod Liver Oil	2.9	-	-	8	17	-	22	5	-	-	
Coconut Oil	0.1	6	47	18	9	3	6	2	-	-	
Corn Oil (Maize Oil)	6.7	-	-	-	11	2	28	58	1	-	
Cottonseed Oil	2.8	-	-	1	22	3	19	54	1	-	
Flaxseed Oil	9.0	-	-	-	3	7	21	16	53	-	
Grape seed Oil	7.3	-	-	-	8	4	15	73	-	-	

Also see <http://www.ars-grin.gov/duke/> for other lipid content.



Pre-formulated lipids, tailored lipids, or balanced lipids and micronutrient delivery to public, can prevent or at least reduce the suffering from many chronic diseases. Such pre-formulated lipids are particularly indispensable for impoverished populations who have inadequate access to medical care, are subjected to poor living conditions, and have poor knowledge to choose lipids making them disproportionately susceptible to infections and diseases. Thus, delivering pre-formulated lipids, tailored lipids, or balanced lipids and micronutrient to public, especially to impoverished populations, can significantly reduce incidence and/or severity of disease.

4. What technologies does this application cover? Provide a brief description of each and indicate how they relate to the patents or patent applications in question 1.

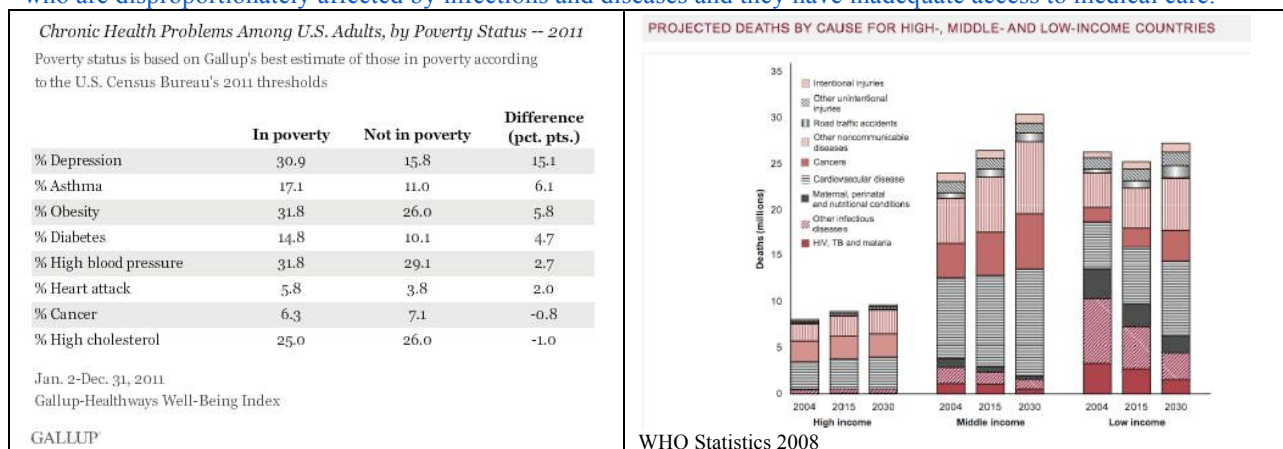
Technologies covered; product name: **LIPILIFE** (subject to change):

- US 12/426,034 and 13/332,251 cover **pre-formulated lipids** containing omega-6 and omega-3 with omega-6 to omega-3 ratios greater than 4:1 or omega-6 greater than 20% of total lipids, wherein their dosages are controlled and/or content of other lipids in controlled. These applications also cover **tailored lipids** delivery wherein ratios and/or amounts of omega-6 and omega-3 are controlled by age, gender, and diet type, and lipid-free or low-lipid foods are designed to complement the tailored lipids.
- US 13/877,847, covers **nutritional managements systems**, which include multi-component nutritional formulations and methods of providing nutrition by demographic cohorts, designed to control the delivery of lipids including omega-6 and micronutrients, including antioxidants and phytochemicals. It also covers computer systems by means of which public can be remotely guided to managing sensitive lipid and phytochemical consumption.
- It is important to manage the dosage of omega-6 and omega-3, and lipids that affect their metabolism, as discussed above. Many variables modulate the metabolism of various fatty acids. It is difficult for consumers to calibrate on a daily basis the demands of the body for various fatty acids, since the requirements of various biologically active unsaturated fatty acids change depending on age, gender, and various life style factors. It is possible that there could exist differences in the requirements of various fatty acids and their co-factors even among members of the same family. (*Bhagat et al. 2 015 Supra, page 808*)

5. What populations are your actions described in this application targeting? Please describe how these populations are impoverished, and how they are affected by the humanitarian issues described in question 4.

The patent applications (see appendices) describe that technologies covered have prophylactic and therapeutic effect on almost all medical conditions, such as menopause, musculoskeletal disorders, mood, cognitive function, neural disorders, mental disorders, obesity, diabetes, endocrine disorders, digestive system disorders, reproductive disorders, pulmonary disorders, renal diseases, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, cancer, infectious diseases, inflammatory diseases, and cardiovascular disease. Further, the described technologies improve quality of life by stabilizing hormones, mood, and sleep for example.

The actions described in this application are beneficial to all populations, particularly to impoverished populations who are disproportionately affected by infections and diseases and they have inadequate access to medical care.















Thus, the disclosed solutions can especially reduce the burden of disease for impoverished populations. Applicant is targeting to provide the disclosed solutions in all economies with large share of impoverished populations.

Scoring Questions

6. Effectiveness – How do the applicants' technologies effectively address the humanitarian issues in question 5? Are any products or services that employ these technologies being used to benefit the target population?

Applicant's technologies effectively address almost all chronic and infectious diseases, which lead to ill health in 117 million people (133 million by some estimates) in US, and in ~2 billion people worldwide (http://www.who.int/healthinfo/global_burden_disease/estimates/en/index2.html). In fact, suffering is more than accounted here. For example, ~80% of females above the age of 13 (not counted in 2 billion) suffer from hormonal fluctuations, which can be debilitating and can be abated with controlled lipid delivery (*Filho et al., Reproductive Health 2011, 8:2*).

 <p>Tailored Lipids are the Most Sensible, Effective, and Sustainable Solution to Chronic Diseases...</p>  <p>133M People in US!</p>	 <p>Tailored And Steady Lipid Consumption Can Optimize Hormones</p>  <p>Very large percentage of teenage girls and women, 80% according to some reports, suffer from hormonal fluctuations and associated symptoms, which can be debilitating with consequences on school, education, work, and family.</p> <p>The instability costs them further in access to education, jobs, and economic and social standing.</p> <p>Hormonal fluctuations and associated symptoms can be abated to a large extent with correct and steady lipid delivery.</p> <p>Lipids affect hormone levels therefore erratic lipid consumption can lead to erratic hormone levels.</p> <p>Lipid requirements for girls and women are different from boys and men. Thus tailored lipids can help prevent health issues associated with hormones.</p>	
 <p>Scientific Evidence – MUFA & PUFA</p> <p>Conclusions from Fatty Acids Symposium by National Lipid Association:</p> <p>Monounsaturated Fatty Acids (such as in olive oils) are associated with atherosclerosis</p> <p>Dietary PUFA (omega-6) may be more protective than MUFA.</p> <p>Omega-3 benefits are elusive</p> 	 <p>Scientific Evidence – PUFA & Cancer</p> <p>An Omega-6 PUFA (LA) inhibited colorectal cancer cell growth</p> <p>Results suggested that this PUFA is toxic to colorectal tumor cells but not normal cells</p>  	 <p>Scientific Evidence – PUFA & Learning Disorders, e.g. ADHD</p> <p>Certain types of Omega-6 and Omega-3 PUFAs are significantly below normal in people with learning disorders</p>  <p>This was particularly true for children. Authors theorized, "Children in Westernized countries may be eating a diet containing suboptimal AA to satisfy their dietary requirements during growth." Antioxidants and phytochemicals can inhibit AA (long-chain omega-6) activity.</p> 

Most tissue contains ~10 times omega-6 as compared omega-3 and utilization of omega-6 is higher than omega-3. Omega-6 and other lipids are critical for optimal functioning of the cells and organisms (see *Bhagat et al, 2015* and *Morse 2009*). Further, immunity is materially enhanced by controlled lipid delivery. Therefore, health effects of the technology are at a broad level. Consumer feedback to LipiLife from preliminary market research has been positive (see table below). Several scientific publications published after the patent applications were filed, also report similar benefits from higher omega-6 consumption. See Appendices.


Thus, significant reduction in the cost of chronic diseases and human suffering can be achieved by implementation of the solutions disclosed in the patent applications. Some of the suffering and cost estimates are as follows:

<p style="text-align: center;">United States Estimates (http://www.cdc.gov/chronicdisease/overview/)</p> <ul style="list-style-type: none"> • 86% percent of all health care spending, ~\$2 trillion annual healthcare spending (2010) • ~117 million people affected by chronic diseases (2012) 	<p style="text-align: center;">Worldwide 2012 Estimates (http://www.who.int/healthinfo/global_burden_disease/estimates/en/index2.html)</p> <ul style="list-style-type: none"> • ~2 billion people suffer from chronic and infectious diseases • Heart disease and stroke ~393 million people • Cancer ~223 million people
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<ul style="list-style-type: none"> • Costs of heart disease and stroke \$315.4 billion (2010) • Costs of cancer care \$157 billion (2010) • Costs of diagnosed diabetes \$245 billion (2012) • Costs of arthritis and related conditions \$128 billion (2003) • Costs linked to obesity \$147 billion (2008) 	<ul style="list-style-type: none"> • Diabetes ~60 million people • Musculoskeletal disorders ~111 million people • Infectious diseases ~432 million people • Neurological conditions ~80 million people
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Additionally, LipiLife solves 100-year old problem of spoilage of unsaturated fats. In the 1900s, hydrogenated fats were introduced to solve the problem that unsaturated fats form toxic compounds sitting on shelf. However, we now know that hydrogenated fats are deleterious. We also know that unsaturated fats are critical for health, but cannot be added to food meant sit on shelf. The most effective solution is to pre-formulate and tailor lipids and deliver separately from the rest of the food, such that they are not made to sit on shelf for long durations, as LipiLife does. LipiLife is prepared separately from rest of the food and delivered in containers that are meant to last 1-4 weeks, i.e. not designed to sit on shelf for months.

Consumer Feedback to LipiLife*




- **LipiLife is a Game Changer**
- **It makes so easy to keep track of fat intake, specifically Omega-3 and Omega-6**
- **It makes eating healthy easy**
- **It reduces the probability of overeating**
- **It makes me think and concentrate better, and I feel more grounded**
- **I sleep better and wake up rested**
- **I haven't had a cold since I started this**
- **I reduced my cholesterol and improved diabetes symptoms**


* Preliminary Market Research

Asha NUTRITION RESEARCH


**LipiLife Solves 100-Year Old Problem
Toxicity of Lipids and Correct Dosage**




Lipids form toxic compounds sitting on shelf over time




Hydrogenated fats were introduced in early 1900s to solve this problem



Hydrogenated fats cause diseases - stopped in early 2000s



Polyunsaturated fats good for health but most vulnerable to forming toxic compounds



LipiLife best solution - replacement bottle/box delivered to consumers every 7 days and used with foods prepared without fat

The product, LipiLife, is in limited supply at present due to limited capital. Significant capital is necessary to effectively solve this problem, which includes public education in addition to product implementation. It is important for the patents to be granted for the Applicant to raise sufficient capital. All of the three applications are currently pending. Faster advancement of these applications is necessary for the applicant to secure sufficient capital and implement the solutions with public education to benefit the target populations.

7. Contribution – What meaningful actions did the applicants take to make the technology more available for addressing humanitarian issues?

Applicant is a small entity with very limited resources. Proprietors of the company have invested their personal intellectual and material resources for 10 years with dedication, without remuneration, to advance and implement the technology. Applicant needs sufficient capital to effectively solve this problem and patents need be granted to raise sufficient capital and effectively implement the solutions.

Applicant has committed to providing subsidized/free products to impoverished populations from part of the income generated from for-profit segments. Applicant plans to direct 10-25% of profits generated for providing subsidized/free products to impoverished populations. Such plans will be opportunistically reevaluated based on Applicant's financial strength. Partnerships will be developed with governments and non-government organizations to collaborate on subsidized/free product distribution to impoverished populations. For example, Applicant has had

discussions for establishing such relationships with the following organizations: The HSC Foundation, The California Endowment, and California Wellness Foundation.

Applicant has invested very significant resources in building worldwide intellectual property portfolio in order to successfully make technology available to impoverished populations in economies with a disproportionate share of impoverished populations, such as Nigeria, Mexico, South Africa, Ukraine, Indonesia, Sri Lanka, China, and India.

8. **Impact** – How has deployment of the technology to benefit the target populations been significantly advanced as a result of the applicants' contributions? Are the target populations using the technology or products and services based on it? Are they benefitting in other ways? Include downstream actions by third parties stemming from the applicants' contributions.

As stated above, Applicant is a small entity. The products are currently in limited supply due to scarce resources. Applicant has put all resources available to deployment of the technology to benefit the target populations. Applicant has committed to providing subsidized/free products to impoverished populations from part of the for-profit segments returns, and to developing partnerships with governments and non-government organizations to collaborate on subsidized/free product distribution to impoverished populations. As evidenced throughout this application unprecedented humanitarian benefits can be realized through this technology.

In the enclosed declarations from Drs. Rustagi, Rucker, and Das, the scientists declared:

“Thus, the art recognized in 1929 that the problem existed as noted in paragraph [0019]. However, the art has failed to solve the long-felt, critical and unmet need until the April 2008 priority date of the subject patent application, i.e. for ~80 years. There have been many persistent attempts as evidenced by the references cited above (e.g. Mark et al., whfoods.com, Lands 1986 and 2005; Simopoulos 1999; Hamazaki et al., 2003 supra), but the problem has not been solved. Lipid art has been struggling to find what are the right combinations of omega-6 and omega-3 and other lipids for consumption, how to keep the fatty acids stable on shelf (without formation of toxic compounds) but bio-available in-vivo (Chen and Chaiyasit supra). Inventions of instant claims 65, 91, 98, 122, 129, and 130 have devised the solutions. Thus, the invention of the subject patent application solves a long-felt critical persistent unmet need, and has great potential to protect and improve public health.” See para [0019]-[0023].

“[The technologies] ... are well-reasoned and directed at much needed lipid solutions, particularly in light of mass erroneous teachings and confusion in the lipid art.” See para [0026].”

Thus, the technology has many immediate and long-term benefits.

- The immediate benefits are reduction in global disease burden and public suffering.
- Long-term benefits include solution to the problem of toxicity from spoilage of unsaturated fatty acids, which has plagued the society for over 100 years.
- Long-term benefits also include that tailored delivery of lipids and micronutrients can prevent diseases from acculturation because of tailoring to demographics.
- The disclosed approach will largely re-align the currently dysfunctional nutrition system.
- The technology has additional long-term benefits, such as when tailored lipids and micronutrients solve the large part of the disease burden, resources and research are focused on solving deeper causes of diseases in populations free of the confounding effects of mismanaged lipid consumption.

Thus, there are numerous immediate and downstream beneficial actions by third parties stemming from the applicants' contributions, which will advance humanitarian causes and make a lasting impact on humanity.

Additional Information

If there's any additional information you would like the judges to consider, include it here. Judges are not required to read more than five pages of material, not counting the pages of this form.

Appendices:

1. Bhagat et al. 2015, "Potential role of dietary lipids in the prophylaxis of some clinical conditions" Arch Med Sci 2015; 11, 4: 807–818
2. Lands, "Renewed Questions about Polyunsaturated Fatty Acids" Nutrition Reviews 1986;44-6:189-95
3. Lands, "Dietary Fat and Health: The Evidence and the Politics of Prevention" Ann. N.Y. Acad. Sci. 1055: 179–192 (2005)
4. Simopoulos, "Essentiality of and Recommended Dietary Intakes for Omega-6 and Omega-3 Fatty Acids" Ann Nutr Metab 1999;43:127–130
5. Calder PC, "Polyunsaturated fatty acids and inflammatory processes: New twists in an old tale" Biochimie 91 (2009) 791–795
6. Johnson et al., "Effect of Dietary Linoleic Acid on Markers of Inflammation in Healthy Persons: A Systematic Review of Randomized Controlled Trials" J Acad Nutr Diet. 2012;112:1029-1041.
7. Baum et al., Journal of Clinical Lipidology 2012;6:216–234 "Fatty acids in cardiovascular health and disease: A comprehensive update"
8. Morse. "A meta-analysis of blood fatty acids in people with learning disorders with particular interest in arachidonic acid" Prostaglandins, Leukotrienes and Essential Fatty Acids 2009;81:373–389
9. Lu et al. "Linoleic acid suppresses colorectal cancer cell growth by inducing oxidant stress and mitochondrial dysfunction" Lipids in Health and Disease 2010, 9:106.
10. Brasky et al., "Plasma Phospholipid Fatty Acids and Prostate Cancer Risk in the SELECT Trial" July 2010
11. Yip et al., "The Omega-3 Fatty Acid Eicosapentaenoic Acid Accelerates Disease Progression in a Model of Amyotrophic Lateral Sclerosis" PLoS ONE 8(4)
12. Declaration from Dr. Pradeep K. Rustagi dated September 29, 2014.
13. Declaration from Dr. Undurti N. Das dated September 30, 2014.
14. Declaration from Dr. Robert B. Rucker dated September 29, 2014.
15. Lipid-Containing Compositions And Methods Of Use Thereof
16. Optimized Nutritional Formulations, Methods For Selection Of Tailored Diets Therefrom, And Methods Of Use Thereof
17. Filho et al. "Essential fatty acids for premenstrual syndrome and their effect on prolactin and total cholesterol levels: a randomized, double blind, placebo-controlled study" Reproductive Health 2011, 8:2

From: Urvashi Bhagat bhagatu@asha-nutrition.com
Subject: Re: 17446 - Asha Nutrition Sciences, Inc. [KS-MAIN.FID1156916]
Date: April 23, 2015 at 12:28 PM
To: Nick Lee nlee@kilburnstrode.com
Cc: Caroline Gage cgage@kilburnstrode.com, Catherine Munday cmunday@kilburnstrode.com, Jamie Atkins jatkins@kilburnstrode.com

Dear Nick,

To tell you the truth Nick, I am very angry with KS. I haven't said so much previously because I am trying to be gracious and I am swamped. (Just like you count your hours my time is also important, even for writing this email). My reasons include the following:

1. There were some problems with the claims that KS did not address in time, e.g. the preparation/selection claim should have been written as I had drafted later on.
2. The unity of invention could have been easily overcome if we had arranged the claims a little bit more smartly; e.g. leave only a 0.1–30% option in claim 1 and move everything else to dependent claims.
3. I had told you that US had raised an objection over "olives" you could have advised to include "mixture of lipids from different sources" in claim 1. Lack of foresight on that point has cost us heavily.
4. You were in a rush to conclude the call with the Chairman when he called. The whole point of setting up the call with him (after 6 weeks of trying) was to reach an agreement. But just moments after he came on line you said, "We should let him go. It is the end of the day for him." I thought that was so odd. If anything we wasted his time by not taking the time to work things out on the call. I expected you to take the lead and sort things out.
5. After the call you should have immediately drafted and sent alternate ARs, but you were not looking out for our interest. You were just worried about how much more you can extract from us.
6. We had regularly paid you for past 20+ months. You should have had the decency to not pressure us for more lump sum payments prior to oral proceedings. You knew we were tight and we were tight because of delay in patent grant.

You are worried about £1037.55 when you have cost us millions. Honestly, you should be embarrassed.

Urvashi Bhagat

Chief Executive Officer

ASHA NUTRITION SCIENCES, INC.

Ph. (650) 322-7861

PO Box 1000

Palo Alto, CA 94302

<http://www.asha-nutrition.com>

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On Apr 23, 2015, at 8:49 AM, Nick Lee <nlee@kilburnstrode.com> wrote:

Dear Urvashi

Your email below has been passed to me.

You have said that "There were several mistakes made by KS in prosecution of our case and due overall mishandling of the case, specifically prior to the oral proceedings..." However, you have not said what they are.

There are two invoices that remain to be paid – KS530496 dated 19 May 2014 for £1037.55 and KS551389 dated 15 December 2014 for £6330.92. As far as I can see, there have been no queries in respect of KS530496 so there appears to be no reason why this cannot be settled. We have corresponded about KS551386 (see enclosed) and I offered a discount of 10% on this invoice if it was settled by the end of January. However, we have seen no payment for this

invoice if it was settled by the end of January. However, we have seen no payment for this invoice nor indeed any further correspondence from you. I think it is reasonable to conclude from this that I have answered the queries satisfactorily.

I am therefore at a loss to understand why you think we are harassing you – we are simply looking for payment of overdue invoices – and why, in the circumstances, you feel our looking for this payment compels you to report Kilburn and Strode.

If you would like to discuss this matter, I would be happy to arrange a telephone call because, as it stands, I do not know why you are not paying our invoices.

Nick Lee
Partner

<image001.png>

For and on behalf of:
Kilburn & Strode LLP
20 Red Lion Street
London WC1R 4PJ

T +44 (0)20 7539 4200
F +44 (0)20 7539 4299
E nlee@kilburnstrode.com
www.kilburnstrode.com

Patent and Trade Mark Attorneys

From: Urvashi Bhagat [<mailto:bhagatu@asha-nutrition.com>]
Sent: 23 April 2015 15:20
To: Catherine Munday
Subject: Re: 17446 - Kilburn & Strode LLP

You need to stop harassing us, otherwise we will be compelled to report Kilburn and Strode (KS) to the Professional Standards Board. There were several mistakes made by KS in prosecution of our case and due overall mishandling of the case, specifically prior to the oral proceedings, our company has suffered a great deal. KS should be embarrassed to ask us for further payments. We have already paid KS more than is fair. KS has only been motivated by billing and invoices, there has not been a concern for protecting our interests.

Urvashi Bhagat
Chief Executive Officer
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On Apr 23, 2015, at 7:01 AM, Catherine Munday
<cmunday@kilburnstrode.com> wrote:

Dear Ms Bhagat,

Please see attached.

Cathy Munday
Credit Control Clerk

<image003.png>

For and on behalf of:
Kilburn & Strode LLP
20 Red Lion Street
London WC1R 4PJ

T +44 (0)20 7539 4200
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E cmunday@kilburnstrode.com
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Patent and Trade Mark Attorneys

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<17446 - Letter.pdf>

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<Mail Attachment.eml>

From: Urvashi Bhagat bhagatu@asha-nutrition.com
Subject: Re: European patent application 09 735 962.4 (EP 2 278 885); Asha ref.: EP2009/041114; BnB ref.: ASHNU.0001 WOEP [B&B-M.FID9660598]
Date: [REDACTED]
To: Dr. Michael Alt Michael.Alt@twobirds.com
Cc: Bird & Bird Patent Prosecution MUNPatent-Prosecution@twobirds.com

On Sep 18, 2017, at 11:01 AM, Urvashi Bhagat <bhagatu@asha-nutrition.com> wrote:

Also Board openly said at the oral proceedings, "we want to ensure that patent does not issue on a case where there may be prior art." You should have rebutted the presumption, stating the Board is wrong because anticipation objection cannot be given if the prior art is not specific or enabled with respect to each limitation (e.g. dosage in our claims), and case of obviousness absolutely cannot be made in this case because of reasons in our appeal brief.

That was your job. You didn't do your job, you just cited passages from specification. You made feeble arguments.

I know that you are a good lawyer. Your performance at the oral proceedings can mean only one thing that you did not work in our best interest.

Urvashi Bhagat
Chief Executive Officer
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On Sep 18, 2017, at 10:13 AM, Urvashi Bhagat <bhagatu@asha-nutrition.com> wrote:

Mr. Alt,

What do you mean there was no divergent case law? I gave you the law in my draft comments (which you deleted) and also in my email of July 15th I said, "There is a strong line of arguments to be made on combination of features and extraction of point values from examples using T201/83 (enclosed with highlights), which we can do going forward." I even gave you copy of the Decision with highlights (enclosed again). You ignored it.

Board did not apply the law on the stricter side, it was on the improper side. You presided over it.

You should have cited T201/83 with proper citations and comparative analysis and put it on record. (If you do not know how to do that, then you are not a good patent lawyer.) Then the Board would have conceded or then we could have insisted on referral to the Enlarged board of appeal. That is your job, it is not to cite passages from Specification, I can do that very well.

Why did I fly all the way over to Munich, if you were to shut me up? We filed a request with the EPO to postpone the oral proceedings so I could argue at the oral proceedings. You even knew that I am prosecuting pro se in US. So you knew I am not uninformed in patent prosecution. I have been prosecuting this case for 10 years in multiple jurisdictions. I know the case inside out. You also knew that it was difficult for me to come to Europe at that time, but I made the time, which you wasted.

You misstated claim interpretation at the oral proceedings, such as "dosage" could be once in a year. That's not how the instant claims are read. They are read as each administration always has to be less than 40g. Each limitation in our claims has a feature that is either not anticipated, or would be a selection invention over prior art. You didn't know how to argue yet you insisted upon speaking over me.

The Board had said there was no issue in my speaking. Even after that you threw your pen when I tried to speak, making it uncomfortable for me to speak. Oral proceedings are very time sensitive, you have to rebut allegations without loss of a moment. You couldn't rebut and you made it difficult for me to do so because later the moment was lost.

For example, the Board said the declarations are identical. You should have immediately rebutted that there is no issue with that, as per case law. I would have done that had you not had the podium.

You are wrong that JPO allowance has no effect on EPO allowance. JPO is one of the trilateral offices (US, JPO and

EPO) and one of the IP5 offices (JPO, USPTO, EPO, SIPO, and KIPO). As such, JPO has a great bearing on allowance at EPO.

You have jeopardized 10 years of work and caused enormous worldwide damage to us. I am dealing with the consequences of your doing and extremely upset about it.

Urvashi Bhagat

Chief Executive Officer

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<1984 Shell EPC123 Limitation from example.pdf>

On Aug 31, 2017, at 7:13 AM, Urvashi Bhagat <bhagatu@asha-nutrition.com> wrote:

Mr. Alt,

You have caused us great harm. Your statements below are incorrect, we will have a lawyer respond to them. You represented EPO at the proceedings not us, and you continue to do so. I also suspect that there must have been a conflict of interest for you to act in the way you did.

I am most disappointed in you. We intend to take legal action.

We will soon inform you whom the cases have been transferred to.

Urvashi Bhagat

Chief Executive Officer

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On Aug 31, 2017, at 5:35 AM, Michael Alt <Michael.Alt@twobirds.com> wrote:

Dear Urvashi,

Thanks for your below mail. Please find my comments in Red in your E-mail.

<Redacted>

Best regards

Michael

From: Urvashi Bhagat [<mailto:bhagatu@asha-nutrition.com>]

Sent: Mittwoch, 16. August 2017 16:53

To: Michael Alt

Cc: Bird & Bird Patent Prosecution

Subject: Re: European patent application 09 735 962.4 (EP 2 278 885); Asha ref.: EP2009/041114; BnB ref.: ASHNU.0001 WOEP [B&B-M.FID9660598]

Dear Michael

Dear Michael,

I have been thinking about how to say this to you, but there is no other way to say this than directly. My reading is that you did not want the case to be allowed. This reading is for the following reasons:<Redacted>

- You did not cite any case law.
The most relevant case law was cited in the submissions and also in the hearing. I referred to, e.g. T 667/08.
- You did not want me to speak. You misstated to me that in Applicant is not allowed to speak. You were afraid that I would argue properly and that might lead to allowance.
I did not misstated anything to you. <Redacted>
Since you never expressed your wish to make statements before the board no such request was filed before the hearing. Thus, I was correct in stating <redacted> you could not plead the case.
<Redacted>
- You weakened my position when you created a huff over my speaking during the oral proceedings.
I did not create a huff but aimed at controlling your submission <redacted>.
- You should have taken a stand that if Board finds divergent case law, then the case be referred to Enlarged Board of Appeals. You let the Board off the hook by withdrawing the appeal.
There was no divergent case law. <Redacted>
- I had informed you that JPO has held all the claims allowable (see my email dated March 17, 2017). <Redacted>
This is of no relevance for the EPO proceedings. In addition the Board had also mentioned in a different context that they know that the standards (in this context) of the US law are different but that they have to follow the EPO practice. This illustrates their lack of interest in what happens in non-European jurisdictions.

Extreme harm has been caused.

Urvashi Bhagat

Chief Executive Officer

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TO THE EUROPEAN PATENT OFFICE

Re the European Patent Application No. 09735962.4

In the name of: Asha Nutrition Sciences, Inc.

Title: LIPID-CONTAINING COMPOSITIONS AND METHODS OF USE THEREOF

DECLARATION UNDER ARTICLE 117 EPC

European Patent Office
Erhardtstrasse 27
D-80298 München
Germany

Sirs:

I, Urvashi Bhagat, hereby testify:

[001] I am the inventor of the above-referenced patent application. Additionally I serve as President and CEO of Asha Nutrition Sciences (hereinafter "Asha"), the assignee of the subject application. I am responsible for day-to-day operations of the company in addition to prosecuting its patents in several jurisdictions. I am allotted stock as compensation for assigning my inventions to Asha and for my role in Asha. I have not received any compensation specifically for preparing this declaration. I have read the above-referenced patent application. I have also read all the other documents referenced in this declaration.

[002] The claimed inventions were conceived mainly because I became aware of serious harm caused to public health because of the erroneous omega-6 and omega-3 teachings coming from international scientists and public media prior to April 2008, in particular from US National Institutes of Health (USNIH) as follows:

"uncontrolled excessive production of omega-6 eicosanoids over prolonged periods of time is associated with heart attacks, thrombotic stroke, arrhythmia, arthritis, asthma,

headaches, dysmenorrhea (menstrual cramps), inflammation, tumor metastases and osteoporosis. ...most people are eating on the order of 20 times more of the essential vitamin-like n-6 linoleic acid than they need. As with vitamin A and vitamin D, from which the body makes potent hormone-like compounds, there is a probable risk in excessive intakes. The website notes evidence for requiring these substances in amounts on the order of **0.5% of calories or less**, but a day's menu in the United States far exceeds that." *WEM Lands* (in collaboration with USNIH) Ann. N.Y. Acad. Sci. 1055: 179–192 (2005), pp183.

Several examples in subject application describe public suffering caused by such teachings. In particular, Examples 12 and 22, where the subjects limited their daily omega-6 intake to ~1 g from EFA supplement and olive oil, and in addition took 1 g/day fish oil (mostly long chain omega-3) supplement and as a result seriously compromised their health. In the examples, at least 11g/day (5% of calories in Example 11) omega-6 was needed to reverse adverse health and it took few weeks to nurture the subjects back to safe health.

[003] There is continuing confusion in the art. For example, *Wikipedia*, the largest and most popular public reference, describes under "Omega-6 fatty acid" "Suggested negative health effects" (Exhibit E, accessed on 29 January 2018),

"Some medical research suggests that excessive levels of omega-6 fatty acids from seed oils relative to certain omega-3 fatty acids may increase the probability of a number of diseases.

Modern Western diets typically have ratios of omega-6 to omega-3 in excess of 10 to 1, some as high as 30 to 1; the average ratio of omega-6 to omega-3 in the Western diet is 15:1–16.7:1.[16] Humans are thought to have evolved with a diet of a 1-to-1 ratio of omega-6 to omega-3 and the optimal ratio is thought to be 4 to 1 or lower,[16] although some sources suggest ratios as low as 1:1.[20] A ratio of 2–3:1 omega 6 to omega 3 helped reduce inflammation in patients with rheumatoid arthritis.[16] A ratio of 5:1 had a beneficial effect on patients with asthma but a 10:1 ratio had a negative effect.[16] A ratio of 2.5:1 reduced rectal cell proliferation in patients with colorectal cancer, whereas a ratio of 4:1 had no effect."

As evidenced above, *Wikipedia* discusses ratios of omega-6 to omega-3, but there is no mention of dosages of omega-6 and omega-3, or of other lipids (phytochemicals and antioxidants) affecting the suitable ratios for omega-6 and omega-3 on the webpages. This is typical of the publications in the art including public media. This is also evidence of noise in the art, *Wikipedia* being a widely referenced publication by general public.

[004] Such teachings, e.g. *Lands* and *Wikipedia*, have created a great public health hazard.

[005] Even after the disclosure of the subject application, although a skilled person in the art can practice the claimed solutions based on the disclosure of the application, but there is little chance that public by and large can practice the solutions because less than 1% of public can understand (even name) or measure lipids in lipid sources (see Exhibit A, US Patents for Humanity Application, November 8, 2015, page iii, 3rd paragraph) and the problem pertains to daily life. Therefore, the solutions have to be implemented at public level, rather than skilled person level. From public health perspective, solutions have to be preformulated for them and they have to be taught how to adapt the solutions in daily life. This is extremely expensive and very challenging. It requires very significant capital and a protected environment to nurture the claimed solutions.

The above backdrop lead me to pursue the subject patent application because in order to effectively solve the problem significant clear public teaching—overcoming the noise in the art—is required, which requires capital and a protected environment to nurture the solutions.

[006] I have been prosecuting corresponding applications in several jurisdictions since April 2009. The following jurisdictions have either granted or held allowable substantially similar claims as in the New Main Request submitted to European Patent Office (EPO) on 9 July 2015: Japan (Application No. 2011-506377), Australia (Patent No. 2009239499), Israel (Application No. 208858), New Zealand (Patent No. 589357), Singapore (Patent No. 165822), and Malaysia (Patent No. MY-157040-A). Further, there is no added matter objection on similar claims in US (application number 12/426,034 and 13/332,251).

For example, Japan Patent Office has held the following claim allowable in corresponding Japanese Application No. 2011-506377 (only part of one dependent claim is under appeal in Japan),

A lipid-containing formulation comprising a mixture of lipids from different sources, wherein the formulation comprises a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater, wherein:

- (i) omega-3 fatty acids are 0.1-20% by weight of total lipids; or
- (ii) dosage of omega-6 fatty acids is not more than 40 grams.

[007] I have found European patent lawyers to be particularly difficult to work with. They typically charge more, are less accommodating in payment terms, and they are fearful of EPO. Some of them have told me that EPO keeps track of law firms' dealings with them and punishes law firms unfavourable to EPO. Consequently, I have found European patent lawyers to be overly concerned about their relationship with EPO and willing to compromise the clients' rights in complaisance to EPO.

[008] Mr. Nick Lee of Kilburn & Strode, then authorized professional representative attended the call with me on 20 January 2015 with Mr. François Leprêtre, Chairman of the Examining Division (ED) at EPO. Mr. Lee abruptly ended the call held on 20 January 2015 within few minutes of starting the call, and excused Mr. Leprêtre from the call stating that it was past 5pm his time and he did not need to stay on the call further. This was odd because it had taken six weeks to arrange the call. Subsequently, Mr. Lee started to pressure me to pay him in advance for preparing for the oral proceedings. It was clear that Mr. Lee did not want the application issues to be sorted out with Mr. Leprêtre on the call, because that would have meant lost billing from the oral proceedings. Mr. Lee was focused on payments and not working in our best interest, therefore I terminated his services, and engaged the law firm of VO, just before oral proceedings with ED. See Exhibit B, my correspondence with Mr. Nick Lee of Kilburn & Strode, 23 April 2015.

[009] My experience with the ED including the oral proceedings held on 11 February 2015 had not been pleasant because I felt that they were autocratic. There was no reason for giving rejections. They gave rejections just because they could and because they held scope of the invention against us. I also think that ED took advantage of the fact that we had to engage a new lawyer, who had to be brought up to speed. Therefore, oral proceedings with ED did not end well. However, I had been told by other lawyers that Boards of Appeal is more honorable, and that at that level they will not give such arbitrary rejections as ED did. Subsequently, Grounds of Appeal with new amended requests were filed on 9 July 2015.

[0010] Mr. Michael Alt of Bird and Bird was engaged to argue at the oral proceedings before the Board of Appeal (Board) with me because I was told that he is a “good lawyer”. I saw Mr. Alt’s value in his knowledge of the law and EPO procedure. I had informed Mr. Alt that I am well versed in patent matters and have prosecuted this case for nearly 10 years before USPTO and several other jurisdictions and that I know the case inside out. For this reason, it was important for me to be present and argue the case with him at the oral proceedings before the Board. However, it was difficult for me to be present at the oral proceedings in Munich on 27 July 2017. Therefore a request for postponement of oral proceedings by two months was submitted to the Board on 19 May 2017, which was denied on 26 May 2017. (It is true that a request for acceleration of proceedings before the Board was also filed on 6 December 2016, but that was to cut back on years of wait, two months of wait was not the issue.)

[0011] I flew to Munich, Germany, on 24 July 2017, from San Francisco, California, so that I could be present and argue at the oral proceeding on 27 July 2017. In preparation for the oral proceedings, I met Mr. Alt in his office at Maximiliansplatz 22, 80333 Munich, Germany, on the afternoon of 26 July 2017.

[0012] During the meeting on 26 July 2017, I was taken aback and perturbed that Mr. Alt warned me that I was not to argue at oral proceedings because clients are not allowed to argue, and that if I spoke at the oral proceedings, he would withdraw representation and then the oral proceedings would be canceled and a new date for oral proceedings would be set. I told Mr. Alt that it was not true that I could not argue at the oral proceedings, having read the Guidelines for Examination in the European Patent Office (e.g., Part E Chapter II.8.5) and asked him to show me where it said in the guidelines that applicants cannot argue at ex parte oral proceedings. He asked his receptionist to bring in a reference book, which was brought in but he never opened it. I did not press him to open the book, because I did not want to blabber the point and strain the relationship. He appeared to have gotten the message that I was reasonably well informed. As we were preparing, Mr. Alt said that it is his understanding that I know the arguments against certain rejections very well. I said that I do and could argue them fairly well. It appeared that he had accepted that I would be arguing at the oral proceedings. I told Mr. Alt's that his value was in his knowledge of the law. I had asked him while preparing response to Board's communication (submitted to EPO on 28 June 2017) and again in an email on 15 July 2017 to argue against added matter objections citing T 201/83 and reminded him of the same on 26 July 2017.

[0013] At the oral proceeding on 27 July 2017, first point to be addressed was problem to be solved by the invention because that ascertains the essential features and the matter obtainable by skilled persons from Specification. Having invented the claimed subject matter and having worked on the application for ~10 years I am the best person to discuss the background of the invention. Therefore, naturally I started to address the problem to be solved by the invention. As I started to make the arguments, Mr. Alt objected to my speaking. Mr. Sieber, Chairman of the Board, said there was no issue with my making the arguments because the proceedings were ex-parte. I submitted that this invention was conceived because I became aware that there is mass confusion and incorrect teachings in the art with respect to omega-6 intake/dosage. Prior art has overwhelmingly taught to reduce omega-6 intake/dosage, which in fact is the most important fatty acid we consume.

[0014] However, even after Mr. Sieber said that there was no issue with my arguing, when I started to argue that the feature "omega-6 to omega-3 ratio of 4:1 or greater" is directly and unambiguously obtained from the Specification as filed, Mr. Alt again created a huff by throwing his pen. This time the Board laughed. To save the situation I said, "I will let the counsel argue this." Mr. Alt cited paragraph [0042], which discloses formulations that "render extra omega-3 unnecessary," which the Board did not accept. From this point on the discussion in oral proceedings deteriorated. Mr. Alt was making feeble arguments, not citing what I wanted him to cite, and obstructing me from speaking, and the Board was an accomplice. There was an apparent collusion between Mr. Alt and the Board to undermine the subject application.

[0015] Although I sporadically tried to argue again during the rest of oral proceedings, it was difficult for me to do so, because of objections and lackluster support from Mr. Alt, and the undercurrent of collusion among the Board and Mr. Alt. Each time I spoke, I spoke worriedly and hurriedly to avoid being cut off and the Board ridiculing and subverting the arguments.

[0016] I have been prosecuting pro se before United States Patent and Trademark Office (USPTO); therefore I know the US prosecution extremely well. Board's phraseology at several points indicated that the Board had read USPTO prosecution history and felt compelled to raise some of the objections raised by USPTO examiner. For example, Board stated during oral proceedings that the Board was focused on Article 123(2) EPC because it had to ensure that patent was not issued on claims that were possibly anticipated by prior art, partly because amount of non-fatty acid lipids in compositions may be very small. However, such issues have been rebutted in USPTO prosecution history and also in Grounds of Appeal submitted to EPO. For example, amount of non-fatty acid lipids in compositions is not always small (e.g., it can be 20% of the composition). It was disconcerting because such imaginary prior art objection cannot be raised under novelty objection—novelty is a question of inevitability not probability—and lack of inventive step objection could not be raised because of obstructive factors.

[0017] Mr. Sieber said that Example 1 is not an example because it is written as general description. Mr. Sieber also stated that original claims 4 and 6-8 were written in US dependency form and not in EPO dependency form, stating, "Why should we follow US, US does not follow us?" Board was not following any principle, following USPTO when convenient and not following USPTO when not convenient. For example, there is no added matter objection in the corresponding US applications, which Board alleged.

[0018] I argued that combination of omega-6/omega-3 ratio is taught in Tables 14-19. Mr. Sieber said that the tables include other features. I wrote on a paper and asked Mr. Alt to argue citing T 201/83 (which I had also asked Mr. Alt to cite before the oral proceedings) that in view of totality of the disclosure omega-6 to omega-3 ratios combined with their percentages in relation to total lipids are features that could be isolated and effectively manipulated separately, and that omega-9 fatty acids were non-essential in Claim 1 of all requests. Mr. Alt declined to argue.

[0019] Mr. Sieber dismissed the scientists' declaration that the claimed subject matter could be directly and unambiguously obtained from the disclosure, stating they are the same. I asked Mr. Alt to argue that as per case law (e.g. T558/95) there was no issue with declarations being the same, but Mr. Alt did not cite case law.

[0020] Board's minutes misrepresent "Conclusions" versus "preliminary views". Accurate statements made near the end of oral proceedings are as follows.

- (1) After Mr. Sieber announced that AR23 would not be admitted into proceedings, Mr. Alt asked if the Board would allow the Applicant to withdraw the appeal at that point?
- (2) Mr. Sieber said, "I have only given Board's preliminary views, not conclusions. Therefore, the Applicant can withdraw the appeal."
- (3) Mr. Alt then said, "Applicant withdraws the appeal."
- (4) Subsequently, Mr. Sieber said, "I will now give Board's conclusion that Claim 1 of main request and auxiliary requests 1 to 22 do not comply with Article 123(2) EPC."

[0021] Upon my return to US, I emailed to Mr. Alt on 16 August 2017, saying that my reading is that he did not want the case to be allowed, because he did not hold the Board to case law, he made feeble arguments, and he obstructed me from making arguments. Mr. Alt responded on 31 August 2017, admitting that he aimed at controlling my submissions. I had emailed him again on 31 August 2017 and on 18 September 2017. See Exhibit C, my correspondence with Mr. Michael Alt of Bird and Bird, August 16, 2017 to September 18, 2017.

[0022] I am extremely upset at the outcome of the subject patent application, because 10 years of work and capital invested, and public health benefit have been compromised due to Board improprieties. Board made "added matter" excuses to deny the patent, while in reality copying USPTO in alleging lack of novelty, despite being fully aware that the recited specific and selection limitations are novel, and that novelty is a question of inevitability, and that there is an overwhelming case of public not being informed in this case, therefore Article 54 EPC is satisfied. Board also colluded with Mr. Alt to obstruct and undermine my submissions at the oral proceedings. Significant window of opportunity has been lost from being able to effectively solve the problem. As such, EPO is working against solving fundamental problems, which is counter to the charge of EPO.

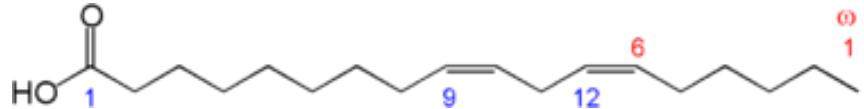
[0023] I further declare that all statements made herein of my own knowledge are true and that statements made of information and belief are believed to be true. I further acknowledge that any willful false statements and the like so made are punishable by fine or imprisonment, or both, and may jeopardize the validity of the application or any patent issuing therefrom.


Urvashi Bhagat

Date: January 30, 2018

Omega-6 fatty acid

Omega-6 fatty acids (also referred to as **ω-6 fatty acids** or ***n*-6 fatty acids**) are a family of pro-inflammatory and anti-inflammatory polyunsaturated fatty acids^[1] that have in common a final carbon-carbon double bond in the *n*-6 position, that is, the sixth bond, counting from the methyl end.^[2]



The chemical structure of linoleic acid, a common omega-6 fatty acid found in many nuts, seeds and vegetable oils.

The biological effects of the omega-6 fatty acids are largely produced during and after physical activity for the purpose of promoting growth and during the inflammatory cascade to halt cell damage and promote cell repair by their conversion to omega-6 eicosanoids that bind to diverse receptors found in every tissue of the body.

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Biochemistry

Linoleic acid (18:2, *n*-6), the shortest-chained omega-6 fatty acid, is one of many essential fatty acids and is categorized as an essential fatty acid because the human body cannot synthesize it. Mammalian cells lack the enzyme omega-3 desaturase and therefore cannot convert omega-6 fatty acids to omega-3 fatty acids. Closely related omega-3 and omega-6 fatty acids act as competing substrates for the same enzymes.^[3] This outlines the importance of the proportion of omega-3 to omega-6 fatty acids in a diet.^[3]

Omega-6 fatty acids are precursors to endocannabinoids, lipoxins, and specific eicosanoids.

Medical research on humans found a correlation (though correlation does not imply causation) between the high intake of omega-6 fatty acids from vegetable oils and disease in humans. However, biochemistry research has concluded that air pollution, heavy metals, smoking, passive smoking, lipopolysaccharides, lipid peroxidation products (found mainly in

vegetable oils, roasted nuts and roasted oily seeds) and other exogenous toxins initiate the inflammatory response in the cells which leads to the expression of the COX-2 enzyme and subsequently to the temporary production of inflammatory *promoting* prostaglandins from arachidonic acid for the purpose of alerting the immune system of the cell damage and eventually to the production of anti-inflammatory molecules (e.g. lipoxins & prostacyclin) during the resolution phase of inflammation, after the cell damage has been repaired.^{[4][5][6][7][8][9][10][11][12][13][14][15]}

Pharmacology

The conversion of cell membrane arachidonic acid (20:4n-6) to omega-6 prostaglandin and omega-6 leukotriene eicosanoids during the inflammatory cascade provides many targets for pharmaceutical drugs to impede the inflammatory process in atherosclerosis,^[16] asthma, arthritis, vascular disease, thrombosis, immune-inflammatory processes, and tumor proliferation. Competitive interactions with the omega-3 fatty acids affect the relative storage, mobilization, conversion and action of the omega-3 and omega-6 eicosanoid precursors (see Essential fatty acid interactions).

Suggested negative health effects

Some medical research suggests that excessive levels of omega-6 fatty acids from seed oils relative to certain omega-3 fatty acids may increase the probability of a number of diseases.^{[17][18][19]}

Modern Western diets typically have ratios of omega-6 to omega-3 in excess of 10 to 1, some as high as 30 to 1; the average ratio of omega-6 to omega-3 in the Western diet is 15:1–16.7:1.^[16] Humans are thought to have evolved with a diet of a 1-to-1 ratio of omega-6 to omega-3 and the optimal ratio is thought to be 4 to 1 or lower,^[16] although some sources suggest ratios as low as 1:1.^[20] A ratio of 2–3:1 omega 6 to omega 3 helped reduce inflammation in patients with rheumatoid arthritis.^[16] A ratio of 5:1 had a beneficial effect on patients with asthma but a 10:1 ratio had a negative effect.^[16] A ratio of 2.5:1 reduced rectal cell proliferation in patients with colorectal cancer, whereas a ratio of 4:1 had no effect.^[16]

Excess omega-6 fatty acids from vegetable oils interfere with the health benefits of omega-3 fats, in part because they compete for the same rate-limiting enzymes. A high proportion of omega-6 to omega-3 fat in the diet shifts the physiological state in the tissues toward the pathogenesis of many diseases: prothrombotic, proinflammatory and proconstrictive.^[21]

Chronic excessive production of omega-6 eicosanoids is correlated with arthritis, inflammation, and cancer. Many of the medications used to treat and manage these conditions work by blocking the effects of the COX-2 enzyme.^[22] Many steps in formation and action of omega-6 prostaglandins from omega-6 arachidonic acid proceed more vigorously than the corresponding competitive steps in formation and action of omega-3 hormones from omega-3 eicosapentaenoic acid.^[23] The COX-1 and COX-2 inhibitor medications, used to treat inflammation and pain, work by preventing the COX enzymes from turning arachidonic acid into inflammatory compounds.^[24] (See Cyclooxygenase for more information.) The LOX inhibitor medications often used to treat asthma work by preventing the LOX enzyme from converting arachidonic acid into the leukotrienes.^{[25][26]} Many of the anti-mania medications used to treat bipolar disorder work by targeting the arachidonic acid cascade in the brain.^[27]

A high consumption of oxidized polyunsaturated fatty acids (PUFAs), which are found in most types of vegetable oil, may increase the likelihood that postmenopausal women will develop breast cancer.^[28] Similar effect was observed on prostate cancer, but the study was performed on mice.^[29] Another "analysis suggested an inverse association between total polyunsaturated fatty acids and breast cancer risk, but individual polyunsaturated fatty acids behaved differently [from each other]. [...] a 20:2 derivative of linoleic acid [...] was inversely associated with the risk of breast cancer".^[30]

Omega-6 consumption

Industry-sponsored studies have suggested that omega-6 fatty acids should be consumed in a 1:1 ratio to omega-3,^[31] though it has been observed that the diet of many individuals today is at a ratio of about 16:1, mainly from vegetable oils.^[31] Omega-6 and omega-3 are essential fatty acids that are metabolized by some of the same enzymes, and therefore an imbalanced ratio can affect how the other is metabolized.^[32] In a study performed by Ponnampalam,^[33] it was noticed that feeding systems had a great effect on nutrient content on the meat sold to consumers. Cynthia Doyle conducted an experiment to observe the fatty acid content of beef raised through grass feeding versus grain feeding; she concluded that grass fed animals contain an overall omega-6:omega-3 ratio that is preferred by nutritionists.^[32] In today's modern agriculture, the main focus is on production quantity, which has decreased the omega-3 content, and increased the omega-6 content, due to simple changes such as grain-feeding cattle.^[16] In grain-feeding cattle, this is a way to increase their weight and prepare them for slaughter much quicker compared to grass-feeding. This modern way of feeding animals may be one of many indications as to why the omega-6:omega-3 ratio has increased.

List of omega-6 fatty acids

Common name	Lipid name	Chemical name
<u>Linoleic acid</u> (LA)	18:2 (<i>n</i> -6)	<i>all-cis</i> -9,12-octadecadienoic acid
<u>Gamma-linolenic acid</u> (GLA)	18:3 (<i>n</i> -6)	<i>all-cis</i> -6,9,12-octadecatrienoic acid
<u>Calendic acid</u>	18:3 (<i>n</i> -6)	8E,10E,12Z-octadecatrienoic acid
<u>Eicosadienoic acid</u>	20:2 (<i>n</i> -6)	<i>all-cis</i> -11,14-eicosadienoic acid
<u>Dihomo-gamma-linolenic acid</u> (DGLA)	20:3 (<i>n</i> -6)	<i>all-cis</i> -8,11,14-eicosatrienoic acid
<u>Arachidonic acid</u> (AA, ARA)	20:4 (<i>n</i> -6)	<i>all-cis</i> -5,8,11,14-eicosatetraenoic acid
<u>Docosadienoic acid</u>	22:2 (<i>n</i> -6)	<i>all-cis</i> -13,16-docosadienoic acid
<u>Adrenic acid</u>	22:4 (<i>n</i> -6)	<i>all-cis</i> -7,10,13,16-docosatetraenoic acid
<u>Osbond acid</u>	22:5 (<i>n</i> -6)	<i>all-cis</i> -4,7,10,13,16-docosapentaenoic acid
<u>Tetracosatetraenoic acid</u>	24:4 (<i>n</i> -6)	<i>all-cis</i> -9,12,15,18-tetracosatetraenoic acid
<u>Tetracosapentaenoic acid</u>	24:5 (<i>n</i> -6)	<i>all-cis</i> -6,9,12,15,18-tetracosapentaenoic acid

It is interesting to note that melting point of the fatty acids increase as the number of carbons in the chain increases.

Dietary linoleic acid requirement

Adding more controversy to the omega-6 fat issue is that the dietary requirement for linoleic acid has been questioned, because of a significant methodology error proposed by University of Toronto scientist Stephen Cunnane.^[34] Cunnane proposed that the seminal research used to determine the dietary requirement for linoleic acid was based on feeding animals linoleic acid-deficient diets, which were simultaneously deficient in omega-3 fats. The omega-3 deficiency was not taken into account. The omega-6 oils added back systematically to correct the deficiency also contained trace amounts of omega-3 fats. Therefore, the researchers were inadvertently correcting the omega-3 deficiency as well. Ultimately, it took more oil to correct both deficiencies. According to Cunnane, this error overestimates linoleic acid requirements by 5 to 15 times.

Dietary sources

Four major food oils (palm, soybean, rapeseed, and sunflower) provide more than 100 million metric tons annually, providing more than 32 million metric tons of omega-6 linoleic acid and 4 million metric tons of omega-3 alpha-linolenic acid.^[35]

Dietary sources of omega-6 fatty acids include:^[36]

- poultry
- eggs
- nuts
- hulled sesame seeds
- cereals
- durum wheat
- whole-grain breads
- most vegetable oils
- grape seed oil
- evening primrose oil
- borage oil
- blackcurrant seed oil
- flax/linseed oil
- rapeseed or canola oil
- hemp oil
- soybean oil
- cottonseed oil
- sunflower seed oil
- corn oil
- safflower oil
- pumpkin seeds



The evening primrose flower (*O. biennis*) produces an oil containing a high content of γ -linolenic acid, a type of omega-6 fatty acid.

See also




- Essential fatty acid interactions
- Essential nutrients
- Linolenic acid
- Omega-3 fatty acid
- Omega-7 fatty acid

- [Omega-9 fatty acid](#)
- [Wheat germ oil](#)
- [Lipid peroxidation](#)
- [Inflammation](#)
- [Cattle feeding](#)
- [Olive oil regulation and adulteration](#)
- [Ratio of fatty acids in different foods](#)

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Attachment B:

Annotated Minutes of Oral Proceedings with the Board, dispatched on 03 August 2017, with Request for Correction of Minutes, submitted on 20 December 2017

European & Chartered Patent Attorneys
Trade Mark Attorneys

European Patent Office
D-80298
München
Germany

Our Ref: P800223EP-PCT/AGT/JDE

Your Ref:

20 December 2017

**SIGNED AND SENT
ELECTRONICALLY**

Dear Sirs

**European Patent Application No. 09735962.4
based on PCT/US2009/041114
Asha Nutrition Sciences, Inc.**

In accordance with instructions received from the Applicant, it is requested that the minutes of the oral proceedings held on 27 July 2017 (in appeal T1712/15-3.3.09) be corrected as set out in the attached document (cf. Guidelines for Examination in the EPO, Part E, Chapter III, 10.4).

If there are any questions in relation to this matter, please do not hesitate to contact me.

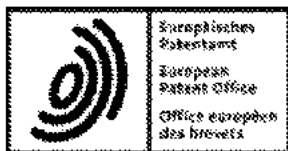
Yours faithfully

**A G Tombling
Professional Representative
WITHERS & ROGERS LLP**

Encs: Corrected minutes of oral proceedings

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Appeal number

T1712/15-3.3.09

Application No.: 09735962.4
Applicant: Asha Nutrition Sciences, Inc.

Minutes of the oral proceedings

of 27 July 2017

Composition of the Board:

Chairman: W. Sieber
Members: N. Perakis
F. Blumer

Start of oral proceedings: 09:00 hours
End of oral proceedings: 12:30 hours

Documents presented:

- Auxiliary Request 23 (claims 1 to 4)

Present on behalf of the appellant:

Mr M. Alt, professional representative, identified by EPO ID-card,
accompanied by Ms U. Bhagat, identified by passport.

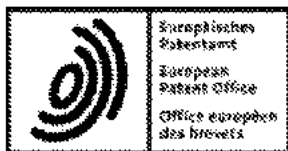
The Chairman declared the oral proceedings open.

He summarised the relevant facts as appearing from the file.

The appellant addressed the Board, and the matter was then discussed
with the appellant as follows:

Initial Requests:

The appellant requested that the decision under appeal be set aside
and that a patent be granted based on the claims of the main request
or one of the auxiliary requests 1 to 20 filed with the grounds of



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Appeal number

T1712/15-3.3.09

appeal (filed on 9 July 2015; filed as clean copies on 15 July 2015) or one of auxiliary requests 21 and 22 filed with letter dated 28 June 2017.

The appellant confirmed that the requests concerning the alleged substantial procedural violations committed by the examining division were not further pursued.

Main Request

Amendments / Article 123(2) EPC

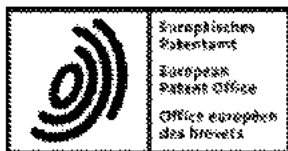
The ~~appellant agreed~~ ^{Board decided} to discuss the invention identified as a) (i) in claim 1 first.

The appellant gave a general overview ~~over~~ ^{of} the invention. Reference was made, in particular, to paragraphs [0006] ~~and~~ ^{to} [0008] of the originally filed description (A2 publication) and to the relevance of omega-6 fatty acids, ~~for health, that prior art had erroneously taught reduction in omega-6 fatty acids, and that omega-6 was the prime focus of the disclosure.~~

It was discussed whether the ranges for the omega-6 to omega-3 ratio and for the percentages of said fatty acids were originally disclosed in combination. Reference was made, in particular, to paragraph ~~[0042]~~ ^{[0021] and} (including Table 3) and paragraph [0043] (including Table 4) ~~as well as to originally filed claims 4 and 6-8.~~ ^{Tables 14-19}. The appellant argued that omega-9 fatty acids were not an essential feature of the claimed subject-matter and made reference to Tables 9, 13, and examples 12, 13, 19-22 which did not involve ~~such~~ ^{omega-9 fatty} acids in the lipid formulation.

~~Chairman Sieber did not accept Appellant's arguments stating that the Board had to ensure that patent was not issued on claims that were possibly anticipated by prior art. Ms. Bhagat attempted to make arguments before the Board when Mr. Alt interrupted her. Chairman said that there was no issue with Ms. Bhagat making the arguments, because the proceedings were ex-parte. However, when Ms. Bhagat attempted to speak again, Mr. Alt threw his pen making it uncomfortable for Ms. Bhagat to speak subsequently. The Board laughed at the lack of support from the counsel.~~
The oral proceedings were interrupted at 09:50 for deliberation.

After the oral proceedings were resumed at 10:10, the Chairman ~~gave~~ ^{said that} the Board's ~~conclusion~~ ^{preliminary view was} that claim 1 did not meet the requirements of Article 123(2) EPC.



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Auxiliary Request 1 to 3

The appellant made no further comments.

Auxiliary Request 4

With respect to the basis for claim 1, the appellant referred, in particular, to Tables 3, 4 and 14 to 19 in the originally filed description.

Auxiliary Requests 5 to 7

The appellant made no further comments.

Auxiliary Request 8

With respect to the basis for claim 1, the appellant referred, in particular, to Tables 3 and 4 and the originally filed claim 4 as well as to tables 9, 12 and 13 and examples 12 and 27.

Auxiliary Requests 13 to 20

The appellant made no further comments.

Auxiliary Requests 21 and 22

The appellant referred, in particular, to originally filed claims 4 and 8 as a basis for claim 1. Regarding the non-essentiality of the omega-9 fatty acids, it referred to examples 11, 12, 15, 17, 19, 26 and 27 which concerned lipid formulations involving only omega-3 and omega-6 fatty acids.

The oral proceedings were interrupted at 10:40.

After the oral proceedings were resumed at 11:00, the Chairman ^{said that} gave the Board's ^{preliminary view was} conclusion that claim 1 of none of Auxiliary Requests 1 to 22 complied with Article 123(2) EPC.



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Appeal number

T1712/15-3.3.09

On request of the appellant, the oral proceedings were then interrupted for 15 minutes.

Auxiliary Request 23

After the oral proceedings were resumed at 11:30, the appellant filed a new auxiliary request 23. The appellant referred to Table 9 of the originally filed application as a basis for claim 1 of the new request.

The oral proceedings were interrupted at 11:40.

After the oral proceedings were resumed at 12:20, the Chairman announced the Board's decision not to admit auxiliary request 23 into the proceedings.

The appellant withdrew the appeal.

The Chairman then closed the oral proceedings.

The Minute Writer:

The Chairman:

F. Blumer

W. Sieber

Minutes electronically authenticated



Attachment C:

Declination of Correction of Minutes to the Oral Proceedings by the Board, dispatched
on 01 January 2018



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Datum / Date
17.01.2018

Zeichen/Reference/Référence P800223EP-PCT	APPR	Anmeldung Nr. / Application No. / Demande n°. // Patent Nr. / Patent No. / Brevet n°. 09735962.4 // 2278885
Anmelder / Applicant / Demandeur // Patentinhaber / Proprietor / Titulaire Asha Nutrition Sciences, Inc.		

Appeal number:

T1712/15-3.3.09

Communication of the Board of Appeal

The Legal Member
The Registrar
Tel.: 089 / 2399 - 3391

F. Blumer
M. Cañueto Carbajo



Registered letter

This document: 2 page(s) including this page

Annex(es):

Communication text

On 20 December 2017, the appellant in appeal proceedings T 1712/15 filed a request to correct the minutes of the oral proceedings held on 27 July 2017.

The Board does not see any reason to correct said minutes more than four months after the minutes were sent and the appeal proceedings were terminated due to the withdrawal of the appeal.

Concerning the substance of the proposed correction in the paragraph drafted by the appellant on page 2 of the minutes, the Board notes that none of its members can remember any of the alleged facts. The Board further notes that the Chairman did explicitly give conclusions (not just preliminary views) on the allowability of the main request and auxiliary requests 1 to 22 under Article 123(2) EPC.

Attachment D:

Petition for Review by the Enlarged Board of Appeal under Article 112(a) EPC submitted
on 26 March 2018
(Attachment “Formal Complaint of 30 January 2018” omitted as it is already attached to
this Petition as Attachment A above.)

March 26, 2018

BY EPOONLINE

European Patent Office, Boards of Appeal
Richard-Reitzner-Allee 8
85540 Haar
Germany

Application No: 09 735 962.4 (EP 2 278 885)
Appeal No: T1712/15-3.3.09
Applicant
And Petitioner: Asha Nutrition Sciences, Inc.

PETITION FOR REVIEW BY ENLARGED BOARD OF APPEAL

According to Article 112a EPC, a review of the “conclusions” imposed in the communication dated 17 January 2018 by the Technical Board of Appeal 3.3.09, and of fundamental procedural defects in the appeal proceedings in case T 1712/15-3.3.09 is requested, due to which the Petitioner is adversely affected in that EP 09735962.4 (EP 2 278 885) was refused, additionally, the erroneously imposed “conclusions” are adversely affecting Petitioner’s divisional application EP 17182663.9, in which the Examiner holds the Petitioner to “conclusions” derived by the Board.

In accordance with Article 112a (2) lit. (c), (d), and (e) EPC instant petition is based on the grounds that,

- (c) a fundamental violation of Article 113 occurred in that Petitioner’s right to be heard was violated;
- (d) a fundamental procedural defect defined in the Implementing Regulations Rule 142 and Article 133(2) occurred in the oral proceedings held on 27 July 2017 in that the Petitioner was unrepresented; and
- (e) a criminal act established under the conditions laid down in the Implementing Regulations had an impact on the oral proceedings and the “conclusions” imposed by the Board, in that there was a collusion between the Board and Mr. Michael Alt of Bird and Bird, Petitioner’s then authorized representative, at the oral proceedings held on 27 July 2017, to undermine the Petitioner.

It is requested that,

- (i) Oral proceedings of 27 July 2017 be invalidated, considering Applicant was unrepresented at the oral proceedings.
- (ii) The appeal proceedings be reopened.

- (iii) All of the members of the Board of Appeal who participated in the oral proceedings be replaced, because they participated in a criminal act of collusion with Petitioner's representative to undermine the Petitioner.
- (iv) The new Board be instructed to promptly render a written decision on entirety of record including the Formal Complaint submitted on January 31, 2018, properly addressing entirety of Applicant's arguments, evidence including skilled person's testimony, and case law cited.
- (v) If the new Board of Appeal maintains the refusal, then the case be immediately referred to Enlarged Board of Appeal under accelerated proceedings in view of the divergent case law.
- (vi) Reimbursement of the fee for the petition for review be ordered.

The fee for the petition in the amount of 2910,00 EUR has been paid (see attached payment receipt from EPO).

REASONS

I. Background

The subject application has a filing date of 20 April 2009, it entered European phase on 19 November 2010. Notice of Appeal was filed on 5 March 2015. Oral proceedings with the Board of Appeal were held on 27 July 2017, in which Applicant was unrepresented. The Board mailed minutes to the oral proceedings on 3 August 2017. Petitioner submitted a request for correction of the minutes on 20 December 2017, in particular pointing out that Mr. Alt had obstructed Ms. Bhagat, Petitioner's Chief Executive Officer, from making arguments at the oral proceedings and that the Board had expressed preliminary views when the appeal was withdrawn (by Mr. Alt). On 17 January 2018, the Board mailed a communication denying recalling that Mr. Alt had obstructed Ms. Bhagat from making arguments at the oral proceedings and denying correcting the minutes and insisting that it had given "conclusions (not just preliminary views)".

II. Facts

The essential facts on which the request is based are evident from the file. Additionally, the Formal Complaint submitted on January 31, 2018, which provides a summary of issues is expressly attached herewith along with the following Exhibits.

- Exhibit A. US Patents for Humanity Application, 8 November 2015
- Exhibit B. Applicant's Correspondence with Mr. Nick Lee of Kilburn & Strode, 23 April 2015

- Exhibit C. Applicant's Correspondence with Mr. Michael Al of Bird and Bird, 16 August 2017 to 18 September 2017
- Exhibit D. Declaration of Ms. Urvashi Bhagat dated January 30, 2018
- Exhibit E. "Omega-6 fatty acid" Wikipedia, accessed January 29, 2018

Some of the facts relevant to the current petition are as follows.

1. Examining Division (ED) rejected Main Request (EDMR) and Auxiliary Requests (EDAR) 1-8 alleging the requests did not meet the requirements of Article 123(2) EPC. ED held that EDAR9-10 met the requirements of Article 123(2) EPC, but ED rejected EDAR9-10 alleging lack of novelty under Article 54 EPC. ED had withdrawn previously applied inventive step objection. See ED Decision dated March 3, 2015, pages 12-16.
2. Petitioner filed a Notice of Appeal against ED Decision on 3 March 2015.
3. Petitioner submitted Grounds of Appeal on 9 July 2015 with New Main Request (NMR) and 20 New Auxiliary Requests (NAR), seriously attempting to overcome ED objections. Petitioner cited T 667/08 asserting that the technical information that the skilled person reading the original disclosure would have derived from its content (description, claims, drawings) is considered in its entirety, and that literal support is not required by the wording of Art. 123(2) EPC. (Grounds, page 10). Petitioner called attention to two separate sets of declarations from skilled persons (two declarations submitted on May 9, 2014 and three declarations submitted on December 4, 2014) declaring that skilled persons can directly and unambiguously obtain the claimed subject matter from the disclosure. Applicant also asserted manipulation of features and extraction of point values from examples is permissible as per case law e.g., T201/83. Therefore, requirements of Article 123(2) EPC were met. (Grounds, pages 13-15).

Petitioner's NAR15-20 were substantially the same as EDAR9-10, which ED had held to meet the requirements of Article 123(2) EPC.

Petitioner also submitted arguments and evidence that the features "total lipids" and "dosage" of total omega-6 and omega-3 formulations as claimed are important contributions over cited art and state of the art made by the subject patent application, and that non-fat or non-fatty acid lipids can be present in large amounts in formulations, e.g. 10% by weight of total lipids. (Grounds, pages 33-34 and 49-50). Petitioner also cited T 270/97, T 12/81 (OJ 1982, 296), T 583/01, T 167/84, T 517/90, and T 536/95 asserting anticipation is question of inevitability and not of probability, and that well-known equivalents not disclosed in the document is a matter of obviousness, not of anticipation. Therefore, requirements of Article 54 EPC were met. (Grounds, pages 50-51).

4. Board mailed a communication on 18 April 2017, raising clarity objections over the terms "different sources" and "dosage". Additionally, Board alleged that the

combination of ratio of omega-6 to omega-3 with weight percentage of omega-6 and omega-3 in relation to total lipids was not disclosed in the Specification as filed, therefore, all of NMR and NAR1-20 added new matter and did not comply with Article 123(2) EPC.

Board's communication of 18 April 2017, disregarded Grounds of Appeal where some of Board's objections had been preemptively refuted, e.g. page 17 explained that Specification is clear that "different sources" differ in nutrient profile rather than in the supplier, and pages 21-22 explained that "dosage" is abundantly clear from Specification and extremely well known in the art. Board disregarded supporting case law citations in the Grounds of Appeal, for example, T 667/08 holding "technical information that the skilled person reading the original disclosure would have derived from its content (description, claims, drawings) considered in its entirety" is considered, "literal support is not required" and T 201/83 holding values described in a specific example can be extracted, and that ED (skilled persons) did not find the combination of ratio of omega-6 to omega-3 with weight percentage of omega-6 and omega-3 in relation to total lipids to add matter and violate Article 123(2) EPC in EDAR9-10.

5. Petitioner responded on 28 June 2017, reasserting that Specification is clear that "different sources" differ in nutrient profile rather than in the supplier, and pages 21-22 of Grounds of Appeal explained that "dosage" is abundantly clear from Specification and extremely well known in the art, and that the EPO routinely allows the terms "dose" or "dosage" in claims as illustrated by several granted EP patents (EP0689454B1, EP0404376B1, and EP1041987B1). Petitioner also submitted two new declarations from skilled persons that "dosage" as claimed is clear from Specification and well known in the art. Petitioner asserted that the combination of ratio of omega-6 to omega-3 with weight percentage of omega-6 and omega-3 in relation to total lipids is explicitly present in the Specification, Example 1, Tables 14-19, and original claim 8, that ED (skilled persons) did not find the combination to add matter (EDAR9-10 were held allowable), and furthermore even if the combination was not explicitly disclosed it is permissible to combine separate items belonging to different embodiments described in one and the same document, if such combination has specifically been suggested citing T 305/87 and Petitioner reminded the Board that "literal support is not required" citing T 667/08. Petitioner asserted that the declarations on file disprove arbitrary rejections/objections. Petitioner also submitted NAR21-22.
6. Petitioner submitted a request to the Board on 19 May 2017, that due to the circumstances of Ms. Urvashi Bhagat, who intends to argue before the Board, it is requested that the date of oral proceedings be changed to not earlier than September 2017. The Board denied the request on 26 May 2017.
7. At the oral proceedings on 27 July 2017, in attendance were W. Sieber (Chairman), N. Perakis, and F. Blumer (minutes writer) comprising the Board, and Mr. M. Alt of Bird and Bird, Applicant's then-authorized professional representative, and Ms. Urvashi

Bhagat, the Inventor and Petitioner's Chief Executive Officer. The proceedings had been in progress for three-and-a-half hours, when Mr. Alt withdrew the appeal and the proceedings were closed. Following are some of the main points from the oral proceedings.

- a. The proceedings almost exclusively focused on alleged non-compliance with Article 123(2) EPC of Claim 1 of all requests. Board stated that it was focused on Article 123(2) EPC because it had to ensure that patent was not issued on claims that were possibly anticipated by prior art. See Exhibit C, Ms. Bhagat's email to Mr. Alt of September 18, 2017, 11:01 AM, and Exhibit D, Ms. Bhagat's testimony paragraph [0016]. Thus, Board admitted that it was denying the patent under the pretense of non-compliance with Article 123(2) EPC.
- b. The Board announced that it will discuss claim 1(a)(i) of the MR first. It was Board's plan to deny the patent under pretense of "added matter" because features claimed in Claim 1(a)(i) of the MR were common to claim 1 of all requests. It is evidenced by Board's communication of 18 April 2017.
- c. With respect to problem to be solved, Ms. Bhagat asserted this invention was conceived because I became aware of mass confusion and incorrect teachings in the art with respect to omega-6 intake/dosage. Prior art has overwhelmingly taught to reduce omega-6 intake/dosage, which in fact is the most important fatty acid we consume. Reference was made to paragraphs [0006] to [0008] of WO2009/131939 A2 (A2), and that all of the Examples 11-27 are focused on omega-6 fatty acids and secondly on omega-3 fatty acids (in Example 14.2 and 22 only omega-6 administration is disclosed). Ms. Bhagat said that the subject matter is highly debated in public and scientific journals, for this reason skilled persons can easily obtain the claimed subject matter from the disclosure.
- d. As Ms. Bhagat was making the arguments above in 7.c., Mr. Alt objected to Ms. Bhagat making the arguments. Mr. Sieber said that there was no issue with Ms. Bhagat making the arguments because the proceedings were ex-parte. See Exhibit D, Ms. Bhagat's testimony (paragraphs [0013]), and Exhibit C, contemporaneous email communications with Mr. Alt shortly after the oral proceedings (dated 16 August 2017 to 18 September 2017).
- e. With respect to support basis for the feature "omega-6 to omega-3 ratio of 4:1 or greater" in Claim 1 of NMR and NAR1-3, Ms. Bhagat argued that paragraph [0021] expressly recites, "The present disclosure incorporates relatively high ratio of omega-6 to omega-3 fatty acids while maintaining optimal daily delivery [dosage] of both omega-6 and omega-3," and that majority of the examples disclose omega-6 to omega-3 ratios greater than 4:1 (Table 3, 7, 9 and 14 to 19 as well as Examples 11, 12, 15.1, 17, 19, 26 and 27), which give a skilled person a direct and unambiguous support for an omega-6 to omega-3 ratio of "4:1 or

greater". Ms. Bhagat cited T201/83 and asserted that it was permissible to extract the exemplified value of at least 4:1 to combine with "*high ratio of omega-6 to omega-3 fatty acids*".

- f. As Ms. Bhagat was making the arguments above in 7.e., Mr. Alt obstructed Ms. Bhagat again, and created a huff by throwing his pen on the table. Board laughed at the lack of support from the counsel. To save the situation, Ms. Bhagat said, "I will let the counsel argue this." Mr. Alt cited paragraph [0042] of A2, which discloses formulations that "render extra omega-3 unnecessary." Board did not accept the argument. Exhibit D, paragraph [0014].
- g. The conduct where when Ms. Bhagat attempted to speak there was obstruction from Mr. Alt and mockery from the members of the Board was repeated during rest of the oral proceedings. In effect, the Board undermined the Petitioner's position in collusion with its own lawyer.

In Exhibit C, contemporaneous email communications shortly after the oral proceedings (dated 16 August 2017 to 18 September 2017), Mr. Alt admits that he obstructed Ms. Bhagat from speaking, stating, "I... aimed at controlling your submission" (Ms. Bhagat's email of 16 August 2017 and Mr. Alt's response of 31 August 2017).

In her testimony, Exhibit D paragraphs, Ms. Bhagat testifies,

"Mr. Alt was making feeble arguments, not citing what I wanted him to cite, and obstructing me from speaking, and the Board was an accomplice. There was an apparent collusion between Mr. Alt and the Board to undermine the subject application." [0014]

"Although I sporadically tried to argue again during the rest of oral proceedings, it was difficult for me to do so, because of objections and lackluster support from Mr. Alt, and the undercurrent of collusion among the Board and Mr. Alt. Each time I spoke, I spoke worriedly and hurriedly to avoid being cut off and the Board ridiculing and subverting the arguments." [0015]

- h. Board alleged that the combination of the features "omega-6 to omega-3 ratio of 4:1..." with "omega-6 fatty acids are 4-75% by weight of total lipids" and/or "omega-3 fatty acids are 0.1-30% by weight of total lipids", which is present in Claim 1 of all of the claim requests, is not disclosed in the application as filed.

Mr. Alt said that the combination is disclosed in Example 1 (paragraphs [0042]-[0043]) of A2, which includes Tables 3 and 4, and in original claims 4 and 6-8. Board said that Example 1 is not an example because it is written as general description. Board also stated that original claims 4 and 6-8 were written in US

dependency form and not in EPO dependency form, stating, “Why should we follow US, US does not follow us?” See Exhibit D, Ms. Bhagat’s testimony paragraph [0017]).

Ms. Bhagat said that Tables 14-19 also teach that formulations comprising ratios of omega-6 to omega-3 fatty acids combined with their concentrations in reference to total lipids. Board said that Tables 14-19 include other features. Ms. Bhagat wrote on paper asking Mr. Alt to argue citing T201/83 that in view of totality of the disclosure omega-6 to omega-3 ratios combined with their percentages in relation to total lipids are features that could be isolated and effectively manipulated separately. Mr. Alt declined to argue. See Exhibit C, Ms. Bhagat’s email dated September 18, 2017; and Exhibit D, Ms. Bhagat’s testimony paragraph [0018].

Regarding non-essentiality of omega-9 in Claim 1, Ms. Bhagat asserted main problem that the claimed inventions are solving is that of correct intake of omega-6 fatty acids relative to omega-3 fatty acids and total lipids, which the prior art has failed to understand (Specification paragraphs [0006]-[0007]). Examples 12, 15, 17, 19, 26, and 27 only recite omega-6 and omega-3 amounts wherein their ratios are evident. Furthermore, descriptions of all the examples 11-27 are concerned about omega-6/omega-3. Mr. Alt said the Tables 9-13 disclose dosage of omega-6 and omega-3 fatty acids, but not that of omega-9.

- i. Ms. Bhagat asserted citing T 667/08, “technical information that the skilled person reading the original disclosure would have derived from its content (description, claims, drawings) considered in its entirety” is considered, “literal support is not required,” and said that we have submitted declarations from skilled persons, wherein they have testified that they can obtain the claimed subject matter from the disclosure.

Mr. Sieber dismissed the declarations stating they are the same in wording. Declarations are not the same; Pan and Shen declaration submitted on 9 May 2014 are different in structure, wording, and expression from Erickson, Rustagi, and Rucker declarations submitted on 5 December 2014. Further, all declarants testified under penalty of false statements that the claimed subject is directly and unambiguously obtained from the disclosure. Furthermore, there is no issue with declarations being the same. In T 558/95, the board held that the fact that the statutory declarations produced by the opponent partly used the same wording and had been drawn up by employees of the opponent did not necessarily mean they should be excluded as inadmissible. Ms. Bhagat asked Mr. Alt to argue that as per case law, there was no issue with declarations being the same, but Mr. Alt did not cite case law. See Exhibit D, Ms. Bhagat’s testimony, paragraph [0019].

- j. Mr. Sieber said that I am looking for support, but I am not finding, making vague statements that Claim 1 of NMR and NAR1-22 did not meet the requirements of Article 123(2) EPC without discussing the case law or the basis or reason for his statements.

- k. Oral proceedings were brought to close as follows.
 - (1) After Mr. Sieber announced that AR23 would not be admitted into proceedings, Mr. Alt asked if the Board would allow the Applicant to withdraw the appeal at that point?
 - (2) Mr. Sieber said, "I have only given Board's preliminary views, not conclusions. Therefore, the Applicant can withdraw the appeal."
 - (3) Mr. Alt then said, "Applicant withdraws the appeal."
 - (4) Subsequently, Mr. Sieber said, "I will now give Board's conclusion that Claim 1 of main request and auxiliary requests 1 to 22 do not comply with Article 123(2) EPC." Then he promptly announced the oral proceedings closed.

The above is testified in Ms. Bhagat's testimony, Exhibit D paragraph [0020].

- 8. The Board mailed minutes to the oral proceedings on 3 August 2017. Petitioner submitted a request for correction of the minutes on 20 December 2017, in particular pointing out that Mr. Alt had obstructed Ms. Bhagat, Petitioner's Chief Executive Officer, from making arguments at the oral proceedings and that the Board had expressed preliminary views when the appeal was withdrawn (by Mr. Alt). On 17 January 2018, the Board mailed a communication denying recalling that Mr. Alt had obstructed Ms. Bhagat from making arguments at the oral proceedings and denying correcting the minutes and insisting that it had given "conclusions (not just preliminary views)".

- 9. Petitioner submitted the enclosed Formal Complaint with Exhibits A-E, on January 31, 2018, requesting that the oral proceedings be invalidated, because Applicant was unrepresented at the oral proceedings, Mr. Alt obstructed the Applicant from speaking at the oral proceedings, there was a sinister collusion between the Board and Mr. Alt at the oral proceedings to undermine the Applicant, and Mr. Alt effectively represented the Board not the Applicant. It was also asserted in the Formal Complaint that Board insists that it gave "conclusions," but it has not given statements crucial to the "conclusions". In particular, why did the Board disregard T 667/08, T 201/83, T 305/87, and T 190/99, and skilled persons testimony, and ED skilled persons who found no added matter in EDAR9-10, substantially same as NAR15-20. Therefore, the oral proceedings and Board's "conclusions" are invalid.

- 10. Mr. W. Crasborn, Director of Legal Research and Administration, EPO Boards of Appeal, responded to the Formal Complaint on 2 February 2018, stating that appeal was closed due to withdrawal of appeal and further proceedings including petitions for review under Article 112a EPC are not pending. Accordingly, this petition is submitted under Article 112a EPC.

In summary, the following has to be derived from these facts:

- A. Mr. Alt himself made feeble arguments or no arguments; further when Ms. Bhagat tried to make arguments he obstructed her; furthermore when Ms. Bhagat requested Mr. Alt to make some important arguments citing established case law, Mr. Alt declined to make the arguments. See 7.d-k. above. Consequently, Mr. Alt obstructed the Petitioner from presenting its case at the oral proceedings and Petitioner's right to be heard was violated.
- B. By laughing when Mr. Alt obstructed Ms. Bhagat from speaking at the oral proceedings, the Board encouraged Mr. Alt and made it uncomfortable for Ms. Bhagat to argue. Thus, there was a sinister collusion between the Petitioner's lawyer and the Board to undermine the Petitioner at the oral proceedings. See 7.f-g. above.
- C. The Petitioner was unrepresented at the oral proceedings. Mr. Alt effectively represented the Board, not the Petitioner. See 7.a-k. above.
- D. By declining to acknowledge that Mr. Alt obstructed Ms. Bhagat from speaking at the oral proceedings, the Board confirmed that it was in collusion with Petitioner's lawyer to undermine the Petitioner. If Board were not in collusion, it would have acknowledged that Mr. Alt obstructed Ms. Bhagat from speaking. It was a failure on part of the Board to have let the oral proceedings continue when the lawyer was clearly obstructing the Applicant, but when the Board actively participated in that impropriety as in laughing and denying its occurrence, the act is elevated to level of crime. Therefore, there were two acts of crime at the oral proceedings, 1) by Mr. Alt in acting against the interests of the client, and 2) by the Board in encouraging and partaking in Mr. Alt's criminal actions. See 8 above.
- E. Mr. Alt's withdrawal of the appeal is invalid, because Mr. Alt was not representing the Petitioner. See 7.f-g., and 7.k. above.
- F. After the appeal was "withdrawn", Board imposed "conclusions" and closed the proceedings. That is further violation of Petitioner's right to be heard. Had the Petitioner known that the Board would insist upon giving "conclusions" after the appeal had been "withdrawn," the Petitioner would have made further arguments and insisted that the Board give statements/basis for the "conclusions" and properly respond to the divergent case law cited in the Grounds of Appeal and at the oral proceedings. See 7.k. above.
- G. Board declined to correct the minutes to reflect "preliminary views," insisting that it gave "conclusions (not just preliminary views)," then the Board's minutes are a "decision" and then appeal cannot be considered withdrawn. See 8 above.

- H. Board gave “conclusions” without giving statements crucial to the “conclusions” or “the reasons” identified in Rule 102(g). In particular, why did the Board disregard T 667/08, T 201/83, T 305/87, and T 190/99, and skilled persons testimony, and ED skilled persons who found no added matter in EDAR9-10, substantially same as NAR15-20. Therefore, Board’s “conclusions” are invalid. See 9 above.

III. Grounds for Petition Under Article 112a

The review procedure is not the right opportunity to argue about correctness of the “conclusion”. Thus, the Petitioner abstains from trying to establish that the conclusions under review are based on wrong assumptions. Rather, the Enlarged Board has to examine whether the accepted principles in the application of Article 113(1) EPC have been violated under Article 112a(2)(c), or other fundamental procedural defect defined in the Implementing Regulations occurred in the appeal proceedings under Article 112a(2)(d), or a criminal act has had in impact on appeal proceedings under Article 112a(2)(e). Applicant demonstrates below that each of the grounds of Article 112a(2) lit. (c), (d), and (e) is applicable in this case.

Article 112a(2)(c)

Article 112a(2)(c) provides that Petition for review by the Enlarged Board of Appeal may be filed when a fundamental violation of Article 113 has occurred. Article 113(1) EPC states that decisions "may only be based on grounds or evidence on which the parties concerned have had an opportunity to present their comments". This provision has been recognized in a number of previous Board of Appeal decisions as being of fundamental importance for ensuring a fair procedure between the EPO and parties conducting proceedings before it (see in particular Opinion G 4/92, OJ EPO 1994, 149, Decision J 20/85, OJ EPO 1987, 102, and Decision J 3/90, OJ EPO 1991, 550), and reflects the generally recognized principle of procedural law that a party to proceedings has "a right to be heard" before a conclusion/decision is issued. This is has been elaborated in detail in T 951/92 (OJ EPO 1996, 53, Reasons, pt. 3(v)):

“In the context of the examining procedure under Articles 96 and 97 EPC, Article 113(1) EPC is clearly intended to ensure that before a decision refusing an application for non-compliance with a requirement of the EPC is issued, the Applicant has been clearly informed of the essential legal and factual reasons on which the finding of non-compliance is based, so that he knows in advance of the decision both that the application may be refused and the legal and factual reasons why the application may be refused; furthermore, before issue of a decision, the Applicant must have a proper opportunity to comment upon such reasons, and if he wishes, to give counter-arguments and reasoning in support of the allowance of the application, and/or to propose amendments to the application so as to avoid refusal of the application. Thus the term "grounds or evidence" in Article 113(1) EPC should not be narrowly interpreted. In particular, in the context of examination procedure the word "grounds" does not refer merely to a ground of objection to the application in the narrow sense of a requirement of the EPC which is considered not to be met. The word "grounds" should

rather be interpreted as referring to the essential reasoning, both legal and factual, which leads to refusal of the application. In other words, before a decision is issued an Applicant must be informed of the case which he has to meet, and must have an opportunity of meeting it.” [Emphasis added].

Accordingly, in the present appeal the right to be heard was violated at least for following reasons:

1. The Board refrained from reading the declarations of skilled persons on record evident from its statement that declarations are the same—they are not the same as discussed in 7.i. above—and the Board did not address the declarations in the minutes. Additionally, the Board refrained from assessing who the skilled person in the field are and what was their common general knowledge on the date of priority, and why they could not arrive at the claimed invention from the disclosure. See 3, 4, 5, 7.e., 7.h-j above.
2. The Board kept the Petitioner in dark about why it disregards ED skilled persons who find no added matter in at least EDAR9-10, substantially same as NAR15-20. See 3, 4, 5, 7.i-j above.
3. The Board kept the Petitioner in dark about why it disregards applicable case law T 667/08, T 201/83, T 305/87, and T 190/99, that under Article 123(2) EPC literal support is not required and technical information that the skilled person reading the original disclosure would have derived from its content is considered, that values described in a specific example can be extracted and claimed, that it is permissible to combine separate items belonging to different embodiments described in one and the same document in the claims, if such combination has specifically been suggested, and that a mind willing to understand is required to construe a patent. See 3, 4, 5, 7.e., 7.h-j above.
4. Mr. Alt obstructed the Petitioner from presenting its case, which the Board encouraged by laughing at such occurrences (see 7.f-g. above).
5. Board announced “conclusions” after Mr. Alt said, “Applicant withdraws the appeal” and promptly after that Board proceeded to announce the oral proceedings closed. Board had induced the “withdrawal” of the appeal and then it proceeded to impose “conclusions” and then to shut the door on the Petitioner from presenting its case by closing the oral proceedings. (See 7.k. above). Had the Petitioner known “conclusions” would be imposed anyway, the Petitioner would have argued the case further and insisted that Board respond to the declarations and cited case law properly.

Thus, the Board kept the Applicant in the dark about legal and factual basis for its conclusion/decision, and the Board obstructed the Petitioner by encouraging Mr. Alt to obstruct the Petitioner from speaking, and by first inducing the withdrawal of the appeal and then closing the oral proceedings immediately after imposing “conclusions” the Board deprived the Petitioner from the opportunity to properly submit its case and assist in giving the Board’s conclusion/decision a correct legal and factual basis. For all the above reasons, Petitioner’s right to be heard was violated at the oral proceedings held on 27 July 2017.

Considering that the alleged “added matter” was the only reason for the Board’s conclusion that none of NMR and NAR1-22 met the requirements of the

Convention, there is a clear casual link between the violation of the Applicant's right to be heard and the refusal of the application. Thus, the violation of the Petitioner's right is also fundamental within the meaning of Rule 104 EPC.

Therefore, clearly a fundamental violation of Article 113 occurred, which is a ground for Petition for review by the Enlarged Board of Appeal under Article 112a(2)(c).

Article 112a(2)(d)

Article 112a(2)(d) provides that Petition for review by the Enlarged Board of Appeal may be filed when any other fundamental procedural defect defined in the Implementing Regulations occurred in the appeal proceedings, which has occurred in the present case as demonstrated below.

Article 133(2) EPC provides, "Natural or legal persons not having their residence or principal place of business in a Contracting State shall be represented by a professional representative and act through him in all proceedings established by this Convention." Furthermore, Rule 142 provides, "Proceedings before the European Patent Office shall be interrupted... (c) in the event of the death or legal incapacity of the representative of an Applicant for or proprietor of a patent, or of his being prevented for legal reasons resulting from action taken against his property from continuing the proceedings... (3) In the case referred to in paragraph 1(c), the proceedings shall be resumed when the European Patent Office has been informed of the appointment of a new representative of the Applicant or when the Office has informed the other parties of the appointment of a new representative of the proprietor of the patent."

As asserted above in 7.a-k., 8, and 9, Mr. Alt had ceased to represent the Petitioner during the oral proceedings held on 27 July 2017. The Board had noted this, and should have interrupted the oral proceedings on lack of legal representation, but rather than interrupt the proceedings, the Board encouraged Mr. Alt more and formed a collusion with Mr. Alt to undermine the Applicant.

Therefore, clearly a fundamental procedural defect defined in the Implementing Regulations occurred in the appeal proceedings **and there is a clear casual link between the lack of the Applicant's legal representation and the refusal of the application**, which is a ground for Petition for review by the Enlarged Board of Appeal under Article 112a(2)(d).

Article 112a(2)(e)

Article 112a(2)(e) provides that Petition for review by the Enlarged Board of Appeal may be filed when a criminal act established under the conditions laid down in the Implementing Regulations may have had an impact on the decision. Further, Rule 105 the Implementing Regulations provides that "A petition for review may be based on Article 112a, paragraph 2(e), if a competent court or authority has finally established that the criminal act occurred; a conviction is not necessary."

Rather than supporting the Petitioner at the oral proceedings held on 27 July 2017, Mr. Alt was obstructing the Petitioner from making its case. Further, it was a failure on part of the Board to have let the oral proceedings continue when the lawyer was clearly obstructing the Applicant,

but when the Board actively participated in that impropriety as in laughing and denying its occurrence, the act is elevated to level of crime. Therefore, there were two acts of crime at the oral proceedings, 1) by Mr. Alt in acting against the interests of the client, and 2) by the Board in encouraging and partaking in Mr. Alt's criminal actions. A legal action against Mr. Alt of Bird and Bird due to wrongdoing in this appeal is in process. The relevant court may find both Mr. Alt and the Board of Appeal guilty of criminal acts.

Therefore, clearly a criminal act established under the conditions laid down in the Implementing Regulations may have had an impact on the decision **and there is a clear casual link between the Applicant's legal representation or lack thereof and the refusal of the application**, which is a ground for Petition for review by the Enlarged Board of Appeal under Article 112a(2)(e).

IV. Obligation to Raise an Objection

A petition under Article 112a, paragraph 2(a) to (d) is only admissible where an objection in respect of the procedural defect was raised during the appeal proceedings and dismissed by the Board of Appeal, except where such objection could not be raised during the appeal proceedings. See Rule 106.

As asserted above in 7.k. appeal was "withdrawn" when Board had given "preliminary views". Subsequently, Board announced "conclusion" and promptly closed the oral proceedings. On 20 December 2017, Applicant requested that minutes be corrected to reflect that the appeal was withdrawn when Board had given preliminary views. On 17 January 2018, the Board mailed a communication denying correcting the minutes and insisting that it had given "conclusions (not just preliminary views)" and it declined to acknowledge that Mr. Alt obstructed Ms. Bhagat from speaking at the oral proceedings, which raised several issues.

1. Board's minutes serve as a "decision", which is adversely affecting examination of Petitioner's divisional application EP 17182663.9.
2. The "minutes-decision" was issued surprisingly after the appeal was withdrawn and the "conclusions" were imposed.
3. Petitioner could not have raised the objection during the appeal proceedings, because appeal proceedings were promptly closed after "preliminary views" were changed to "conclusions."
4. Board's "minutes-decision" is lacking in that it does not provide "reasons" for the decision (Rule 102 EPC). Therefore, the "minutes-decision" is invalid.
5. Board's collusion with Mr. Alt was confirmed on 17 January 2018, when the Board declined to acknowledge that Mr. Alt obstructed Ms. Bhagat from speaking at the oral proceedings. If Board were not in collusion with Mr. Alt, it would have acknowledged that Mr. Alt obstructed Ms. Bhagat from speaking. See 8 above.
6. Mr. Alt's withdrawal of the appeal is invalid, because Mr. Alt was not representing the Petitioner; he was effectively representing the Board. See 7.f-g., and 7.k. above.

7. Board should have interrupted the oral proceedings after it noted that Mr. Alt was obstructing the Petitioner, rather than colluding with Mr. Alt. Therefore, the oral proceedings held on 27 July 2017, are invalid.

These objections could not have been raised during the appeal proceedings, because they arise from and are manifested by Board's refusal to correct the minutes on 17 January 2018. See Rule 106. Accordingly, Petitioner has two-month deadline expiring on **27 March 2018** (two months from the notification of the decision on 17 January 2018 and 10 days postal notification as per Rule 126) to file the Petition. Therefore, this petition is timely filed before 27 March 2018.

As for the allowability of the petition, a similar case occurred in T 0832/09-3.2.02, EP 03009955.0, where via Decision R 0015/11 Petition for review under Article 112a(2)(c) was allowed re-opening the appeal procedure with total refund of the fee for the petition for review. R 0015/11 specifically states,

2.3 In the circumstances of the present case it is immaterial for the purposes of Rule 106 EPC whether or not these submissions give a true account of the conduct of the final stage of the oral proceedings before the Board of Appeal. If they do, the total and final refusal to hear the Petitioner effectively hindered the Petitioner from exercising its right to be heard and, at the same time, prevented its representative from raising a relevant objection under Rule 106 EPC (either directly or in reaction to the refusal to comment on the new objection). If for whatever reason the Petitioner's submissions regarding the final stage of the oral proceedings in question were not taken into account by the Enlarged Board of Appeal, then there would be no indication at all that the Petitioner could possibly have been aware before notification of the decision under review that it would be based, within the meaning of Article 113(1) EPC, on the lack of clarity in respect of the auxiliary request.

3. Thus, on either view, the relevant objection could not be raised by the Petitioner during the appeal proceedings. It follows that Rule 106 EPC is satisfied.

...

7. Under these circumstances the Enlarged Board of Appeal is not in a position to establish that the Petitioner's right to be heard has been respected. So it has to be assumed that a violation of the Petitioner's rights under Article 113(1) EPC occurred which qualifies as fundamental within the meaning of Article 112a(2)(c) EPC because it concerned the ground on which the appeal was eventually dismissed by the decision under review.

Similar to R 0015/11, the Enlarged Board of Appeal should find that the procedure at oral proceedings on 27 July 2017 was improper to say the least, as a result at least the Petitioner's right to be heard was violated and Petitioner was adversely affected that the application was refused. Further, the violations became clear on 17 January 2018, when to Board insisted that it gave "conclusions" and when it was confirmed that the Board intentionally overlooked Mr. Alt's impropriety and effectively colluded with the Mr. Alt to undermine the Petitioner.

V. Relief Requested

It is requested that,

- (i) Oral proceedings of 27 July 2017 be invalidated, considering Applicant was unrepresented at the oral proceedings, and Board's "minutes-decision" be invalidated.
- (ii) The appeal proceedings be reopened.
- (iii) All of the members of the Board of Appeal who participated in the oral proceedings be replaced, because they participated in a criminal act of collusion with Petitioner's representative to undermine the Petitioner.
- (iv) The new Board of Appeal be instructed to promptly render a written decision on entirety of record including the Formal Complaint submitted on January 31, 2018 (attached herewith), properly addressing entirety of Applicant's arguments, evidence including eight scientists declarations on record, and case law cited including T 667/08, T 201/83, T 305/87, and T 190/99.
- (v) If the new Board of Appeal maintains the refusal, then the case be immediately referred to Enlarged Board of Appeal under accelerated proceedings in view of the divergent case law.
- (vi) Reimbursement of the fee for the petition for review be ordered.

Encls.

Formal Complaint dated 30 January 2018

Exhibit A. US Patents for Humanity Application, 8 November 2015

Exhibit B. Applicant's Correspondence with Mr. Nick Lee of Kilburn & Strode, 23 April 2015

Exhibit C. Applicant's Correspondence with Mr. Michael Al of Bird and Bird, 16 August 2017 to 18 September 2017

Exhibit D. Declaration of Ms. Urvashi Bhagat dated January 30, 2018

Exhibit E. "Omega-6 fatty acid" Wikipedia, accessed January 29, 2018

Attachment E:

Communication of the Enlarged Board of Appeal, dispatched on 12 June 2018



Boards of Appeal Richard-Reitzner-Allee 8 85540 Haar Tel. +49 89 / 2399 - 0 Fax +49 89 / 2399 - 4465	Europäisches Patentamt Große Beschwerdekammer	European Patent Office Enlarged Board of Appeal	Office européen des brevets Grande Chambre de recours
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Date/Date

12.06.18

Zeichen/Ref./Réf. P800223EP-PCT	Anmeldung Nr./Application No./Demande n°/Patent Nr./Patent No./Brevet n° 09735962.4 - 1105 / 2278885
Anmelder/Applicant/Demandeur/Patentinhaber/Proprietor/Titulaire Asha Nutrition Sciences, Inc.	

Case number:

R0004/18

Communication of the Enlarged Board of Appeal

D. Rogers
Rapporteur

P. Cremona
Registrar
Tel. +49 89 2399 3341

Enclosures: 11 pages

This communication is sent to indicate to the petitioner, (the appellant/applicant in the appeal proceedings), the provisional and non-binding views of the Enlarged Board of Appeal on some, but not necessarily all, of the issues of the case (see Article 13 RPEBA). The function of the Enlarged Board in its current composition pursuant to Rule 109(2) (a) EPC is to examine whether or not the petition is admissible and allowable on the basis of the petition. For ease of reading the petitioner will also be referred to as the appellant.

Facts and Submissions

- I. The petition for review concerns appeal proceedings T 1712/15 of the Board of Appeal 3.3.09. The appeal was against a decision of the Examining Division.
- II. Oral proceedings were held before the Board of Appeal on 27 July 2017. At the end of the oral proceedings the appellant's representative (hereafter "Representative 1") withdrew the appeal. The CEO of the appellant also attended these oral proceedings.
- III. Under cover of a letter dated 3 August 2017 a copy of the minutes of the oral proceedings before the Board was sent to Representative 1.
- IV. Under cover of a letter (Form 3324) dated 8 August 2017 Representative 1 was informed that the Board had closed the proceedings without a substantive decision due to the withdrawal of the appeal during the oral proceedings.

- V. On 7 November 2017 the appellant authorised a new representative (hereafter "Representative 2").
- VI. Under cover of a letter dated 20 December 2017 Representative 2 requested a correction of the minutes of the oral proceedings before the Board.
- VII. In a communication dated 17 January 2018 the Board informed Representative 2 that it saw no reason to correct the minutes.
- VIII. On 26 March 2018 Representative 2 filed a petition for review under Article 112a EPC. On the same date the fee for a petition for review was paid.
- IX. In the petition for review the petitioner submitted that:
- "...a review of the "conclusions" imposed in the communication dated 17 January 2018 by the Technical Board of Appeal 3.3.09, and of fundamental procedural defects in the appeal proceedings in case T 1712/15-3.3.09 is requested due to which the Petitioner is adversely affected in that EP 09735962.4 (EP 2278885) was refused, additionally, the erroneously imposed "conclusions" are adversely affecting Petitioner's divisional application EP 17182663.9, in which the Examiner holds the Petitioner to "conclusions" derived by the Board".
- X. The petitioner bases its petition on Article 112a(2), (c), (d) and (e) EPC, that is:

"(c) a fundamental violation of Article 113 occurred in that the Petitioner's right to be heard was violated;

(d) a fundamental procedural defect defined in the Implementing Regulations Rule 142 and Article 133(2) EPC occurred in the oral proceedings held on 27 July 2017 in that the Petitioner was unrepresented; and

(e) a criminal act established under the conditions laid down in the Implementing Regulations had an impact on the oral proceedings and the "conclusions" imposed by the Board, in that their (sic) was a collusion between the Board and [Representative 1], Petitioner's then authorized representative, at the oral proceedings held on 27 July 2017, to undermine the Petitioner".

XI. The request to amend the minutes of the oral proceedings before the Board, and the Board's refusal to amend are an important part of the petitioner's case. One of the amendments that the petitioner sought to have made to the minutes was to change the word "conclusion" to "preliminary view". This is best illustrated by an example (emphasis added by Enlarged Board). The Board wrote in the minutes, bottom of page 2:

"After the oral proceedings were resumed at 10:10, the Chairman gave the Board's conclusion that claim 1 did not meet the requirements of Article 123(2)EPC".

The petitioner sought to have this changed to:

"After the oral proceedings were resumed at 10:10, the Chairman said that the Board's preliminary view

was that claim 1 did not meet the requirements of Article 123(2)EPC”.

The petitioner argues that its recollection that the Board expressed a “preliminary view” and not a “conclusion” is correct. The consequence of the Board expressing a “conclusion” is that this turns the minutes into a decision - see points G and 8 and IV.1 on pages 9, 8 and 13 respectively of the petition.

Preliminary opinion of the Enlarged Board

Is there a decision at all?

1. Article 112a(1)EPC provides that any party to appeal proceedings adversely affected by the decision of the Board of Appeal may file a petition for review of the decision by the Enlarged Board of Appeal.
2. Thus a prerequisite for both an appeal and a petition for review is the existence of a decision (see T0263/00, point 1; T0934/91 OJ 1994, 184, point 1). The Enlarged Board considers that “decision” in Articles 106 and 107 EPC has the same meaning as “decision” in Article 112a EPC.
3. In order to address this point the petitioner would need to convince the Enlarged Board that the minutes of the oral proceedings held on 27 July 2017, with or without the Board’s 17 January 2018 refusal to amend these minutes, constitute a decision.

What is a decision?

4. According to the case law of the Boards, whether a document constitutes a decision depends upon the substance of its contents rather than its form (see J0008/81, OJ 1982, 10, point 3).
5. The criterion of substance has to be assessed in the procedural context (see T0713/02, OJ 2006, 267, point 2.1.4). In the present case the procedural context is that of minutes of oral proceedings, the oral proceedings ending with the withdrawal of the appeal.
6. Another feature of a decision is that it involves a reasoned choice between legally viable alternatives (see T0934/91, OJ 1994, 184, point 5). This is not the case for minutes of oral proceedings, and any correction thereof, the purpose of which is to reflect the course of the oral proceedings (see T0231/99, points 1.1 and 1.2).
7. The consistent case law of the Boards of Appeal has been that the minutes of oral proceedings, and the correction thereof, are not decisions in the sense of Article 106 EPC (see T0838/92, point 3; T0212/97, point 2.2; T0231/99, points 1.1 and 1.2; CLBA 8th edition 2016, IV.E.2.2.2(b)(viii)).
8. The Enlarged Board does not see how the use of "conclusion" instead of "preliminary view", in the context of the minutes of an oral proceeding can transform these minutes into a decision. The Enlarged Board notes that the common practice of the Boards is

to express views or conclusions on the substantive issues before it during the course of the oral proceedings. A decision on the case is then made at the end of the oral proceedings. As regards procedural issues, such as admission of documents and claim requests, the Board necessarily makes decisions on such issues during the course of the oral proceedings. An example of such a decision (the word "decision" is used) is found on page 4 of the minutes. It concerns the decision not to admit Auxiliary Request 23. Other than this decision on admissibility of a claim request, the minutes do not show that any other decision was made.

Conclusion on "decision" issue

9. The Enlarged Board sees no reason to deviate from the case law cited above, and hence considers that there is no decision of the Board of Appeal in this case. The petition is thus inadmissible and the question of allowability does not arise.

Further issues

10. For the sake of completeness, the Enlarged Board addresses below some other aspects of the petition.

Right to be heard and non-representation of the petitioner

11. These are two heads of complaint, (see points (c) and (d) in point X above), that overlap somewhat. The petitioner implicitly argues that, because it was not represented at the oral proceedings before the Board,

it was not heard (see point 4 on page 11, and arguments under "Article 112a(2) (d)" on page 12 of the petition).

12. The Enlarged Board cannot follow this argument. The petitioner's CEO was present at the oral proceedings before the Board, as was its duly appointed professional representative, Representative 1. The petitioner itself admits this in point (e) of the complaint, (see point X above), and point 7 on page 4 of the petition, where the petitioner refers to Representative 1 as its "then authorised representative". It was not until three months after these oral proceedings that Representative 1 was replaced by Representative 2. These heads of complaint appear to be an expression of the petitioner's dissatisfaction with the professional performance of Representative 1. This cannot be the subject of a petition for review.

Some further remarks on the right to be heard

13. In addition the petitioner argues (on pages 10 and 11 of its petition) that it was not heard on the essential reasoning, both legal and factual, which led to the finding that all the claim requests did not satisfy the requirement of Article 123(2) EPC. This was because the petitioner was kept "... in the dark about the legal and factual basis for [the Board's] conclusion/decision".
14. The Enlarged Board notes that the minutes of the oral proceedings and the Board's communication refusing to correct these minutes, are the only documents that the petitioner has put forward as containing a decision.

The minutes serve the purpose of describing in summary form what happened at the oral proceedings. They do not have the purpose of setting out why the Board reached any conclusions, opinions, or decisions. It is therefore not surprising that they do not contain the "...legal and factual basis for [the Board's] conclusion/decision".

The Enlarged Board notes that the minutes show that issues concerning added subject matter under Article 123(2) EPC were extensively discussed with the petitioner or its representative.

Withdrawal of appeal

15. The petitioner withdrew its appeal at the end of the oral proceedings. The Board then, correctly, closed the oral proceedings and, again correctly, did not issue a decision. The Enlarged Board cannot see how the Board, as argued by the petitioner, (see point 5 on page 11 of the petition), induced the withdrawal of the appeal.

Lack of representation

16. The petitioner states on page 12 of its petition that Representative 1 ceased to represent it during the oral proceedings of 27 July 2017 and that "...The Board had noticed this...".
17. There is no evidence that the petitioner terminated Representative 1's mandate during the course of the oral proceedings, nor is there evidence that the Board noticed this. The evidence is that Representative 1 continued to be the authorised representative of the

petitioner until 7 November 2017 (see point V above). The minutes themselves, (including the minutes with the corrections proposed by the petitioner), show that Representative 1 continued to represent the petitioner throughout the oral proceedings.

A criminal act

18. Article 112a(2)(e) and Rule 105 EPC provide that a petition for review may be based on a criminal act that may have had an impact on the decision if a competent court or authority has finally established that the criminal act occurred; a conviction is not necessary.
19. The petitioner has not put forward any argument or evidence that a competent court or authority has finally established that a criminal act occurred. Indeed, the petitioner's own statements on page 13 of its petition indicate (without giving any details) that a legal action against Representative 1 "is in process". This head of complaint is thus inadmissible. The Enlarged Board takes no position on the possible existence and nature of the alleged criminal act and legal action.

Rule 106 EPC - obligation to raise objections

20. The Enlarged Board will confine itself to commenting on the "lack of representation" objection, (see point 16 and 17 above). The Enlarged Board cannot see why the petitioner was unable to raise this objection at the oral proceedings on 27 July 2017.

No request for oral proceedings before the Enlarged Board

21. The Enlarged Board notes that the petitioner has not requested oral proceedings. Thus, once the Enlarged Board has digested the petitioner's reply (if any) to this communication, and the time limit for responding to this communication has expired, the Enlarged Board will be in a position to issue a decision.

Conclusion

22. The petition will, with a high degree of certainty, be found to be inadmissible.

"Formal Complaint" dated 30 January 2018

23. The Enlarged Board has no competence under Article 112a EPC to examine the merits of a board's decision or to go into the substance of a case (see R 13/10, point 4; R 19/11, point 2.3; and R 6/13, point 3). In addition, procedural defects that occurred in first instance proceedings may not be subject to a petition for review (see R 20/10, point 2.4; and R 8/11, point 1.2.2). The Enlarged Board has therefore refrained from commenting on the petitioner's "Formal Complaint" addressed to Mr Ernst and others.

Time limit for commenting

23. The petitioner is given the opportunity to comment on this preliminary view of the Enlarged Board within ONE (1) MONTH from receipt of this communication (Rule 109(1) EPC.

David ROGERS (Rapporteur)

Attachment F:

Response to Communication of the Enlarged Board of Appeal, submitted on 22 July
2018

July 22, 2018

BY EPOONLINE

European Patent Office, Boards of Appeal
Richard-Reitzner-Allee 8
85540 Haar
Germany

Case Number: R0004/18 (Regarding Petition Under Article 112a)
Application No: 09 735 962.4 (EP 2 278 885)
Appeal No: T1712/15-3.3.09
**Applicant/
Appellant/
And Petitioner: Asha Nutrition Sciences, Inc.**

**RESPONSIVE TO THE COMMUNICATION OF THE
ENLARGED BOARD OF APPEAL OF 12 JUNE 2018**

This response is timely filed, as the Communication of the Enlarged Board of Appeal (hereinafter “EBoA”) of 12 June 2018 (hereinafter, “Communication”) sets a one-month period for response (see last point at page 11 of the Communication) from receipt of the communication, therefore including the 10-day EPO's postal notification period, the response is due by 22 July 2018, which is Sunday. Hence the response can be filed up until Monday, **23 July 2018**.

At the outset it is noted that the Petitioner considers the Communication of EBoA to be improper because it justifies improprieties of the Board of Appeal (hereinafter “BoA”) further compromising the credibility of the European Patent Office (EPO). For example, with the Petition the Petitioner submitted evidence (in particular Exhibits C and D) of **serious offenses** by BoA in colluding with Petitioner's legal representative to undermine the Petitioner. EBoA disregarded the evidence and expressed no regret on part of EPO over having maltreated the Applicant and the application. EBoA is a high-ranking authority and representative of EPO, entailing higher responsibility and greater accountability towards applicants.

The point numbers in the detailed response below correspond to the point numbers in the Communication.

Facts and submissions

Evidence Not Acknowledged by EBoA

In the Communication EBoA has not acknowledged evidence Exhibits A-E expressly called to attention at pages 2-3, 8, and 15 of the Petition, of which Exhibits C and D below are of particular relevance to the Petition, and were repeatedly cited in the Petition (see page 5 (points 7.a, 7.d), page 6 (points 7.f-g), page 7 (points 7.h-i), and page 8 (points 7.k and 9)).

- Exhibit C. Applicant's Correspondence with Mr. Michael Alt of Bird and Bird [Representative 1], 16 August 2017 to 18 September 2017
- Exhibit D. Declaration of Ms. Urvashi Bhagat, Applicant/Appellant/Petitioner's CEO, dated January 30, 2018. Ms. Bhagat was present at the oral proceedings held on 27 July 2017.

Legitimacy of Exhibit C has been testified to in Exhibit D, paragraph [0021].

Further, in Exhibit D, Ms. Bhagat has testified at paragraph [0023],

"I further declare that all statements made herein of my own knowledge are true and that statements made of information and belief are believed to be true. I further acknowledge that any willful false statements and the like so made are punishable by fine or imprisonment, or both, and may jeopardize the validity of the application or any patent issuing therefrom."

The statements of employees of one of the parties were regarded as sufficient evidence in a series of appeal cases, e.g. T 162/87 and T 627/88, T 124/88, T 482/89 (OJ 1992, 646), T 363/90, T 830/90 (OJ 1994, 713), T 838/92 and T 327/91, T 190/05, J 10/04. Therefore, Petitioner has submitted abundant evidence in support of the facts.

EBoA's enumeration of "Facts" is corrected below considering the evidence.

II. Correction is made to this fact:

At the end of the oral proceedings held on 27 July 2017, the Appellant's Representative 1 on paper, but **in fact in collusion with BoA during oral proceedings** withdrew the appeal. There were five persons present at the oral proceedings, three BoA members, Representative 1 in collusion with the Board, and the CEO of the Appellant. The CEO was outnumbered and ganged upon by four persons in collusion (three BoA members and Representative 1) against the CEO.

Petitioner made this assertion numerous times in the Petition that Representative 1 represented the Applicant on paper, but in reality Representative 1 represented the BoA and the Applicant was unrepresented. See Petition points II.7.d, II.7.f-i, II.8-9, II.A-E, III pages 11-13, and IV.5-7.

In evidence Exhibit C, contemporaneous email communications shortly after the oral proceedings (dated 16 August 2017 to 18 September 2017), Mr. Alt admits that he obstructed Ms. Bhagat from speaking, stating, “I... aimed at controlling your submission” (Ms. Bhagat’s email of 16 August 2017 and Mr. Alt’s response of 31 August 2017); and in Exhibit D, Ms. Bhagat’s testimony, paragraphs [0014], [0015], and [0020]-[0022] she testifies that Mr. Alt was in collusion with the BoA, for example as follows.

“Mr. Alt was making feeble arguments, not citing what I wanted him to cite, and obstructing me from speaking, and the Board was an accomplice. There was an apparent collusion between Mr. Alt and the Board to undermine the subject application.” Paragraph [0014].

“Although I sporadically tried to argue again during the rest of oral proceedings, it was difficult for me to do so, because of objections and lackluster support from Mr. Alt, and the undercurrent of collusion among the Board and Mr. Alt.” Paragraph [0015].

See Petition II.7.d, II.7.g, and II.9.

IV. Correction is made to this fact:

Appellant never received Form 3324 from EPO, or from Representative 1 if it was mailed to Representative 1.

It cannot be expected that the Petitioner should prove a negative, that is the non-receipt of a letter, or provide a plausible explanation for non-receipt; additionally Petitioner has no duty to monitor the proceedings themselves by regularly inspecting the electronic file. (See R0004/17, points 2-4).

V. Correction is made to this fact:

Representative 1 had clearly ceased to represent Applicant during the oral proceedings when instead of representing the Applicant he represented the BoA. Evidence of this has been cited in the Petition (see point II. above). For example, in Exhibit C, Ms. Bhagat’s email dated 31 August 2017 to Representative 1, authenticated in Exhibit D paragraph [0021], she states,

“You represented EPO at the proceedings not us, and you continue to do so.”

Clearly, finding and effectuating replacement of Representative 1 took time, but that was a formality, Representative 1 had ceased to represent Applicant during the oral proceedings.

VII. It is called to attention here that BoA Communication dated 17 January 2018, actually states, “The Board does not see any reason to correct said minutes...” (emphasis added).

In other words BoA did not decline to amend the minutes, but BoA declined to correct the minutes, that is even if the minutes are incorrect.

X. Correction is made to this fact:

There is a typographical error at page 1 point (e) of the Petition, in that the word “there” was mistyped as “their”, corrected language is produced below which also adopts the designation “Representative 1” for “Mr. Michael Alt of Bird and Bird” as per EBoA Communication, point II.

“(e) a criminal act established under the conditions laid down in the Implementing Regulations had an impact on the oral proceedings and the “conclusions” imposed by the Board, in that there was a collusion between the Board and [Representative 1], Petitioner’s then authorized representative, at the oral proceedings held on 27 July 2017, to undermine the Petitioner.” Emphasis is added to show amended parts.

XI. Correction is made to this fact:

BoA minutes of the oral proceedings held on 27 July 2017 (hereinafter “Minutes”), repeat twice as follows:

“After the oral proceedings were resumed at 10:10, the Chairman gave the Board’s conclusion that claim 1 did not meet the requirements of Article 123(2) EPC.” (Page 2 last paragraph, emphasis added).

“After the oral proceedings were resumed at 11:00, the Chairman gave the Board’s conclusion that claim 1 of none of Auxiliary Requests 1 to 22 complied with Article 123(2) EPC.” (Page 3 last paragraph, emphasis added).

Further, Petitioner does not just “argue” that its “recollection” is that the Board expressed a “preliminary view,” Petitioner has submitted evidence to this effect cited in the Petition (point II.7.k), Exhibit D Ms. Bhagat’s testimony, wherein at paragraph [0020] reproduced below she testifies to the procedural context and deliberate replacement of the terms “preliminary views” to “conclusion” by BoA,

“Board’s minutes misrepresent “Conclusions” versus “preliminary views”. Accurate statements made near the end of oral proceedings are as follows.

(1) After Mr. Sieber announced that AR23 would not be admitted into proceedings, Mr. Alt asked if the Board would allow the Applicant to withdraw the appeal at that point?

(2) Mr. Sieber said, “I have only given Board’s preliminary views, not conclusions. Therefore, the Applicant can withdraw the appeal.”

(3) Mr. Alt then said, “Applicant withdraws the appeal.”

- (4) *Subsequently, Mr. Sieber said, “I will now give Board’s conclusion that Claim 1 of main request and auxiliary requests 1 to 22 do not comply with Article 123(2) EPC.”*

The recitation of “conclusion” in the Minutes, the procedural context of steps (1)-(4) above in which the words “preliminary views” were deliberately replaced with “conclusion” during the oral proceedings, the dictionary definition of “conclusion”, BoA’s refusal to “correct” the Minutes to state “preliminary views”, and the Minutes being the terminating step of the proceedings with conclusive effect on the matter, all confirm that Minutes in substance are a “decision.” **EPO itself has interpreted the Minutes as “decision”, a definitely settled matter from BoA.** The “Written Opinion” (hereinafter “Written Opinion”) of EPO in application no. 17182663.9 (divisional of the subject application) states at Form 1507, page 2, paragraph 2,

“In the present case, the earlier (Parent) application has been refused for deficiencies under Article 123(2) EPC.”

However, **if** the Minutes were not a “decision” and the Appeal no. T1712/15-3.3.09 is treated as withdrawn, then the parent application was **not** refused for deficiencies under Article 123(2) EPC, because in that case the decision of the Examining Division stands, which did not find any added matter in the admitted AR9 and AR10 (which the Written Opinion finds added matter in) that were improperly refused under the allegation of lack of novelty. See Examining Division (ED) Decision (Form 2916) dated March 3, 2015, pages 14-16. **Thus, by stating, “(Parent) application has been refused for deficiencies under Article 123(2) EPC” in Written Opinion, the EPO itself has confirmed the Minutes are a “decision,” a definitely settled matter from BoA.**

The foregoing facts are further substantiated in points 4-9 below.

There is a decision

1. Petitioner does not dispute that Article 112a(1) EPC states, “Any party to appeal proceedings adversely affected by the decision of the Board of Appeal may file a petition for review of the decision by the Enlarged Board of Appeal.” Petitioner demonstrated in the Petition filed on 26 March 2018 and above (Fact XI) that BoA did issue a “decision” and the Petitioner is adversely affected by the decision, which is further substantiated below (points 4-9).
2. Petitioner acknowledges that “decision” in Articles 106 and 107 EPC has the same meaning as “decision” in Article 112a EPC.

3. Petitioner should not have to convince the EBoA that the Minutes with or without BoA's 17 January 2018 refusal to "correct" the minutes constitute a decision, because EBoA is aware from the Petition and the case history, that the Minutes in this case have the substance including finality effect of a decision. EBoA as high-ranking body of the EPO has a duty to correct application of the law and to fairness of the process. However, since EBoA has requested the Petitioner explains again.

The following confirm that the Minutes are a decision

4. EBoA has acknowledged citing J0008/81, point 3, which ruled, "Whether a document constitutes a decision or a communication depends on the substance of its contents, not upon its form." In the cited case, the Legal Board of Appeal held "The appellant corporation's [Caterpillar Tractor Co.] representatives were justified in treating the letter as an appealable decision." The Board also ruled in point 3,

"[t]he contents of the letter ought to have been identified as a decision, so as to preserve the clear distinction made in the Convention and Implementing Regulations between decisions and communications; cf. e.g., Rules 68 and 70 EPC. The letter ought also to have drawn attention to the possibility of appeal and the provisions of Articles 106 to 108 EPC, in conformity with Rule 68 (2) EPC. The fact that the requirements of Rule 68(2) EPC were not fully complied with does not, however, mean that that the letter was merely a communication."

The ruling that a document constitutes a decision depends on the substance of its contents, not upon its form has been maintained by EPO in numerous cases, including:

"This conclusion applies regardless of the title or form of the document that purports to be a decision, for clearly the legal status of that document must depend on its substance, rather than its mere form or title." T0934/91 OJ 1994, 184, point 5.

"Whether a document issued by the EPO constitutes a decision or a communication depends on the substance of its contents, not on its form (e.g. decision J 8/81, OJ EPO 1982, 10). Hence it is not relevant that the text in question was in the form of a mere letter and sent as an enclosure to a "Brief Communication", nor does it matter that it stated "...it is decided" to allow the request. Nor is the fact decisive that the Notice of the Vice-President DG 2 cited above uses in point I.23 the wording "Decisions concerning the correction of errors (Rule 88 EPC)". T0713/02, point 2.1.4."

Therefore, even a document titled "Minutes of the oral proceedings" can constitute a decision, depending on the substance of its contents even if the contents have not been

identified as “decision”, although in the current case the content in the Minutes have been identified as “conclusion” meaning “decision” as per several dictionaries. See point 8 below.

5. EBoA has acknowledged that criterion of substance has to be assessed in the procedural context of the case, citing T0713/02, point 2.1.4, of which relevant text is as follows.

“The criterion of substance has to be assessed in its procedural context, in particular by also taking into account the consequences of irreversibly determining the matter at stake—here the addition of an earlier priority—at the given stage of the proceedings, namely in the middle of the substantive examination, and before it had been concluded, as provided for in Article 97 EPC, by a decision to grant a patent or to refuse the application.” [Emphasis added].

Applying the above case law to the present case, it is clear that the Minutes have irreversibly determined the matter at stake concluding the proceedings in refusal of the subject application and adversely affecting applicant’s divisional application (Fact XI above).

The Communication disregards the evidence that the appeal was withdrawn by Representative 1 in collusion with BoA (see Fact II above) in stating that the oral proceedings ended with withdrawal of the appeal. The Communication also disregards the full procedural context of the withdrawal of the appeal, which has been asserted in the Petition (II.7.k) and evidenced in the testimony of Petitioner’s CEO (Exhibit D, paragraph [0020]) present at the oral proceedings, and is repeated below:

“Accurate statements made near the end of oral proceedings are as follows.

- (1) After Mr. Sieber announced that AR23 would not be admitted into proceedings, Mr. Alt asked if the Board would allow the Applicant to withdraw the appeal at that point?*
- (2) Mr. Sieber said, “I have only given Board’s preliminary views, not conclusions. Therefore, the Applicant can withdraw the appeal.”*
- (3) Mr. Alt then said, “Applicant withdraws the appeal.”*
- (4) Subsequently, Mr. Sieber said, “I will now give Board’s conclusion that Claim 1 of main request and auxiliary requests 1 to 22 do not comply with Article 123(2) EPC.”*

As evident from Ms. Bhagat’s testimony, Mr. Sieber induced withdrawal of the appeal by stating “*I have only given Board’s preliminary views, not conclusions. Therefore, the Applicant can withdraw the appeal*” but right after the statement, “*Applicant withdraws the appeal,*” he promptly announced “Board’s conclusion” and the oral proceedings closed, shutting the door on further arguments. Had the Petitioner known “conclusions” would be imposed anyway, the Petitioner would have argued the case

further and insisted that Board respond to all the arguments, evidence, and cited case law on record.

Luring the Applicant into withdrawing the appeal by stating “preliminary views” and switching to “conclusion” is similar to business tactics known as “Bait-and Switch”, a form of fraud, outlawed in several European countries, e.g. in England and Wales, bait and switch is banned under the Consumer Protection from Unfair Trading Regulations 2008.

Therefore, in the procedural context of this case that the Applicant was unrepresented (Fact II above), BoA induced withdrawal of the appeal and switched to “conclusion” right after the withdrawal of appeal, and the Minutes irreversibly determined the matter at stake concluding the proceedings in refusal of the subject application and adversely affecting applicant’s divisional application.

6. EBoA has misapplied T0934/91, point 5, and improperly alleged that BoA did not make a reasoned choice between legally viable alternatives. T0934/91, point 5, provides that,

“[a] "decision" does need to involve a reasoned choice between legally viable alternatives and where, as is the case here, there is, by reason of the doctrine of RES JUDICATA no alternative at all, there can by definition be no such choice, and hence there can be no "decision" either within the meaning of that term in the EPC. This conclusion applies regardless of the title' or form of the document that purports to be a decision, for clearly the legal status of that document must depend on its substance, rather than its mere form or title.”

The present case is different from T0934/91. In the present case there was no RES JUDICATA (a matter that has been adjudicated by a competent court and may not be pursued further by the same parties) restriction upon BoA, and there were legally viable alternatives available to BoA in finding or not finding “added matter”, including:

- A. Properly reading the disclosure in subject application. For example, there is absolutely no justification for finding “added matter” in Claim 1 of MR or AR1-22. Original Claim 1 is very clearly drawn to “optimal amounts of fatty acids”, (a “dosage” of fatty acids) based on a complete list of demographic factors (also a “dosage”), and Claim 3 is drawn **only to** “omega-6 and omega-3 fatty acids and wherein the ratio of omega-6 to omega-3 fatty acids and their amounts are controlled based on one or more factors [dosage].” Thus, only ingredients are omega-6 and omega-3 (which are fatty acids and also phytochemicals because animals cannot make them; Specification paragraph [0004]) and **open-ended ratio** and **dosage** of which is recited in Claim 3 with guidance in Specification “the present disclosure incorporates relatively high ratio of omega-6 to omega-3 fatty acid, while maintaining optimal daily delivery of both omega-6 and omega-3 [dosage],” (Specification paragraph [0021]).

- B. Responding to arguments submitted in the Grounds of Appeal (Petition point II.3), response submitted on 28 June 2017 (Petition point II.5), and at the oral proceedings (Petition points II.7.b-c, e, h-i).
- C. Honoring case law of the Boards of Appeal (T 667/08) that the technical information that the skilled person reading the original disclosure would have derived from its content (description, claims, drawings) is considered in its entirety, and that literal support is not required by the wording of Art. 123(2) EPC. Honoring two separate sets of declarations from skilled persons (two declarations submitted on May 9, 2014 and three declarations submitted on December 4, 2014) declaring that skilled persons can directly and unambiguously obtain the claimed subject matter from the disclosure. (Petition points II.3-5, II.7.i, II.9, II.H).
- D. Honoring case law of the Boards of Appeal that manipulation of features and extraction of point values from examples is permissible, e.g., T201/83. (Petition points II.3-5, II.7.e, II.7.h, II.9, II.H).

Therefore, despite that original Claims 1 and 3 are clearly limited only to omega-6 and omega-3 in open-ended ratios, and extraction of “4:1 or greater” from examples is perfectly permissible in accordance with T201/83, BoA disregarded all of the above and not only **made the choice** to disallow MR, but **also made the choice** to disallow AR1-22 on allegation of added matter.

Additional evidence cited at Petition II.7.a of **reasoned choice** made by BoA is Exhibit D, Petitioner’s CEO’s testimony, where in paragraph [0016] she testifies,

“Board stated during oral proceedings that the Board was focused on Article 123(2) EPC because it had to ensure that patent was not issued on claims that were possibly anticipated by prior art, partly because amount of non-fatty acid lipids in compositions may be very small. However, such issues have been rebutted in USPTO prosecution history and also in Grounds of Appeal submitted to EPO. For example, amount of non-fatty acid lipids in compositions is not always small (e.g., it can be 20% of the composition). It was disconcerting because such imaginary prior art objection cannot be raised under novelty objection—novelty is a question of inevitability not probability—and lack of inventive step objection could not be raised because of obstructive factors.”

Therefore, BoA made a reasoned choice to refuse the application under the pretense of “added matter”.

Petitioner’s contention is that BoA did make reasoned choices, but improperly, because it neither considered nor responded to all arguments, evidence and case law in Grounds of Appeal and presented at the oral proceedings, and BoA’s conclusion/decision is contrary to a large body of

EPO case law, in particular T 667/08 and T201/83, and kept it the Petitioner in dark about the legal and factual basis of its decision.

It has already been established above (see points 4-5) that any document, including minutes of oral proceedings, can be a “decision” depending on the substance contained in them, procedural context of the proceedings, and the finality effect of the document in proceedings. This is further substantiated below.

7. EBoA has cited T0838/92, point 3; T0212/97, point 2.2; T0231/99, points 1.1 and 1.2 alleging in those cases the Boards did not consider the minutes of oral proceedings to constitute decisions.

However, Petitioner contends that legal, factual, and procedural context of the cited cases was different from the current case. Most importantly, in the cited cases the minutes of oral proceedings did not terminate the proceedings; in each of the cited cases a separate document titled “Decision” was issued by EPO; further unlike the present case, in none of the cases EPO itself had held the minutes to definitely settle the matter (Fact XI above). For example in T0838/92, T0212/97, and T0231/99, points 1.1 and 1.2 the Board stated that the minutes of the hearing do not constitute a decision and cannot be "canceled" by the Board of Appeal—**significant to the procedure is that a separate formal decision was issued in each case.**

In contrast, in the present case BoA improperly imposed “conclusion” in substance “decision”, in the Minutes themselves, and the proceedings terminated with the Minutes having a character of final settlement, no additional “Decision” was issued by EPO, and EPO itself held the Minutes to definitely decide the matter in the Written Opinion issued in the divisional application of the subject application (Fact XI above).

Therefore, keeping in perspective that substance of contents of a document determines whether it is a “decision” (point 4 above), and procedural context, specifically finality effect of the document, determines the “substance” (point 5 above), in this case it is clear that the Minutes function as “decision.”

8. EBoA states that it “does not see how the use of “conclusion” instead of “preliminary view”, in the context of the minutes of an oral proceeding can transform these minutes into a decision.” Petitioner reminds EBoA that CEO of the Applicant who was present at the oral proceedings has testified in Exhibit D, paragraph [0020] that,

“Accurate statements made near the end of oral proceedings are as follows.

- (1) After Mr. Sieber announced that AR23 would not be admitted into proceedings, Mr. Alt asked if the Board would allow the Applicant to withdraw the appeal at that point?*
- (2) Mr. Sieber said, “I have only given Board’s preliminary views, not conclusions. Therefore, the Applicant can withdraw the appeal.”*
- (3) Mr. Alt then said, “Applicant withdraws the appeal.”*

(4) *Subsequently, Mr. Sieber said, “I will now give Board’s conclusion that Claim 1 of main request and auxiliary requests 1 to 22 do not comply with Article 123(2) EPC.”*

As evident from the above Mr. Sieber considered there to be an important distinction between “preliminary views” and “conclusion”, as he expressly stated in point (2) above, *“I have only given Board’s preliminary views, not conclusions. Therefore, the Applicant can withdraw the appeal.”* It is evident that Mr. Sieber has chaired numerous oral proceedings, and he considers that when “preliminary views” have been announced appeal can be withdrawn, but not after “conclusion” has been announced. Therefore, Mr. Sieber carefully chose the words “preliminary views” in point number (2) above to give rise to, or induce, withdrawal of the appeal. Subsequently, Mr. Sieber chose the word “conclusion” in point number (4) because he wanted to put “conclusion” on the record.

Dictionary definition of “conclusion” is “decision” as evidenced below:

“the final decision in a law case”

<https://www.merriam-webster.com/dictionary/conclusion>

“a decision made after a lot of consideration”

<https://dictionary.cambridge.org/us/dictionary/english/conclusion>

“A judgement or decision reached by reasoning”

<https://en.oxforddictionaries.com/definition/conclusion>

Whereas dictionary definition of “preliminary” is “something that precedes or is introductory or preparatory” but undecided as evidenced below:

“something that precedes or is introductory or preparatory”

<https://www.merriam-webster.com/dictionary/preliminary>

“coming before a more important action or event, esp. introducing or preparing for it” e.g., “Preliminary results show that the vaccine is effective, but this has to be confirmed by further medical trials.”

<https://dictionary.cambridge.org/us/dictionary/english/preliminary>

“Preceding or done in preparation for something fuller or more important”

<https://en.oxforddictionaries.com/definition/preliminary>

Therefore, Petitioner is correct to assert that when BoA refused to correct the minutes to state “preliminary views” instead of “conclusion”, BoA confirmed that it had issued a “decision” as evidenced by multiple dictionary definitions. Further, BOA statement in the refusal to correct the Minutes itself confirms that BoA considers there to be an important distinction between “preliminary views” and “conclusion”. The Communication of the Board of Appeal dated 17 January 2018, states,

“The Board further notes that the Chairman did explicitly give conclusions (not just preliminary views) on the allowability of the main request and auxiliary requests 1 to 22 under Article 123(2) EPC.” (Emphasis added).

Furthermore, “conclusion” in the BoA Minutes means “decision” is evidenced by EPO’s own interpretation of the Minutes. For example, The “Written Opinion” issued by EPO in case divisional application (of the subject application) no. 17182663.9 states at Form 1507, page 2 paragraph 2,

“In the present case, the earlier (Parent) application has been refused for deficiencies under Article 123(2) EPC.”

It is clear from the statement above in the “Written Opinion” that EPO itself treats the Minutes issued by BoA as “decision” because **if** the Minutes were not a “decision” and the Appeal no. T1712/15-3.3.09 is treated as withdrawn then the parent application was **not** refused for deficiencies under Article 123(2) EPC, because in that case the “decision” of the Examining Division stands, which did not find any “added matter” in the admitted AR9 and AR10 (which the “Written Opinion” finds “added matter” in), which were improperly refused under the allegation of lack of novelty. See Examining Division (ED) Decision (Form 2916) dated March 3, 2015, pages 14-16. Thus, if the appeal was withdrawn, then the parent application was refused under alleged lack of novelty, **not** “deficiencies under Article 123(2) EPC.” **Thus, by stating, “(Parent) application has been refused for deficiencies under Article 123(2) EPC” EPO itself confirmed the Minutes are a “decision.”**

Conclusion on the “decision” issue:

9. Therefore, there is a “decision” in this case because of at least the following:
 - A. As demonstrated in point 4 above, “Whether a document [including minutes of oral proceedings] constitutes a decision or a communication depends on the substance of its contents, not upon its form.” J0008/81, point 3; also see T0934/91 OJ 1994, 184, point 5; and T0713/02, point 2.1.4.
 - B. As demonstrated in point 5 above, “The criterion of substance has to be assessed in its procedural context, in particular by also taking into account the consequences of irreversibly determining the matter at stake.” T0713/02, point 2.1.4. In the current case the procedural context is that the Applicant was unrepresented at the oral proceedings, BoA induced withdrawal of the appeal and switched to “conclusion” right after the withdrawal of appeal, and the Minutes irreversibly determined the matter at stake concluding the proceedings in refusal of the subject application and adversely affecting applicant’s divisional application.

- C. As demonstrated in point 6 above, in accordance with T0934/91, point 5, there was no RES JUDICATA restriction upon BoA, and there were legally viable alternatives available to BoA in finding or not finding “added matter”. BoA did make reasoned choices, but keeping the Petitioner in dark on the legal and factual basis of why it chose to disregard arguments, evidence and case law in Grounds of Appeal and presented at the oral proceedings, in particular T667/08 and T201/83.
- D. As demonstrated in point 7 above, legal, factual, and procedural context of T0838/92, T0212/97, and T0231/99 was different from the current case, in particular, a separate formal decision from minutes of oral proceedings, was issued in each case. In contrast, in the present case BoA improperly imposed “conclusion”, (defined as “decision” in most credible dictionaries) in the Minutes themselves, and the proceedings terminated with the Minutes having a character of final settlement, no additional “Decision” was issued by EPO, and EPO itself held the Minutes to definitely decide the matter in the Written Opinion issued in the divisional application of the subject application (Fact XI above).
- E. As demonstrated in point 8 above, the dictionary definition of “conclusion” is “decision”, and of “preliminary” is “not confirmed” or “undecided”. Therefore, when BoA refused to correct the minutes to state “preliminary views” instead of “conclusion”, BoA confirmed that it had issued a “decision”; not only that BoA expressly insisted that it “did explicitly give conclusions (not just preliminary views)”; and finally the Minutes have been interpreted as “decision” by EPO itself in the divisional application.

Therefore, contrary to EBoA’s position, the cited case law supports Petitioner’s position that there is a “decision” in this case. There is no reason for EBoA to misstate the law.

Right to be heard and non-representation of the petitioner

11. The violation of right to be heard is **an independent basis** for the Petition and was independently argued in the Petition under the heading “Article 112a(2)(c) at pages 10, 11, and ending at top of page 12. Specifically, Petition page 11, points 1, 2, 3, and 5 list in detail how the right to be heard was violated, irrespective of non-representation of the Petitioner.

Non-representation of the Petitioner is **an independent basis** for the petition and was independently argued in the Petition under the heading “Article 112a(2)(d) at page 12. Specifically, Petitioner asserted that fundamental procedural defect defined in the Implementing Regulations occurred in the appeal proceedings in that Article 133(2) EPC and Rule 142 were violated because,

“ Mr. Alt [Representative 1] had ceased to represent the Petitioner in the oral proceedings held on 27 July 2017... The Board had noted this, and should have interrupted the oral proceedings on lack of legal representation, but rather than interrupt the proceedings, the Board encouraged Mr. Alt more and formed a collusion with Mr. Alt to undermine the Applicant. Therefore, clearly a fundamental procedural defect defined in the Implementing Regulations occurred in the appeal proceedings and there is a clear casual link between the lack of the Applicant’s legal representation and the refusal of the application, which is a ground for Petition for review by the Enlarged Board of Appeal under Article 112a(2)(d).” See Petition page 12.

Therefore, the non-representation is a fundamental procedural defect defined in the Implementing Regulations (see Rule 142) and grounds for Petition under Article 112a(2)(d), **in addition** the disorder created by the actions of Representative 1 at the oral proceedings and BoA’s encouragement of the same also violated Appellant’s right to be heard because the disorder diverted focus from the full case being heard and holding BoA accountable for informing the Applicant about legal and factual basis for its conclusion/ decision. EPC case law is clear that, “It is important that Board should control the proceedings” and “The main criterion to be considered is that the Board should be fully informed of all relevant matters before deciding the case.” (See G0002/94, points 2, 3, and answer to the referred questions 2(a)).

12. This point has been addressed above. See Fact II. In reality, Representative 1 had ceased to represent the Petitioner; he was in fact in collusion with BoA to undermine the application. EBoA can appreciate that the Petitioner had no way of predicting that Representative 1 would betray the Petitioner in such a manner and that BoA would participate in such impropriety. This unraveled in real time as the oral proceedings took place. Four persons (Representative 1 and 3 BoA members) outnumbered and ganged upon the CEO of the Petitioner at the oral proceedings. The CEO had no reaction time. It is a well-accepted principle in oral proceedings at EPO that an applicant, petitioner, or appellant should be given time to react to new issues that come up at the oral proceedings. See Rules 71(a) and 116(1). Mutatis mutandis, same principle applies in this case. The Petitioner was taken by surprise by the actions of Representative 1 and BoA.

It is incorrect to state that the Petitioner was dissatisfied with professional capabilities of Representative 1; Petitioner has very clearly asserted that the Petitioner holds Representative 1 (and BoA) guilty of criminal act (Petition pages 12-13). As evidence, Petitioner has submitted Exhibit C, Petitioner’s CEO’s contemporaneous email communications shortly after the oral proceedings (dated 16 August 2017 to 18 September 2017) with Representative 1, wherein the CEO asserted as follows:

“I have been thinking about how to say this to you, but there is no other way to say this than directly. My reading is that you did not want the case to be

allowed... You did not want me to speak. You misstated to me that in Applicant is not allowed to speak. You were afraid that I would argue properly and that might lead to allowance... You weakened my position when you created a huff over my speaking during the oral proceedings.” CEO’s email to Representative 1, dated 16 August 2017.

“You represented EPO at the proceedings not us, and you continue to do so. I also suspect that there must have been a conflict of interest for you to act in the way you did.” CEO’s email to Representative 1, dated 31 August 2017.

“I know that you are a good lawyer. Your performance at the oral proceedings can mean only one thing that you did not work in our best interest.” CEO’s email to Representative 1, dated 18 September 2017.

Malice on part of Representative 1 is also evident from, Exhibit D, paragraphs [0012]-[0015], [0018]-[0019], and [0021]-[0022]. It took time to find a new Representative and effectuate the replacement of Representative 1, but the record is clear that Representative 1 had ceased to represent the Petitioner at the oral proceedings, which is a fundamental procedural defect defined in the Implementing Regulations (see Rule 142) and grounds for Petition under Article 112a(2)(d).

Further remarks on the violation of right to be heard

13. Petitioner reasserts that it was not heard on essential reasoning, both legal and factual, BoA kept the Petitioner is dark about the legal and factual basis for its conclusion/ decision, which led to the allegation of “added matter” in all the claim requests. See pages 10-11, and top of page 12 of the Petition.
14. This point has been rebutted above in point 4-9 that in this case Minutes function as a decision.

In the refusal to correct the Minutes on 17 January 2018, BoA itself has stated, “The Board further notes that the Chairman did explicitly give conclusions (not just preliminary views) on the allowability of the main request and auxiliary requests 1 to 22 under Article 123(2) EPC.” (Emphasis added).

Thus, BoA insists that “preliminary views” are distinct from “conclusion”, dictionary meaning of “preliminary” is “undecided” and that of “conclusion” is “decision”, and EPO itself has interpreted the Minutes as “decision” in the Written Opinion in case of the divisional application. See point 8 above. Therefore, “conclusion” is a “decision”. Therefore, the Board has a legal requirement to set out the legal and factual basis for why

the Board reached the conclusion/decision that it reached. See pages 10-11, and top of page 12 of the Petition.

Petitioner disagrees with EBoA statement that “the minutes show that issues concerning added subject matter under Article 123(2) EPC were extensively discussed with the petitioner or its representative.” **Petitioner requests EBoA to point out where in the Minutes-Decision are the following point (from page 11 of the Petition, also submitted in Grounds of Appeal filed on 9 July 2015) addressed?**

1. The Board refrained from reading the declarations of skilled persons on record evident from its statement that declarations are the same—they are not the same as discussed in 7.i. above—and the Board did not address the declarations in the minutes. Additionally, the Board refrained from assessing who the skilled person in the field are and what was their common general knowledge on the date of priority, and why they could not arrive at the claimed invention from the disclosure. See 3, 4, 5, 7.e., 7.h-j above.
2. The Board kept the Petitioner in dark about why it disregards ED skilled persons who find no added matter in at least EDAR9-10, substantially same as NAR15-20. See 3, 4, 5, 7.i-j above.
3. The Board kept the Petitioner in dark about why it disregards applicable case law T 667/08, T 201/83, T 305/87, and T 190/99, that under Article 123(2) EPC literal support is not required and technical information that the skilled person reading the original disclosure would have derived from its content is considered, that values described in a specific example can be extracted and claimed, that it is permissible to combine separate items belonging to different embodiments described in one and the same document in the claims, if such combination has specifically been suggested, and that a mind willing to understand is required to construe a patent. See 3, 4, 5, 7.e., 7.h-j above.

Of course the above points, which are fundamental to the “added matter” question were left unanswered by BoA. Thus, the Board kept the Applicant in the dark about legal and factual basis for its conclusion/decision.

Considering that the alleged “added matter” was the only reason for the Board’s conclusion that none of NMR and NAR1-22 met the requirements of the Convention, there is a clear casual link between the violation of the Applicant’s right to be heard and the refusal of the application. Thus, the violation of the Petitioner’s right is also fundamental within the meaning of Rule 104 EPC.

Therefore, clearly a fundamental violation of Article 113 occurred, which is a ground for Petition for review by the Enlarged Board of Appeal under Article 112a(2)(c).

Withdrawal of appeal

15. This point has been discussed above under point no 5. For completeness it is repeated below.

The Communication disregards the full context of the withdrawal of the appeal, which has been asserted in the Petition (II.7.k) and evidenced in the testimony of Petitioner’s CEO (Exhibit D, paragraph [0020]) present at the oral proceedings, and is repeated below:

“Accurate statements made near the end of oral proceedings are as follows.

- (1) After Mr. Sieber announced that AR23 would not be admitted into proceedings, Mr. Alt asked if the Board would allow the Applicant to withdraw the appeal at that point?*
- (2) Mr. Sieber said, “I have only given Board’s preliminary views, not conclusions. Therefore, the Applicant can withdraw the appeal.”*
- (3) Mr. Alt then said, “Applicant withdraws the appeal.”*
- (4) Subsequently, Mr. Sieber said, “I will now give Board’s conclusion that Claim 1 of main request and auxiliary requests 1 to 22 do not comply with Article 123(2) EPC.”*

As evident from Ms. Bhagat’s testimony, Mr. Sieber induced withdrawal of the appeal by stating *“I have only given Board’s preliminary views, not conclusions. Therefore, the Applicant can withdraw the appeal”* but right after the statement, *“Applicant withdraws the appeal,”* he promptly announced “Board’s conclusion” and the oral proceedings closed, shutting the door on further arguments. Had the Petitioner known “conclusions” would be imposed anyway, the Petitioner would have argued the case further and insisted that Board respond to all the arguments, evidence, and cited case law on record. Therefore, whether it was “the end of oral proceedings” is also incorrect because the oral proceedings may have gone longer in case of further submissions.

Luring the Applicant into withdrawing the appeal by stating “preliminary views” and switching to “conclusion” is similar to business tactics known as “Bait-and Switch”, a form of fraud, outlawed in several European countries, e.g. in England and Wales, bait and switch is banned under the Consumer Protection from Unfair Trading Regulations 2008.

EBoA is reminded that BoA considers there to be important distinction between “preliminary views” and “conclusions” as evidenced not only by Exhibit D, paragraph [0020], but also by BoA’s own statement in the refusal to correct the Minutes, stating *“The Board further notes that the Chairman did explicitly give conclusions (not just preliminary views) on the allowability of the main request and auxiliary requests 1 to 22 under Article 123(2) EPC.”* (Emphasis added).

Therefore, BoA improperly induced withdrawal of the appeal, and then imposed decision, interpreted as such in EPO's Written Opinion in the divisional case.

Lack of representation

16. It has been evidenced that Representative 1 “had ceased to represent the Petitioner during the oral proceedings held on 27 July 2017” and “The Board had noted this...”
17. EBoA must be aware that CEO of the Petitioner who was present at the oral proceedings is not a patent attorney, and may not be fully aware of all procedural aspects of proceedings. It is evident that the CEO was in shock that Representative 1 could betray the Petitioner and that BoA could collude with the representative, and the CEO did not have sufficient reaction time to assess whether or not Representative 1's mandate during the oral proceedings could be or should be formally terminated. However, there is more than sufficient evidence that has been called to attention in the Petition namely Exhibit C (email communications starting August 16, 2017) and Exhibit D, also discussed in point 12 above. Specifically, Ms. Bhagat states in her email of 31, August 2017, to Representative 1, “You have caused us great harm. Your statements below are incorrect, we will have a lawyer respond to them.”

In this instance, the CEO, a non-lawyer, was caught in an unexpected situation where four opposing persons have significantly more legal background (Representative 1 and three BoA members) were in collusion against the Petitioner. In all legal proceedings, leeway is given to non-attorney parties. EBoA is requested to keep this in perspective.

Note that the Petitioner did request the following correction to the Minutes page 2,

“Ms. Bhagat attempted to make arguments before the Board when Mr. Alt interrupted her. Chairman said that there was no issue with Ms. Bhagat making the arguments, because the proceedings were ex-parte. However, when Ms. Bhagat attempted to speak again, Mr. Alt threw his pen making it uncomfortable for Ms. Bhagat to speak subsequently. The Board laughed at the lack of support from the counsel.”

Further, Exhibit D, Ms. Bhagat's testimony, paragraph [0014]-[0015] evidences that BoA had noted that Representative 1 had ceased to represent the Petitioner.

*“However, even after Mr. Sieber said that there was no issue with my arguing, when I started to argue that the feature “omega-6 to omega-3 ratio of 4:1 or greater” is directly and unambiguously obtained from the Specification as filed, **Mr. Alt again created a huff by throwing his pen. This time the Board laughed.** To save the situation I said, “I will let the counsel argue this.”*

*Mr. Alt cited paragraph [0042], which discloses formulations that “render extra omega-3 unnecessary,” which the Board did not accept. From this point on the discussion in oral proceedings deteriorated. Mr. Alt was making feeble arguments, not citing what I wanted him to cite, and obstructing me from speaking, and **the Board was an accomplice. There was an apparent collusion between Mr. Alt and the Board to undermine the subject application...***

*Although I sporadically tried to argue again during the rest of oral proceedings, it was difficult for me to do so, because of objections and lackluster support from Mr. Alt, and **the undercurrent of collusion among the Board and Mr. Alt. Each time I spoke, I spoke worriedly and hurriedly to avoid being cut off and the Board ridiculing and subverting the arguments.***

[Emphasis added].

Thus, it has been evidenced that Representative 1 “had ceased to represent the Petitioner during the oral proceedings held on 27 July 2017” and “The Board had noted this...”

A criminal act

18. Article 112a(2)(e) provides that, “a criminal act established under the conditions laid down in the Implementing Regulations **may have had** an impact on the decision.” (Emphasis added). Therefore, the language “may have had” leaves open the possibility that a petition under Article 112a(2)(e) is admissible when a criminal act is not finally established by a court, but may have had an impact on the decision.
19. Petitioner has submitted evidence of criminal acts on part of Representative 1 and BoA in Exhibits C and D. EBoA is aware that establishment of a criminal act by a court can take several years. If the EPC does not provide an adequate relief in such situations then the parties’ rights would be severely compromised in such situations. Therefore, considering the circumstances of the case, EBoA should find the Petition admissible under Article 112a(2)(e).

Rule 106 EPC – obligation to raise objections

20. The question as to why the Petitioner was unable to raise objection on the point of “lack of representation” at the oral proceedings held on 27 July 2017, has been answered above in point 17, but for completeness is repeated below.

The CEO of the Petitioner who was present at the oral proceedings is not a patent attorney, and is not fully aware of all procedural aspects of proceedings. It is evident that the CEO was in shock that Representative 1 could betray the Petitioner and that BoA could collude with the representative, and the CEO did not have sufficient reaction time to formally raise an objection on the point of “lack of representation” at the oral proceedings, but the CEO was aware that BoA had noted this and was encouraging the impropriety.

In this instance, the CEO, a non-lawyer, was caught in situation where four opposing persons having significantly more legal background (Representative 1 and three BoA members) were in collusion against the Petitioner. In all legal proceedings, leeway is given to non-attorney parties. EBoA is requested to keep this in perspective.

Further, as has been repeatedly asserted in the Petition, Exhibit D, and in points 16-17 above BoA had noted that Representative 1 was not representing the Petitioner, but instead of interrupting the oral proceedings in accordance with Article 133(2) and Rule 142 of EPC, BoA became an accomplice to Representative 1. Specifically, Rule 106, provides, “A petition under Article 112a, paragraph 2(a) to (d), is only admissible where an objection in respect of the procedural defect was raised during the appeal proceedings and **dismissed by the Board of Appeal.**” (Emphasis added). In this case, it is evident that BoA had noticed lack of representation but not only dismissed it but also encouraged it. Board of Appeal is expected to maintain control of the oral proceedings.

Board’s collusion with Representative 1 was also confirmed on 17 January 2018, when the Board declined to acknowledge that Representative 1 obstructed the Petitioner from speaking at the oral proceedings. Therefore, this objection could not be raised earlier.

No request for oral proceedings before the Enlarged Board

21. Petitioner requests that any necessary further communications be also handled in writing.

EBoA might understand that the Petitioner has participated in two oral proceedings at the EPO, first on 11 February 2015 with the Examining Division, and second on 27 July 2017 with BoA. On both occasions Petitioner has been disappointed by the conduct of EPO personnel at the proceedings. Therefore, Petitioner’s confidence in EPO is impaired.

Petitioner hopes that a fair decision by EBoA on this petition will restore Petitioner’s confidence in EPO.

Conclusion

22. Petitioner strongly believes that the Petition should be found admissible and allowable.

As demonstrated above (point 4-9), any document can be a decision based on its content, there is a decision in the Minutes in BoA's own assertion in the refusal to correct the Minutes that "conclusion" is "not just preliminary views", dictionary definition of "conclusion" is "decision", the Minutes are the final determining step in the procedure, and EPO's own Written Opinion in the divisional case holds the Minutes as a decision.

Further, it is very clear that the Petition is admissible under Article 112a(2)(c) in that the Petitioner's right to be heard was violated, and that this objection could only be raised when the Board refused to correct the minutes on 17 January 2018 to state "preliminary views" instead of "conclusion" which means "decision".

Further, the Petition is also admissible under Article 112a(2)(d) in that the Petitioner's was unrepresented at the oral proceedings. Representative 1 was in collusion with BoA and effectively represented BoA not the Petitioner. The Board had noted this, and should have interrupted the oral proceedings on lack of legal representation under Article 133(2) and Rule 142 EPC, but rather than interrupt the proceedings, the Board encouraged Representative 1 more and formed a collusion with him to undermine the Applicant. Board of Appeal is expected to maintain control of the oral proceedings, which BoA failed.

Further, the Petition should also be admissible under Article 112a(2)(e) because the language "may have had" in Article 112(2)(e) leaves open the possibility that a petition is admissible when a criminal act is not finally established by a court, but may have had an impact on the decision.

Finally, the Petition should be found allowable in accordance with Decision R 0015/11 as asserted at page 14 of the Petition.

"Formal Complaint" dated 30 January 2018

23. Petitioner acknowledges that EBoA has limited competence under Article 112a. However, Petitioner asserts the Formal Complaint provides back up to points expressly asserted in the Petition on the violation of right to be heard, the lack of representation by Representative 1, the collusion between Representative 1 and BoA, the lack of legal and factual explanations provided by BoA to the arguments and case law cited in the Grounds of Appeal and at the oral proceedings held on 27 July 2017. The Formal Complaint is authored by Petitioner's CEO (see page 34 of the compliant) who was present at the oral

proceedings, therefore it provides a firsthand detailed account of the oral proceedings. Therefore, the Formal Complaint should be considered by EBoA as back up to what is already in the Petition.

Time limit for commenting

23. This response is timely filed as with 10-day EPO's postal notification period the response is due by 22 July 2018, which is Sunday, hence the response can be filed up until Monday, **23 July 2018**.

Attachment G:

Annotated Decision of the Enlarged Board of Appeal of 10 October 2018



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Datum/Date
22.10.18

Zeichen/Ref./Réf. P800223EP-PCT	Anmeldung Nr./Application No./Demande n° // Patent Nr./Patent No./ Brevet n°. 09735962.4 - 1105 / 2278885
Anmelder/Applicant/Demandeur//Patentinhaber/Proprietor/Titulaire Asha Nutrition Sciences, Inc.	

22.10.18

Case number:

R 04/18

Please find enclosed a copy of the decision of the Enlarged Board of Appeal dated 10 October 2018.


C. Eickhoff
The Registrar
Tel. 089 / 2399 - 3010

Registered letter



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Board of Appeal

Grande
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(B) [X] To Chairmen and Members
(C) [] To Chairmen
(D) [] No distribution

**Datasheet for the decision
of 10 October 2018**

Case Number: R 0004/18

Appeal Number: T 1712/15 - 3.3.09

Application Number: 09735962.4

Publication Number: 2278885

IPC: AC23D7/00

Language of the proceedings: EN

Title of invention:
Lipid-containing compositions and methods of use thereof

Applicant:
Asha Nutrition Science, Inc

Headword:
Decision, existence of

Relevant legal provisions:
EPC Art. 106, 112a

Keyword:
Petition for review - inadmissible;
No decision by Board of Appeal

Decisions cited:
G 0008/91, J 0008/81, T 0934/91, T 0838/92, T 0212/97,
T 0231/99, T 0713/02

Catchword:
-



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Case Number: R 0004/18

DECISION
of the Enlarged Board of Appeal
of 10 October 2018

The annotations on the following have been added by the Petitioner/Applicant after the issuance of the Decision. EBoA refers to Enlarged Board of Appeal, BoA refers to Board of Appeal.

Petitioner: Asha Nutrition Sciences, Inc
(Applicant) PO Box 1000
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California 94302 - USA

Representative: Tombling, Adrian George
Withers & Rogers LLP
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London SE1 2AU - GB

Issue under review: Proceedings in T 1712/15 before the Technical
Board of Appeal 3.3.09 of the European Patent
Office.

Composition of the Board:

Chairman: C. Josefsson
Members: D. Rogers
M. Harrison

Exhibits C (Applicant's Correspondence with Mr. Michael Alt of Bird and Bird [Representative 1], 16 August 2017 to 18 September 2017) and Exhibit D (Declaration of Ms. Urvashi Bhagat, Applicant/Appellant/Petitioner's CEO, dated January 30, 2018).

Exhibits C and D were repeatedly cited in the Petition (see page 5 (points 7.a, 7.d), page 6 (points 7.f-g), page 7 (points 7.h-i), and page 8 (points 7.k and 9)), and it was emphasized in the response submitted to EBoA on 22

Summary of Facts and Submissions

- I. The petition for review concerns appeal proceedings T 1712/15 of the Board of Appeal 3.3.09. The appeal was against a decision of the Examining Division.
- II. Oral proceedings were held before the Board of Appeal on 27 July 2017. At the end of the oral proceedings the appellant's representative (hereafter "Representative 1") withdrew the appeal. The CEO of the appellant also attended these oral proceedings. The appellant will, where appropriate, also be referred to as the "Petitioner" in this decision.
- III. Under cover of a letter dated 3 August 2017 a copy of the minutes of the oral proceedings before the Board was sent to Representative 1.
- IV. Under cover of a letter (Form 3324) dated 8 August 2017 Representative 1 was informed that the Board had closed the proceedings without a substantive decision due to the withdrawal of the appeal during the oral proceedings.
- V. On 7 November 2017 the appellant authorised a new representative (hereafter "Representative 2").
- VI. Under cover of a letter dated 20 December 2017 Representative 2 requested a correction of the minutes of the oral proceedings before the Board.
- VII. In a communication dated 17 January 2018 the Board informed Representative 2 that it saw no reason to correct the minutes.

VIII. On 26 March 2018 Representative 2 filed a petition for review under Article 112a EPC.

IX. In the petition for review the Petitioner submitted that:

"...a review of the "conclusions" imposed in the communication dated 17 January 2018 by the Technical Board of Appeal 3.3.09, and of fundamental procedural defects in the appeal proceedings in case T 1712/15 - 3.3.09 is requested due to which the Petitioner is adversely affected in that EP 09735962.4 (EP 2278885) was refused, additionally, the erroneously imposed "conclusions" are adversely affecting Petitioner's divisional application EP 17182663.9, in which the Examiner holds the Petitioner to "conclusions" derived by the Board".

X. The Petitioner bases its petition on Article 112a(2), (c), (d) and (e) EPC, that is:

"(c) a fundamental violation of Article 113 occurred in that the Petitioner's right to be heard was violated;

(d) a fundamental procedural defect defined in the Implementing Regulations Rule 142 and Article 133(2) EPC occurred in the oral proceedings held on 27 July 2017 in that the Petitioner was unrepresented; and

(e) a criminal act established under the conditions laid down in the Implementing Regulations had an impact on the oral proceedings and the "conclusions" imposed by the Board, in that their (sic) was a collusion between the Board and [Representative 1],

Petitioner's then authorized representative, at the oral proceedings held on 27 July 2017. to undermine the Petitioner".

- XI. The request to amend the minutes of the oral proceedings before the Board, and the Board's refusal to amend are an important part of the Petitioner's case. One of the amendments that the Petitioner sought to have made to the minutes was to change the word "conclusion" to "preliminary view". This is best illustrated by an example (emphasis added by Enlarged Board). The Board wrote in the minutes, bottom of page 2:

"After the oral proceedings were resumed at 10:10, the Chairman gave the Board's conclusion that claim 1 did not meet the requirements of Article 123(2)EPC".

The Petitioner sought to have this changed to:

"After the oral proceedings were resumed at 10:10, the Chairman said that the Board's preliminary view was that claim 1 did not meet the requirements of Article 123(2)EPC".

- XII. The Petitioner argues that its recollection that the Board expressed a "preliminary view" and not a "conclusion" is correct. The consequence of the Board's minutes expressing a "conclusion" is that the minutes are to be considered as being a decision.

Petitioner did NOT just assert recollection, petitioner submitted TESTIMONIAL EVIDENCE. See Exhibit D paragraph [0020].

- XIII. The Enlarged Board issued a communication setting out its preliminary opinion on the case.

XIV. The Petitioner filed its reply to this communication within the time limit provided for doing so.

XV. In this reply the Petitioner expanded upon the arguments in the petition. In particular the Petitioner argued that the Examining Division dealing with application No. 17182663.9 (a divisional application of the application in suit in T 1712/15, the appeal underlying this petition, hereafter "the Divisional application") treated the minutes in T 1712/15 as being a decision. According to the Petitioner this was evidenced by page 2, paragraph 2 of "Form 1507" (the Enlarged Board notes that this is in fact Form 1703) of 14 March 2018, where the Examining Division stated:

"In the present case, the earlier (Parent) application has been refused for deficiencies under Article 123(2) EPC."

XVI. In its reply the Petitioner further argues that the minutes are to be considered as a decision due to their procedural context. Further, the Petitioner argued that it was unrepresented at the oral proceedings before the Board of Appeal and that the Board itself induced the withdrawal of the appeal. Once the appeal was withdrawn, the Board switched to a "conclusion". Hence the minutes:

"...irreversibly determined the matter at stake concluding the proceedings in refusal of the subject application and adversely affecting the applicant's divisional application." - (point 9.B, page 12 of 22, Petitioner's Reply)

XVII. On the issue of inducing the withdrawal of the appeal, the Petitioner's CEO gave her own recollection of this part of the oral proceedings before the Board of Appeal as follows [the anonymization is by the Enlarged Board]:

TESTIMONY not RECOLLECTION

"Accurate statements made near the end of oral proceedings are as follows.

(1) After Mr. S announced that AR23 would not be admitted into proceedings, Mr. A asked if the Board would not allow the Applicant to withdraw the appeal at that point?

(2) Mr. S said, "I have only given the Board's preliminary views, not conclusions. Therefore, the Applicant can withdraw the appeal."

(3) Mr. A then said, "Applicant withdraws the appeal."

(4) Subsequently, Mr. S said, "I will now give Board's conclusion that claim 1 of main request and auxiliary requests 1 to 22 do not comply with Article 123(2) EPC."

Reasons for the Decision

Preliminary Issues

1. As preliminary issues the Enlarged Board will deal with the following matters: non-representation of the Petitioner at the oral proceedings; negative impact of Board of Appeal minutes on the Divisional application; the Board of Appeal inducing the withdrawal of the appeal; and collusion between Representative 1 and the Board of Appeal.

Non-representation of the Petitioner before the Board of Appeal

2. This preliminary issue concerns the Petitioner's assertion that it was not represented at the oral proceedings before the Board of Appeal. The Petitioner's CEO was present at the oral proceedings before the Board, as was its duly appointed professional representative, Representative 1. There is no evidence to suggest that the mandate of Representative 1 was ever terminated by the Petitioner during the course of those proceedings. Quite to the contrary, all the evidence available shows that

EBoA closes its eyes to the evidence submitted, Exhibit C and D that Representative 1 was in collusion with the BoA and then falsely states there is no evidence.

Representative 1 continued with its mandate to represent the Petitioner throughout the oral

EBoA disregarded the requested correction of 20 December 2017 at page 2, "Mr. Alt threw his pen making it uncomfortable for Ms. Bhagat to speak subsequently. The Board laughed at the lack of support from the counsel." Exhibit C dated one month after the oral proceedings confirms that Representative 1 obstructed the Applicant at the oral proceedings.

proceedings. The minutes with corrections proposed by the Petitioner indeed confirm this. It was not until three months after these oral proceedings that Representative 1 was replaced by Representative 2. The

Applicant petitioned under Art 112a when EPO atrocities piled on with improper divisional examination above improprieties of BoA.

Enlarged Board thus finds that the Petitioner was represented at the oral proceedings before the Board of Appeal.

EBoA extremely improperly disregards evidence, e.g., Exhibit C, emails between Petitioner and Representative 1 evidencing that he obstructed Petitioner during oral proceedings and that CEO is not an attorney, not fully aware of procedure, and BoA's refusal to correct minutes to acknowledge the obstruction also confirmed BoA's wrongdoing.

Examination of Divisional application negatively influenced by Minutes issued by Board of Appeal

3. Turning now to whether the Examining Division dealing with the Divisional application considered the minutes in case T 1712/15 as being a decision: the wording in Form 1703 does not support this. It is quite evident that the Examining Division was referring to the decision of the Examining Division that led to case T 1712/15, not to any decision of the Board of Appeal. The Form 1703 in question deals with added matter

Not true because Examining Division decision does not have a res judicata effect (T 1254/06, #1.1).

issues (i.e. issues under Article 76(1) and 123(2) EPC). The decision of the Examining Division that led to case T 1712/15 found that the subject-matter of the claims according to the Main Request and Auxiliary Requests 1 to 8 did not fulfil the requirement of Article 123(2) EPC, Auxiliary Requests 9 and 10 containing claims with subject-matter which was found ^{alleged} not to be novel. The set of claims in the single request discussed in Form 1703 concerns the claims of the application as filed. The Examining Division's aim in Form 1703 was to suggest possible acceptable claims upon the basis of the application as filed and to avoid those issues that arose with the requests containing amended claims in the parent application. Thus an adverse effect (if any) on the Divisional application comes from the decision of the Examining Division to reject the Petitioner's European Patent application No. 09735962.4.

EBoA is WRONG because Form 1703 in divisional case applies the kind of "added matter" objections as BoA not as ED in case of parent application. For example, ED understood that elements could be selected from Table 4 in this case.

Did the Board of Appeal induce the withdrawal of the appeal?

4. As regards the suggestion that the Board of Appeal induced the withdrawal of the appeal, the evidence of the Petitioner itself shows that the Chairman of the Board simply informed Representative 1 of the procedural situation in response to a direct question on whether it was still possible to withdraw the appeal. The Enlarged Board notes that paragraph (4) of the Petitioner's CEO's recollections (see point XVII) corresponds neither to the minutes of the oral proceedings, nor to the amendments to these minutes that the Petitioner requested. **Yes it does!**

It is not clear what EBoA means by "paragraph (4)". It appears that the EBoA means paragraph [0020] of Exhibit D, Ms. Bhagat's testimony, which MOST CERTAINLY DOES relate to the amendments to the minutes requested by the petitioner, which requested that the "conclusion" be amended to "preliminary views". The evidence, Exhibit D [0020], shows that right after Representative 1 withdrew the appeal BoA switched from "preliminary views" to "conclusions", and that BoA refused to amend the minutes to state "preliminary views" insisting "the Chairman did explicitly give conclusions (not just preliminary views)." That shows "bait and switch" in other words "inducement".

Collusion between Representative 1 and the Board of Appeal

5. The Enlarged Board can find no evidence of collusion between Representative 1 and the Board of Appeal. As evidence of collusion the Petitioner has merely put forward its CEO's criticism of Representative 1's professional performance.

EBoA has a mind desirous of not finding the evidence. EBoA FAILS TO EVEN ACKNOWLEDGE Exhibits C & D submitted by the Petitioner. What other evidence did EBoA expect? Only five people were in the room. Four of them (the lawyer and BoA) were in collusion. The fifth, the Applicant's CEO gave testimony, Exhibit D, supported with Exhibit C. Are the minutes a decision?

Besides the Applicant's CEO, does EBoA expect the walls to testify? It is noted that EPO ensures that there is no evidence of its wrongdoings at the oral proceedings by generally not allowing any cameras and sound recordings.

6. Article 112a(1) EPC provides that any party to appeal proceedings adversely affected by the decision of the Board of Appeal may file a petition for review of the decision by the Enlarged Board of Appeal.
7. Thus a prerequisite for a petition for review is the existence of a Board of Appeal decision. The Enlarged Board finds that "decision" in Articles 106 and 107 EPC has the same meaning as "decision" in Article 112a EPC.
8. According to the case law of the Boards, whether a document constitutes a decision depends upon the substance of its contents rather than its form (see e.g. J 0008/81, OJ 1982, 10, point 3).
9. The criterion of substance has to be assessed in the procedural context (see T 0713/02, OJ 2006, 267, point 2.1.4). In the present case the procedural context is that of an appeal proceedings that were ended by the withdrawal of the appeal by the sole appellant.
10. Another feature of a decision is that it involves a reasoned choice between legally viable alternatives

(see T 0934/91, OJ 1994, 184, point 5). This is not the case for minutes of oral proceedings, and any correction thereof, the purpose of which is to reflect the course of the oral proceedings (see T 0231/99, points 1.1 and 1.2).

11. The consistent case law of the Boards of Appeal has been that the minutes of oral proceedings, and the correction thereof, are not decisions in the sense of Article 106 EPC (see T 0838/92, point 3; T 0212/97, point 2.2; T 0231/99, points 1.1 and 1.2; CLBA 8th edition 2016, IV.E.2.2.2(b)(viii)). That, in all these cases, a separate formal decision was issued does nothing to alter the conclusion that minutes are not considered to be a decision. The Enlarged Board also notes that in the present case, T 1712/15, the minutes did not terminate the proceedings (see point 7, page 10 of 22 of the Petitioner's Reply): the proceedings were terminated by the appellant's withdrawal of its appeal.

The proceedings were terminated by Representative 1 in collusion with BoA, so baited and induced by BoA.

12. The key argument of the Petitioner is that the use of the word "conclusion" in the minutes makes the minutes into a decision on the issues upon which a conclusion had been made. Thus in the present case, if the Petitioner's view were followed, the Board of Appeal made a decision that claim 1 of the Main Request and Auxiliary Requests 1 to 22 did not meet the requirement of Article 123(2) EPC. The Enlarged Board does not see how the use of "conclusion" instead of "preliminary view", in the context of the minutes of an oral proceeding can transform these minutes into a decision.

Because BoA itself insisted "the Chairman did explicitly give conclusions (not just preliminary views)" on 17 Jan 2018. The Enlarged Board notes that the common practice of

the Boards is to express views or conclusions on the substantive issues before them during the course of the

However, on 17 Jan 2018, BoA insisted "the Chairman did explicitly give conclusions (not just preliminary views)". Then it is improper for EBoA to say "views or conclusions" as alternates because BoA insisted that "conclusions" are "not just preliminary views" in other words they are more than "views." Petitioner provided dictionary definition of "conclusion" versus "preliminary views" in the response to EBoA filed on 22 July 2018.

oral proceedings. A decision on the case is then made at the end of the oral proceedings. As regards procedural issues, such as admittance of documents and claim requests, the Board necessarily makes decisions on such issues during the course of the oral proceedings. An example of such a decision (the word "decision" is used) is found on page 4 of the minutes. It concerns the decision not to admit Auxiliary Request 23. Other than this decision on the admissibility of a request containing a new claim 1, the minutes do not show that any other decision was made. In this case the appeal proceedings were terminated by the withdrawal of the appeal. This ended the suspensive effect of the appeal and the decision of the Examining Division became final (see G 0008/91, OJ EPO 1993, 346).

EPO is making up its own language as convenient. On 22 July 2018 (pp. 11) it was evidenced "conclusion" and "decision" are synonyms.

13. The Enlarged Board hence finds that there is no decision of the Board of Appeal in this case. The petition is thus inadmissible and the question of allowability does not arise.

EBoA's holding that there is no decision from BoA under the circumstances is improper, but since EBoA has so held, it must be respected by the Examining Division in the divisional case that there IS NO DECISION FROM THE APPEAL BOARD IN THE PARENT CASE.

However, the Petitioner finds it extremely improper that EBoA has disregarded Exhibit C and D, and conflated Article 112a (2) lit. (c), (d), and (e) grounds. EBoA was not present at the oral proceedings, when Petitioner has provided email communications dated one month after the oral proceedings demonstrating that Representative 1 obstructed the Applicant from speaking and there was improper collusion between BoA and Representative 1 and provided testimony to this effect, EBoA should render justice to Petitioner and show grave concern that such actions are happening at EPO that are abusive to inventors, applicants, and are sabotaging implementation of innovation for public benefit.

Order

For these reasons it is unanimously decided that:

The petition for review is rejected as clearly inadmissible.

The Registrar:

The Chairman:



C. Eickhoff



C. Josefsson

Attachment H:

Formal Complaint Upon Enlarged Board of Appeal Decision R 4/18 submitted on 12
November 2018
(Attachment “Annotated Decision of the Enlarged Board of Appeal of 10 October 2018”
omitted as it is already attached with this petition as Attachment G)



November 12, 2018

BY EPOONLINE

European Patent Office, Boards of Appeal
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Christoph Ernst, Chairman, Administrative Council of the European Patent Organisation
C. Josefsson, D. Rogers, and M. Harrison, Members of Enlarged Board Of Appeal
Antonio Campinos, President
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Raimund Lutz, Vice-President Directorate-General Legal/ International Affairs
Karin Seegert, Director, Chief Operating Officer Healthcare, Biotechnology & Chemistry
Reinoud Hesper, Head of Department, Patentlaw: Filing & Euro-PCT

Case Number: R0004/18 (Regarding Petition Under Article 112a)
Application No: 09 735 962.4 (EP 2 278 885)
Appeal No: T1712/15-3.3.09
Applicant/Appellant/And Petitioner: Asha Nutrition Sciences, Inc.

FORMAL COMPLAINT
Upon Enlarged Board Of Appeal Decision
R 4/18 Dated 10 October 2018

Dear Mr. Ernst, Members of the Enlarged Board of Appeal, and Relevant EPO Officers,

Petitioner is in receipt of the Decision of the Enlarged Board of Appeal issued on 10 October 2018 (hereinafter "Decision"). The Decision fills the Petitioner with indignation and is not well taken. Petitioner considers it a duty to make its contentions known so that at some point European Patent Office will wake up to the harm it is causing to the innovators, applicants, and public at large.

Annotated copy of the Decision marking the improprieties is enclosed herewith, and summary of main contentions are provided below. In the following, EBoA refers to the Enlarged Board and BoA refers to Board of Appeals.

1. EBoA has disregarded evidence Exhibits C and D repeatedly cited in the Petition (see page 5 (points 7.a, 7.d), page 6 (points 7.f-g), page 7 (points 7.h-i), and page 8 (points 7.k and 9)), and throughout in the response to EBoA communication. The statements of employees of one of the parties were regarded as sufficient evidence in a series of appeal cases, e.g. T 162/87 and T 627/88, T 124/88, T 482/89 (OJ 1992, 646), T 363/90, T

830/90 (OJ 1994, 713), T 838/92 and T 327/91, T 190/05, J 10/04. Accordingly, EBoA should have honorably considered the Exhibit C and D.

2. What other evidence does the EBoA expect? Only five people were present in the oral proceedings. Four of them (Representative 1 and BoA) were in collusion against the Petitioner. Partners in crime do not implicate other partners. The fifth, the Applicant's CEO gave testimony, Exhibit D, supported with Exhibit C. Besides the Applicant's CEO, does EBoA expect the walls to testify? It is noted that EPO ensures that there is no evidence of its wrongdoings at the oral proceedings by generally not allowing any cameras and sound recordings.
3. When the BoA expressly stated in its refusal to correct the minutes “the Chairman did explicitly give conclusions (not just preliminary views) on the allowability of the main request and auxiliary requests 1 to 22 under Article 123(2) EPC,” (emphasis added) it confirmed that “conclusion” is different from “preliminary views”. BoA made it clear that it did not use “views” or “conclusions” as alternates, or synonyms. In other words, BoA insisted that it gave a decision. Further, in the submission of 22 July 2018 (pp. 11) it was evidenced "conclusion" and "decision" are synonyms in the English language. EPO cannot distort the language per its convenience.
4. BoA wanted its minutes to be treated as a “decision” without having to formally issue a decision, that is why it insisted it gave “conclusions” and therein lays a major wrongdoing.
5. When BoA refused to correct the minutes on 17 January 2018 to acknowledge the obstruction from Representative 1 at the oral proceedings, it confirmed that BoA was in collusion with Representative 1, because Exhibit C evidences that Representative 1 did indeed obstruct the Petitioner during oral proceedings. BoA did not admit to the obstruction because it participated in the obstruction by laughing when Mr. Alt threw his tantrums, because admittance would reflect upon BoA’s own improprieties.
6. For the reasons above, both the oral proceedings and the withdrawal of the appeal are invalid.
7. Examining Division in the divisional case did take the minutes as a decision, because the objections applied are similar to BoA’s objections in the minutes. For example, Examining Division in the parent case understood that elements from Table 4 could be selected in view of totality of the disclosure without “adding matter”, but BoA did not, and the Examining Division in the divisional case followed BoA minutes in alleging that elements could not be selected from Table 4.

Since EBoA has held that there is no decision from BoA, the Examining Division in the divisional case must respect that there is no decision from the BoA in the parent case, and the minutes are irrelevant.

However, the Petitioner finds it extremely improper that EBoA has disregarded Exhibits C and D, and conflated Article 112a (2) lit. (c), (d), and (e) grounds. EBoA was not present at the oral proceedings. When Petitioner has provided email communications dated one month after the oral proceedings demonstrating that Representative 1 obstructed the Applicant from speaking at the oral proceedings and there was improper collusion between BoA and Representative 1 and provided testimony to this effect, EBoA should have shown grave concern that such actions are happening at EPO that are abusive to inventors, applicants, and are sabotaging implementation of innovation for public benefit. Under the circumstances EBoA should have invalidated the oral proceedings to discourage such behavior. Instead EBoA's actions will embolden wrongdoing at EPO and that is extremely detrimental to innovation, public benefit and EPO's charter.



Urvashi Bhagat
Chief Executive Officer

Enclosure: Annotated copy of the Decision dated 10 October 2018

Attachment I:

Applicant's Response Submitted on 25 June 2019 in the Divisional Case
(Attachments omitted, which are available at
<https://register.epo.org/application?number=EP17182663&lng=en&tab=doclist>)

European Patent Office
D-80298 München
Germany
(Filed electronically via CMS)

25 June 2019

EP Application No: 17182663.9
Country/Region: European Divisional Application
Application: Divisional of EP09735962.4 (parent)
Title: “Lipid-Containing Compositions and Methods of Use Thereof”
Applicant: Asha Nutrition Sciences, Inc.
Our Ref: 1166/P001-EP-Div

Dear Sirs

I am writing further to Examination Report issued by the EPO on 25 February 2019 with respect to the above identified patent application.

Please find enclosed with this Response a new set of amended claims comprising claims 1 to 15, which new set is to replace the old set of claims currently on file, and should form the basis of any further examination of the present application.

For the avoidance of any doubt, none of the amendments or revisions of any of the claims constitute abandonment of subject matter and the applicant is entitled and should therefore be allowed to return to any of the subject matter described in the application as originally published.

The Examiner would hopefully appreciate that arguments were filed with respect to each of the outstanding objections in the Applicant’s reply on 11 October 2018 and 2 November 2018, supported by additional documents (R1-R24 - Annex A - enclosed) and further submissions, but no real comments were provided in the present Examination Report in reply to these filings. Moreover, Applicant has submitted over a dozen responses in the parent case and overwhelming evidence that despite numerous attempts and heated debate to solve the problem, public is not in possession of the claimed inventions and the subject matter is poorly understood and public continues to suffer at a large scale. In light of such circumstances, it is improper to delay the patent grant, which has already been dragged for ten years.

In order to expedite proceedings in the present case and with a sincere wish to reduce further unnecessary delay and importantly costs to the Applicant, below are detailed basis for the new set of amended claims and arguments which would hopefully alleviate the Examiner’s concerns and lead to expedited grant.

Claim amendment and basis from WO2009/131939 A2

New claim 1 – finds basis in at least original claims 1 and 3, page 6 lines 5-7 and lines 11-19 of the application as originally published, Table 4, Tables 9-13, Table 16, Table 17, and original claim 40.

New claim 2 – finds basis in at least original claim 4 and Tables 3 and 9.

New claim 3 – finds basis in at least Table 9, and Table 11.

New claim 4 – finds basis in at least Table 4 and original claim 40.
New claim 5 – finds basis in at least Table 4.
New claim 6 – finds basis in at least original claims 4, 6, 7, 8, and 12.
New claim 7 – finds basis in at least page 8 paragraph [0029], original claims 21, 22 and 25.
New claim 8 – finds basis in at least paragraphs [0011], [0028] and original claims 21, 23, 25, 26, 27, 30 and 31.
New claim 9 – finds basis in at least original claim 19 and 20, Tables 3, 9, and 20 paragraphs [0029] and [0032], third sentence of paragraph [0042], and paragraph [0055].
New claim 10 – finds basis in at least paragraphs [0022], [0032], and [0055]-[0058], and Tables 4 and 20, and original claims 13, 15, and 36.
New claim 11 – finds basis in at least original claims 1, 3, 10 and 16, and Tables 5-20, and paragraph [0033].
New claim 12 – finds basis in at least original claim 1, 3, and 28, paragraphs [0008], [0018] and [0020].
New claim 13 – finds basis in at least original claims 7, 10, 28 and 29, paragraphs [0008], [0018] and [0020].
New claim 14 – finds basis in at least original claims 1, 3, 4, 10 and 28, paragraphs [0021]-[0022], [0033] and Tables 5-20 of the application as originally published.

New claim 15 is substantially the same as new claims 2-5 above, therefore supported by the original application as asserted above.

Art. 123(2) EPC

In the present divisional application, all the pending claims are based on original claims and/or the description. Accordingly, the newly amended claims meet the requirements of Art. 123(2) EPC.

The Examiner has objected that: *“a range of values...has been accepted if the same range is valid for all the embodiments...”*.

As the Examiner would be aware, Guidelines for Examination (GL)- H-IV, 2.4 reads as follows:

“In the case of a disclosure of both a general and a preferred range, a combination of the preferred disclosed narrower range and one of the part ranges lying within the disclosed overall range on either side of the narrower range may be derivable from the original disclosure of the application.”

In addition,

“It is ... essential, when deciding on issues of added subject-matter, to identify the actual teaching conveyed by the original disclosure, i.e. the technical information that the skilled person reading the original disclosure would have derived from its content (description, claims, drawings) considered in its entirety. This approach might lead to the identification of subject-matter which has not been explicitly revealed as such in the application as filed, but nevertheless derives directly and unambiguously from its content. Literal support is not required by the wording of **Art. 123(2) EPC**.”

.... When assessing the conformity of the amended claims to the requirements of Art. 123(2), the focus should be placed on what is really disclosed to the skilled person by the documents as filed as directed to a technical audience. In particular, the examining division should avoid disproportionately focusing on the structure of the claims as filed to the detriment of the subject-matter that the skilled person would directly and unambiguously derive from the application as a whole....

.... If this were not the case, the original disclosure would be deprived of a part of the information it actually contains, namely the technical teaching that the skilled person would retrieve from the application but which may typically extend beyond a mere literal interpretation of the original text.”

(T667/08, Reason 4.1.4, and GL H-IV, 2.2).

According to T 201/83: “The test for compliance with Article 123(2) EPC is basically a **novelty test**, i.e. no new subject-matter must be generated by the amendment. Normally the test for novelty calls for an inquiry whether or not a document, or article in use, contains sufficient information so that the person skilled in the art could derive the subject-matter in question from it directly and unambiguously, including any features implicit therein (cf. Guidelines for Examination C IV - 7.2).”

According to G 001/93: “With regard to Article 123(2) EPC, the underlying idea is clearly that an applicant shall not be allowed to improve his position by adding subject-matter not disclosed in the application as filed, which would give him an unwarranted advantage and could be damaging to the legal security of third parties relying on the content of the original application. (Reason #9)

*“The extent of the protection conferred by a European patent or a European patent application is governed by the provisions of Article 69 EPC. In this respect, it is to be noted that according to Article 69(2) EPC, the patent as granted or as amended in opposition proceedings shall determine retroactively the protection conferred by the application, insofar as such protection is not thereby extended. In other words: **even if the claims of the patent as granted are broader than those of the application as published, which may be the case provided there is a basis for that in the application as filed**, third parties' rights are not affected by such broadening for the period up to grant of the patent; if, on the other hand, the claims of the patent as granted are narrower than those of the application as published, third parties are benefiting from this as from the outset.” (Reason #10) (Emphasis added).*

*“Whether or not the adding of an undisclosed feature limiting the scope of protection conferred by the patent as granted would be contrary to the purpose of Article 123(2) EPC to prevent an applicant from getting an unwarranted advantage by obtaining patent protection for something he had not properly disclosed and maybe not even invented on the date of filing of the application, **depends on the circumstances**. If such added feature, although limiting the scope of protection conferred by the patent, has to be considered as providing a technical contribution to the subject-matter of the claimed invention, it would, in the view of the Enlarged Board, give an unwarranted advantage to the patentee contrary to the above purpose of Article 123(2) EPC.*

Consequently, such feature would constitute added subject-matter in the sense of that provision.

*A typical example of this seems to be the case, where the limiting feature is creating an inventive selection not disclosed in the application as filed or otherwise derivable therefrom. **If, on the other hand, the feature in question merely excludes protection for part of the subject-matter of the claimed invention as covered by the application as filed, the adding of such feature cannot reasonably be considered to give any unwarranted advantage to the applicant**. Nor does it adversely affect the interests of third parties (cf. paragraph 12 above). In the view of the Enlarged Board, such feature is, on a proper interpretation of Article 123(2) EPC, therefore not to be considered as subject-matter extending beyond the content of the application as filed in the sense of that provision. It follows that a patent containing such a feature in the claims can be maintained without violating Article 123(2) EPC or giving rise to a ground for opposition under Article 100(c) EPC. The feature being maintained in the claims, there can be no violation of Article 123(3) EPC either.” (Reason #16) (Emphasis added).*

According to G 002/10: “The test to be applied is whether the skilled person would, using common general knowledge, regard the remaining claimed subject-matter as explicitly or implicitly, but directly and unambiguously, disclosed in the application as filed.” (Reason #4.5.4)

“It is in principle for the applicant to determine the scope of protection he desires by the manner in which he drafts his claims. There is no provision in the EPC which would oblige an applicant to seek, in the individual application under consideration, a protection corresponding to the broadest possibility offered by the disclosure of the application. Nor is there an obligation to draft claims in such a way as to include the preferred embodiment in their scope.” (Reason #4.5.5)

Claims meet the requirements of 123(2) EPC for the following reasons:

The broadest teaching conveyed by the application as filed is that the prior art (including the cited art) had neither taught nor suggested or worst still completely misunderstood the importance of omega-6 fatty acids¹ in health.

Before the priority date of the presently claimed subject matter, the importance of omega-6 fatty acids, its requirement relative to other dietary lipids, including omega-3 fatty acids were completely unappreciated.

1 New claim 1:

1.1 New term “: or greater: ...” has replaced the term “ ... at least ...”.

- (a) Original Claims 1 and 3 recite “*A lipid-containing composition comprising... omega-6 and omega-3 fatty acids and wherein the ratio of omega-6 to omega-3 fatty acids and their amounts are controlled based on one or more [demographic] factors...*”

There is no upper limit for the omega-6 to omega-3 ratio in the claim.

In Claims 1 and 3 net effect of “optimal amounts” and “controlled based on one or more [exhaustive demographic] factors”, is “dosage of omega-6 and omega-3”, because definition of dosage is “specified amount to ingest at one time or regularly during a period of time” (See Oxford, Merriam Webster, Collins, and MacMillan Dictionary). Also see broadly recited “*demographic factors [or type]*” in paragraphs [0007], [0033], [0081], [0099], and [0103].

Omega-6 and omega-3 can also be phytochemicals, and no other fatty acids or phytochemicals are recited in original Claims 1 and 3.

In the new claim 1, the demographic factors from the original claims 1 and 3 are represented in the “dosage [for a subject]” and the “*omega-6 to omega-3 ratio*” in claim 3 is combined with “4:1 or greater” “*the preferred disclosed narrower range and one of the part ranges [lower limit] lying within the disclosed overall [open-ended] range*” expressly recited in original claim 4 (and derivable from the original disclosure of the application in Tables 9, 14, 17, and 18) as per GL H-IV, 2.4, T 201/83, and G 0001/93.

- (b) Furthermore, the disclosure overall supports the open-ended upper limit. Paragraph 21 in general description, recites, “*In one aspect, the present disclosure incorporates relatively high ratio of omega-6 to omega-3 fatty acids;*” the lower limit of “4:1” among high ratios is disclosed in Tables 9, 14, 17, and 18 and claimed in original claim 4.

In accordance with GL H-IV, 2.4, T 201/83 (Reason #11), G 0001/93, and T667/08 (Reason 4.1.4)).

Amending claim 1 to recite the term “*the present disclosure incorporates relatively high ratio of omega-6 to omega-3 fatty acids, wherein the ratio of 4:1 or greater*” i.e., include the “*preferred disclosed narrower range and one of the part ranges [lower limit] lying within the disclosed overall [open-ended] range*”, which is the same as “*omega-6 to omega-3 fatty ratio of 4:1 or greater*” does not offend the requirements of Art. 123(2) EPC.

- (c) Further, in accordance with T 201/83 and G 0001/93, the disclosures in original claims 1+3+4 and paragraph 21 destroys the novelty of the feature “*an omega-6 to omega-3 ratio of 4:1 or greater*” for any third parties. Therefore, no new matter is added.

¹ In this document omega-6, n-6, n6, o-6, and O6 are used interchangeably, and omega-3, n-3, n3, o-3, and O3 are used interchangeably, as is standard in the art.

1.2 Examiner alleges that no basis could be found in the application a[s] filed for the feature “*wherein the amount of omega-3 fatty acids is between 0.1 to 20% by weight of total lipids.*” Without conceding and to reduce issues, the feature has been replaced with “wherein: omega-6 fatty acids are 4-75% by weight of total lipids and omega-3 fatty acids are 0.1-30% by weight of total lipids” on the basis of Table 4.

- (a) Table 4, discloses a general range of various unsaturated fatty acids in the formulations.
- (b) For avoidance of doubt, the upper limit of 20% of omega-3 fatty acids in the formulation is inherent in Claim 1.a)(i) as it is the inevitable consequence of the first requirement “omega-6 to omega-3 ratio of 4:1 or greater” recited in the claim. No lack of clarity is created by the explicit recitation of the upper limit of 30%.
- (c) Regarding the alleged “limiting context” in Table 4 of the Application.

Table 4 does not list a particular recipe of ingredients which are comprised in a single formulation. Based on the title of Table 4 alone “Contents of Various Unsaturated Fatty Acids”, the skilled person would immediately appreciate that the table merely illustrates different percentage ranges of various unsaturated fatty acids each percentage range representing a proportion or the unsaturated fatty acid in the total lipids. There is no wording in the table to suggest that each unsaturated fatty acid must be present in the lipid formulation.

Moreover, the above would also be immediately apparent when we consider that the sum of the upper limits adds up to more than 100%.

Example 1, introductory [0042] recites, “The formulations may include specific ratios of various lipid components...”

Also, introductory [0043] to Table 4 starts with the expression: “... In some embodiments, the lipid formulation calls for specific percentages of omega-9, omega-6, and omega-3 fatty acids, as shown in Table 4 below,” which clearly means all embodiments do not contain all elements.

Moreover, paragraph [0043] does not refer to Vitamin E-alpha/gamma. This further emphasizes that the ingredients mentioned in Table 4 are examples only and not specific formulations.

Out of 27 examples, omega-9 fatty acids and Vitamin E do not appear in 16 example formulations (Examples 12-27).

It is evident from original claim 1 that omega-9 fatty acids and Vitamin E-alpha/gamma are not an essential part of the invention. Omega-9 fatty acids do not appear in the original claims until dependent Claim 6 and Vitamin E does not appear until dependent Claim 13. Original claim 6 recites, “The composition of claim [1 and] 3, **further** comprising one or more omega-9 fatty acids.” [emphasis added].

The problem which is addressed by the present invention could be identified in paragraph [0007] as follows:

“The traditional emphasis on increasing omega-3 and reducing omega-6 consumption often does not result in satisfactory relief because of the uncertainties introduced by dietary and demographic factors.”

Accordingly, improved treatments, using improved lipid compositions, for medical conditions are still needed. In fact, on January 26, 2009, for the first time the American Heart Association issued an advisory to correct the perception that omega-6 are unhealthy.”

There is no “*limiting context*” created by the presence of omega-9 and vitamin E in Table 4. Considering the problem to be solved is correct delivery of omega-6 fatty acids, “expert would treat them [omega-9, vitamin E] as features of the design that could be separately considered... Although such a component contributes to the total effect, it can still be considered separately in view of its specific role on its own.” (T 201/83, Reason #9; G 0001/93, Reason #16).

1.2.1 Regarding the terms, “...by weight of total lipids” in the present Claim 1, Applicant submits the following.

Examiner acknowledges that Table 4 discloses “weight of omega-3 per weight of total lipids, weight of omega-3 per volume of total lipids, or volume of omega-3 per volume of total lipids.”

(a) Original Claim 35 expressly recites “omega-3...by weight of total lipid” seven times, clearly preferred feature. Original claims 36 and 38 also refer to “by weight of total lipids”. Each time omega-3, omega-6, omega-9, and vitamin-E concentrations are disclosed, they are in relation to total lipids (please see for example Table 4 and claims 8, 12-15), and original claims 35, 36, and 38 make it clear that “by weight of total lipids” is the preferred feature; that is a selection from the options “weight by weight, weight by volume, or volume by volume” presented in Table 4.

The above basis is also valid for the feature “...*i*) omega-6 ... by weight of total lipids;...”.

(b) “If...the feature in question merely excludes protection for part of the subject-matter of the claimed invention as covered by the application as filed, the adding of such feature cannot reasonably be considered to give any unwarranted advantage to the applicant. Nor does it adversely effect the interests of third parties (cf. paragraph 12 above). In the view of the Enlarged Board, such feature is, on a proper interpretation of Article 123(2) EPC, therefore not to be considered as subject-matter extending beyond the content of the application as filed in the sense of that provision.” (G 0001/93, Reason #16) (Emphasis added).

Following this same logic, excluding “*weight of omega-3 per volume of total lipids, or volume of omega-3 per volume of total lipids*” or “*weight of omega-6 per volume of total lipids, or volume of omega-6 per volume of total lipids*” recited in Table 4 from new claim 1, cannot and should not be considered to give any unwarranted advantage to the applicant, nor does it adversely affect the interests of third parties.

Therefore, it should not be regarded by the Examiner to represent subject-matter extending beyond the content of the application as originally filed.

1.2.2 Turning specifically to the Examiner’s concern regarding the term “... % by weight of total lipids” (alleged added matter and alleged lack of clarity of the term – Art 84 EPC)

Basis for this term can be identified in Table 4, as well as Table 5, Table 6 and original claim 35.

Table 4 refers to percentage of a given ingredient of a lipid formulation (e.g. Omega 6) as a percentage (%) of total lipids. This percentage could be determined on the basis of w/w, w/v, or v/v, but relevantly with reference “*of the total lipids*” in the lipid-formulation or lipid-composition.

However “... *percent by weight of total lipid...*” has been used with preference in the application as originally filed, for example see original claims 35, 36, and 38.

“% v/v”, “% w/w” and “% w/v”

By way of example only the term “% v/v” is to be understood to represent a volume concentration of a solution which stands for volume per volume. This nomenclature is generally used when chemicals or constituents in a solution are liquid. In the context of the present patent application, where the lipids are in liquid state the following simple calculation would be familiar to the skilled person. As an example, when 45ml of Omega-6 fatty acid and 5ml of Omega-3 fatty acid are both diluted with 50ml of ethanol, there will be 45ml Omega-6 and 5 ml of Omega-3 fatty acid in a total volume of 100ml. Therefore, as contemplated in the present application, the concentration of such a solution would be expressed as 45% v/v of Omega-6 fatty acid and 5%v/v of Omega-3 fatty acid.

Similar principles would apply when calculating %w/w in the case of weight concentration of a solution or when calculating mass concentration of a solution %w/v.

Calculating percentages

Each percentage type can be calculated by introducing small changes to the above method.

For example, to find a %w/v of a solution the calculation would be:

$$\text{Mass of solute (g) / Volume of solute (ml) x100}$$

Therefore, in a simple example, to find out the % w/v of a 100 ml solution that is made up of 5g solid lipid (as the Examiner seems to express concerns) we would divide 5g by 100 ml and then multiply by 100. This would determine that there is a solid lipid solution of 5%w/v.

The above simple mathematical principles and formulae would be well known to the skilled person and therefore these need not be detailed in the application as originally filed.

Therefore, the Examiner’s concerns that there may be some confusion or lack of clarity when the lipid formulations may contain different lipids which may have variable level of density would be addressed readily not only by the application as originally filed which clearly provides basis for the terms “% *by weight of total lipids*” but also using the knowledge in the art when calculating percentages in total solutions or formulations (in the present case lipid formulations).

- 1.3 According to Article 69(1) EPC “*The extent of the protection conferred by a European patent application shall be determined by the claims,*” and “*the description and drawings shall be used to interpret the claims.*”

It would therefore be unfair on the Applicant if the Examiner was to restrict the new claims to embodiments which mention optional constituents for instance Example 1, Table 3 and Table 4.

To avoid confusion, it is pointed out that Examiner refers to paragraphs 40 and 41 from WO2009/131939 A9 version, which are paragraphs 42 and 43 in the A2 version. A2 publication is the basis for divisional application filed on 21 July 2017, because the EPO in the Parent case, namely the Board of Appeal (BoA), had reverted to A2 version.

- 1.4 It is alleged that no basis could be found for the feature: “*dosage of total omega-6 fatty acids is not more than 40 grams*”.

Original claim 3 was directed to dosage of omega-6 and omega-3 wherein “[t]heir amounts are controlled based on one or more [demographic] factors”, is a “dosage”. Please see reasoning in point #1.1(a) above.

Thus, Original Claim 3 discloses open-ended “dosage of omega-6 and omega-3”.

Furthermore, there are numerous general statements in the Application as originally filed that disclose amounts of omega-6 fatty acids affect health at foundational level.

By way of example only, [0004] states, “Dietary deficiency or excess of the two essential fatty acids may cause many illnesses” and [0106] states “It is further suspected that both omega-6 and omega-3 are anti-inflammatory in small doses and inflammatory in large doses.”

Therefore, “dosage of total omega-6 fatty acids is not more than e.g. X amount” is an unambiguous consequence of the explicit disclosure in the Application, as originally filed.

A preferred range lying within the open-ended over all range of original Claim 3 with the upper limit of omega-6 dosage of 40 grams recited in Tables 9, 11, and 13 is not adding matter.

- 1.5 Claim 1.b) recites the features: “polyunsaturated, monounsaturated, and saturated fatty acids, wherein the omega-6 fatty acids are greater than 20% by weight of the total lipids and nutrients comprising one or more polyphenols, or one or more phytochemicals selected from...”.

The features “polyunsaturated, monounsaturated, and saturated fatty acids, wherein the omega-6 fatty acids are greater than 20% by weight of the total lipids” are recited in original Claim 40, and in Tables 16 and 17, and are the unambiguous clear consequence of the same. There is no “limiting context” created by the presence of “olive oil and sunflower oil” in the original claim 40 or other features in Tables 16 and 17, particularly because the claimed features apply to all demographic types in Tables 16 and 17. Phytochemicals are recited in paragraph [0022] as “compositions comprising supplementation with **one or more** of the following.” [emphasis added]. Considering the problem to be solved is correct delivery of omega-6 fatty acids, “expert would treat them [olive oil, sunflower oil, and other aspects] as features of the design that could be separately considered... Although such a component contributes to the total effect, it can still be considered separately in view of its specific role on its own.” (T 201/83, Reason #9; G 0001/93, Reason #16)

Accordingly, new claim 1 does not add subject matter and therefore meets the requirements of Art. 123(2) EPC.

2 New claim 2:

- 2.1. The Examiner has asserted that no basis could be found in the earlier application a[s] filed for the feature: “... the omega-6 to omega-3 ratio is in the range of 4:1 to 50:1”.

- (a) Table 3 discloses “Omega-6 to Omega-3 Fatty Acids” – Under the heading: “Approximate Ratio Range” it lists “1:1 - 50:1”.

Original claim 4 discloses preferred lower limit of the range is “4:1”.

“In the case of a disclosure of both a general and a preferred range, **a combination of the preferred disclosed narrower range and one of the part ranges lying within the disclosed overall range on either side of the narrower range** may be derivable from the original disclosure of the application.” GL H-IV, 2.4. Also see T 201/83 (Reason #11), G 0001/93 (Reason #16), and T667/08 (Reason 4.1.4).

- (b) Regarding the alleged, “limiting context” in Table 3, the arguments provided above with respect to Table 4 also apply to the disclosed in Table 3.

In particular: [0042] “The formulations **may** include specific ratios of various lipid components as shown below in Table 3,” which means all embodiments may not include all features. Further, it is evident from how the original claims are written that monounsaturated and saturated fatty acids are **not an essential part** of the invention. Monounsaturated and saturated fatty acids do not appear in original claim 1, 2, 3, 4, and 5.

Accordingly, new claim 2 does not add subject matter and therefore meets the requirements of Art. 123(2) EPC.

3 On file claim 2 (New claim 3):

It is alleged that table of on file claim 2 (new claim 3) adds matter.

The table in new claim 3 merely identified dosage ranges of omega-6 fatty acids for human subjects which ranges are determined on bases of age, sex, medical condition. Basis for such dosage ranges can be found in the application as originally filed in Table 9 and 11 and original claims 1 and 3. The dosage ranges of omega-6 fatty acids recited in Tables 9-13 are summarised in the comparative table below.

	O6 –g Table 9 ----- New Claim 3	O6 –g Table 10	O6 –g Table 11 ----- New Claim 3	O6 –g Table 12
Infants				
7-12 mo	1-10	1-10	1-10	1-10
Children				
1-3 y	2-15	2-15	2-15	2-15
Males				
4-8 y	2-25	2-20	2-25	2-20
9-13 y	2-30	2-25	2-30	2-25
14-18 y	2-35	2-30	2-35	2-30
19-30 y	2-40	2-35	2-40	2-35
31-50 y	2-40	2-35	2-40	2-35
51-70 y	2-30	2-25	2-30	2-25
>70 y	2-30	2-25	2-30	2-25
Females				
4-8 y	2-25	2-20	2-25	2-20
9-13 y	2-25	2-20	2-25	2-20
14-18 y	2-30	2-25	2-30	2-25
19-30 y	2-30	2-25	2-30	2-25
31-50 y	2-30	2-25	2-30	2-25
Pregnancy	2-35	2-30	2-35	2-30
Lactation	2-35	2-30	2-35	2-30
Menopause	2-30	2-25	2-30	2-25

In addition, Examples 14.2 and 22 of the Application as originally filed recite dosages of omega-6 only, i.e. without even stating the dosage of omega-3, while Examples 11-27 teach how to calibrate dosages of omega-6, because the disclosure is focused on correct delivery of omega-6.

Accordingly, new claim 3 does not add subject matter and therefore meets the requirements of Art. 123(2) EPC.

4. On file claim 3 (New claim 4):

Basis for the features “omega-6 fatty acids are 4-75%” and “omega-6 fatty acids are greater than 20%” can be identified in Tables 4, 16-17, and original Claim 40, as discussed above in 1.2 and 1.5.

Regarding “*by weight of total lipids*” basis can be identified in original claim 35 expressly recites “*omega-6...by weight of total lipid*” seven times confirming that it is a preferred feature.

Accordingly, new claim 4 does not add subject matter and therefore meets the requirements of Art. 123(2) EPC.

5. On file claim 4 (New claim 5):

It is alleged that there is no basis for the term “*omega-9 fatty acids at 10% to 90% by weight of total lipids*”.

Basis for this term can be identified in at last Table 4 as discussed above under new claim 1.

Accordingly, new claim 5 does not add subject matter and therefore meets the requirements of Art. 123(2) EPC.

6. On file claim 5 (New claim 6):

6.1. The feature “the ratio of omega-9 to omega-6 fatty acids is 1:1 to 5:1, such as 1:1 to 3:1” in new claim 6(a) finds basis in at least original claim 7.

In addition, in a general embodiment and non-limiting context of “The formulations may include specific ratios of various lipid components” various ratios are disclosed in Table 3 which includes omega-9 to omega-6 “approximate ratio range” (see column heading) of “0.5:1 – 6:1”.

Furthermore, narrower omega-9 to omega-6 ratios of 1:1-3:1 and 1:1-5:1, are disclosed in more defined examples with strong emphasis (1:1-3:1 in Tables 9-12, 14, 18, and 19, and 1:1-5:1 in Table 13, 14, 18, and 19 and original claim 7).

Even if original Table 13 and original claim 7 are recited in context of medical conditions, based on overall disclosure a skilled person can directly and unambiguously derive an omega-9 to omega-6 ratio recited in Table 13 and claim 7 for general health.

Also note that omega-9 to omega-6 ratio recited in Table 13 of 1:1-5:1 is the same for all medical conditions. Thus, there is a similar connection between omega-9 and omega-6 ratios with health, driven from the broader concept that omega-9 can interfere with omega-6 activity, therefore needs to be controlled to achieve requirements of omega-6 fatty acids.

Further, omega-9 and omega-6 are nutrients, not new chemical entities that there is such a tight distinction between when the ratio is applicable to a disease versus healthy state. Whether or not matter has been added, “depends on the circumstances” (G1/93, Reason #16).

Choosing from an overall ratio range in Table 3, “Omega-9 to Omega-6 Fatty Acids, Approximate Ratio Range “0.5:1 – 6:1” with the disclosed narrower ranges 1:1-3:1 or 1:1-5:1 in tables 9-14, 18, and 19, lying within the range disclosed in Table 3 does not add matter. See T 201/83 (Reason #9-12), T 667/08 (Reason 4.1.4), and GL H-IV, 2.4.

6.2. It is unambiguous to skilled persons to choose the design choice of “*the ratio of omega-9 to omega-6 fatty acids is 1:1 to 5:1, such as 1:1 to 3:1*” in health or disease.

Accordingly, new claim 6 does not add subject matter and therefore meets the requirements of Art. 123(2) EPC.

7. On file claim 6 (New claim 7):

7.1. Examiner alleges that new claim 7(b)(i) adds matter by reciting, “*the formulation comprises one or more of seeds, nuts, legumes, dairy, cocoa, lentils, and grains, in their whole form or their oils.*”

Basis for this term can be identified in [0028] as follows:

“In one aspect, the disclosure provides compositions that include seeds, nuts, and/or oils. In another aspect the compositions include legumes, dairy, cocoa, lentils, and/or grains. In one embodiment the composition can include one or more edible oils, culinary nuts and/or seeds in their whole form or their oils such as, but not limited to...”

Thus [0028] in first sentence states “compositions that include”, then in second sentence states, “In another aspect the compositions include legumes”, then in the third sentence states, “In one embodiment the composition can include one or more edible oils...”. Therefore, the paragraph is describing the same compositions or list further in the second and third sentence.

It is not the case of “two lists” alleged by the Examiner. This is exemplified in Example 10, paragraph [0068] that recites, “The formulation can include two or more of by % weight of total composition: peanuts or peanut oil (4-35), almonds or almond oil (2%-25%), olives or olive oil (3%-45%), legumes or grains (15%-45%)...”.

Paragraph [0037] of A2 ([0035] of A9) that Examiner mentioned does not recite, “cocoa, lentils”; the paragraph discloses a different embodiment of the invention. Therefore, seeds, nuts, legumes, dairy, cocoa, lentils, and grains can be present in the same formulations.

Thus, no new matter is added in Claim 7(b)(i). The claim has been amended for further clarity. See principles of law recited above.

7.2. Examiner alleges that there is no basis to include corn oil and coconut oil in the list on claim 6(b)(iii).

Original claim 21 recites, “one or more of the following components: peanut oil, vegetable oil...”. Instead of a general “*one or more...vegetable oil*” Applicant chose preferred “*corn oil*” and “*coconut oil*” please see Table 2, Examples 9-10 paragraphs [0065]-[0068].

It is of note that in the Parent case (EP09735962.4), the EPO did not find this feature to add matter in Claim 5(iii) of AR10 (attached). Please See Decision 2015 (pages 15-16).

The rest of the Examiner’s objections with regard to this claim have been addressed above.

Accordingly, new claim 7 does not add subject matter and therefore meets the requirements of Art. 123(2) EPC.

8. On file claim 7 (New claim 8):

8.1. New claim 8A: Examiner objects to the expression “*at least two of*” in new claim 8A-2, which

has been deleted in the amended claims without any acquiescence.

Definition of “*vegetable oil*” is “fats extracted from seeds [or nuts which are also seeds], or less often, from other parts of fruits” (see https://en.wikipedia.org/wiki/Vegetable_oil).

The basis for present Claim 8A-2 is original claim 23, which recites “vegetable oil” in a broad sense, i.e., any oil that is of vegetable origin as opposed to animal origin. This is evidenced by the fact “peanut oil” (a vegetable but specifically a nut oil), “avocado oil” and “olive oil” (vegetable but specifically fruit oils), and “sunflower oil” and “safflower oil” (vegetable but specifically seed oils) are recited separately by common name of plant in original claim 23. In other words, the claim does not say, “nut oil 8-56%, seed oil 2-34%, fruit oil 3-32%, and vegetable oil 8-46%,” in which context “vegetable oil” might have a limited meaning excluding “nut oils”. The claim simply calls out specific percentages of “peanut oil”, “avocado oil”, “olive oil”, “sunflower oil”, and “safflower oil” in the composition but leaves the 8-46% open for other types of oils of vegetable origin. In the context of original claim 23, skilled person would unambiguously interpret “vegetable oil” as broadly of any vegetable source including the nuts and seeds.

The oils recited in new claim 8A-2 are from paragraph [0028], which recites, “the composition can include one or more edible oils, culinary nuts and/or seeds in their whole form or their oils.”

It is of note that in the Parent case did not find any added matter by this feature in claim 2 of AR10. See Decision 2015 (pages 15-16).

8.2. New claim 8E: Applicant disagrees with the allegation that the recitation “*at least three of*” in Claim 8E adds matter.

Paragraph [0011] reads as follows,

“One embodiment of such composition comprises three or more of the following substances (or the oil thereof) in certain defined concentrations: peanuts, almonds, olives, soybeans, cashews, flaxseeds, pistachios, pumpkin seeds, sunflower seeds, sesame seeds, walnuts, anhydrous butter, and, coconut meat. Another example of such composition comprises a safflower oil, sunflower oil, peanut oil, almond oil, and anhydrous butter oil.”

Thus, “three or more of” as per [0011] refers to all components including “a safflower oil, sunflower oil, peanut oil, almond oil, and anhydrous butter oil.”

Examples 9-10 [0065]-[0068] recite similar compositions, with “two or more” of the sources.

Moreover, in the Parent case did not find any added matter by this feature in claim 2 of AR9-10. See Decision 2015 (pages 14-16).

8.3. Claim 8A-2 has been amended to delete, “at least two of”. The other point has been addressed above.

8.4. Claim 8E: has been addressed above.

Accordingly, new claim 8 does not add subject matter and therefore meets the requirements of Art. 123(2) EPC.

9. On file claim 8 (New claim 9):

9.1. Claim 9(b)(ii) the feature, “the dosage of omega-6 fatty acids is from 1 to 40 grams” appears in Tables 9 and 11 and accommodates all embodiments of original Claim 3. Claim 9(b)(iii): The feature “omega-3 fatty acids is from 0.1 to 6.0 grams” appears in Tables 10, 12 and 13, and accommodates all embodiments of original Claim 3; Table 12 is reproduced below, which provides “range of omega-3 content in grams designed by age and gender with increasing strength of omega-3, low, medium, and high” (paragraph [0059]).

Table 12. Lipid Dosages Based on Age and Sex for Various Levels of Omega-3 Fatty Acids

	Range Total Fat - g	Range Mono:Poly	Range Mono:Sat	Range O6 - g	Range O9:O6	Range O6:O3	Low Strength Range O3 - g	Med. Strength Range O3 - g	High Strength Range O3 - g
Infants									
7-12 mo	10-50	1:1-3:1	1:1-5:1	1-10	1:1-3:1	1:1-45:1	0.1-1.0	1.0-2.0	2.0-3.0
Children									
1-3 y	10-60	1:1-3:1	1:1-5:1	2-15	1:1-3:1	1:1-45:1	0.1-1.0	1.0-2.0	2.0-3.0
Males									
4-8 y	10-75	1:1-3:1	1:1-5:1	2-20	1:1-3:1	1:1-45:1	0.1-1.0	1.0-2.0	2.0-5.0
9-13 y	15-80	1:1-3:1	1:1-5:1	2-25	1:1-3:1	1:1-45:1	0.1-1.0	1.0-2.0	2.0-5.0
14-18 y	20-100	1:1-3:1	1:1-5:1	2-30	1:1-3:1	1:1-45:1	0.2-1.0	1.0-2.0	2.0-6.0
19-30 y	20-100	1:1-3:1	1:1-5:1	2-35	1:1-3:1	1:1-45:1	0.2-1.0	1.0-2.0	2.0-6.0
31-50 y	20-80	1:1-3:1	1:1-5:1	2-35	1:1-3:1	1:1-45:1	0.2-1.0	1.0-2.0	2.0-6.0
51-70 y	15-80	1:1-3:1	1:1-5:1	2-25	1:1-3:1	1:1-45:1	0.2-1.0	1.0-2.0	2.0-6.0
>70 y	15-80	1:1-3:1	1:1-5:1	2-25	1:1-3:1	1:1-45:1	0.2-1.0	1.0-2.0	2.0-6.0
Females									
4-8 y	12-70	1:1-3:1	1:1-5:1	2-20	1:1-3:1	1:1-45:1	0.1-1.0	1.0-2.0	2.0-4.0
9-13 y	15-80	1:1-3:1	1:1-5:1	2-20	1:1-3:1	1:1-45:1	0.1-1.0	1.0-2.0	2.0-4.0
14-18 y	20-80	1:1-3:1	1:1-5:1	2-25	1:1-3:1	1:1-45:1	0.2-1.0	1.0-2.0	2.0-5.0
19-30 y	20-80	1:1-3:1	1:1-5:1	2-25	1:1-3:1	1:1-45:1	0.2-1.0	1.0-2.0	2.0-5.0
31-50 y	15-80	1:1-3:1	1:1-5:1	2-25	1:1-3:1	1:1-45:1	0.2-1.0	1.0-2.0	2.0-5.0
Pregnancy	24-100	1:1-3:1	1:1-5:1	2-30	1:1-3:1	1:1-45:1	0.2-1.0	1.0-2.0	2.0-5.0
Lactation	24-100	1:1-3:1	1:1-5:1	2-30	1:1-3:1	1:1-45:1	0.2-1.0	1.0-2.0	2.0-5.0
Menopause	15-80	1:1-3:1	1:1-5:1	2-25	1:1-3:1	1:1-45:1	0.1-1.0	1.0-2.0	2.0-4.0

The “dosage of eicosapentaenoic acid (C20:5) is not more than 0.5 grams, and/or the dosage of docosahexaenoic acid (C22:6) is not more than 0.2 grams” is evident from Table 20. Relevant part of Table 20 is reproduced below.

Eicosapentaenoic 20:5 g	0-0.5
Erucic 22:1 g	0-0.3
Docosapentaenoic 22:5 g	0-0.5
Docosahexaenoic 22:6 g	0.01-0.2
Phytosterols mg	90-150

Based on general statements and numerous tables in the disclosure regarding dosage of omega-3 and teachings (e.g. Examples 12 and 22) against fish oils (well-known sources of EPA/DHA) Table 20 can be combined with dosage of omega-3 recited in the disclosure.

“[s]eparate features of the original document may be combined without necessarily generating new subject-matter. If the same document contains instructions as to certain concentrations,

proportions and sizes in respect of one or more constituents, it would be within the ordinary skill of the person to select exactly one or more of these numerical values when trying to reproduce an article or process falling within the scope of a general disclosure.” (T 201/83, Reason #11)

Further, this feature is not open-ended, because new claim 9(b)(ii) requires “omega-3 fatty acids is from **0.1** to 6.0 grams”, wherein EPA/DHA are optional.

It is also of note that in the Parent the EPO did not find any added matter in this feature in claim 6(c)(vi) of AR10. See Decision 2015 (pages 15-16). See principles of law recited above.

9.2. Claim 9(b)(iv): Examiner’s allegation, Applicant has combined features which add subject matter.

All the claimed features are supported in **Table 9** itself (reproduced below). The features in Claim 9(b)(iv) are highlighted in red boxes below. Mono:Poly, Mono:Sat, O9:O6, and O6:O3 ranges are the same for all factors.

For dosage of total fat, O6, and O3 simply outer ranges were taken to accommodate all embodiments.

	Range Total Fat - g	Range Mono:Poly	Range Mono:Sat	Range O6 - g	Range O9:O6	Range O3 - g	Range O6:O3
Infants							
7-12 mo	10 -50	1:1-3:1	1:1-5:1	1 -10	1:1-3:1	0.1 -3	4:1-45:1
Children							
1-3 y	10-60	1:1-3:1	1:1-5:1	2-15	1:1-3:1	0.1-3	4:1-45:1
Males							
4-8 y	10-75	1:1-3:1	1:1-5:1	2-25	1:1-3:1	0.1-4	4:1-45:1
9-13 y	15-80	1:1-3:1	1:1-5:1	2-30	1:1-3:1	0.1-4	4:1-45:1
14-18 y	20-100	1:1-3:1	1:1-5:1	2-35	1:1-3:1	0.2-5	4:1-45:1
19-30 y	20- 100	1:1-3:1	1:1-5:1	2-40	1:1-3:1	0.2-5	4:1-45:1
31-50 y	20-80	1:1-3:1	1:1-5:1	2- 40	1:1-3:1	0.2- 5	4:1-45:1
51-70 y	15-80	1:1-3:1	1:1-5:1	2-30	1:1-3:1	0.2-5	4:1-45:1
>70 y	15-80	1:1-3:1	1:1-5:1	2-30	1:1-3:1	0.2-5	4:1-45:1
Females							
4-8 y	12-70	1:1-3:1	1:1-5:1	2-25	1:1-3:1	0.1-3	4:1-45:1
9-13 y	15-80	1:1-3:1	1:1-5:1	2-25	1:1-3:1	0.1-3	4:1-45:1
14-18 y	20-80	1:1-3:1	1:1-5:1	2-30	1:1-3:1	0.2-4	4:1-45:1
19-30 y	20-80	1:1-3:1	1:1-5:1	2-30	1:1-3:1	0.2-4	4:1-45:1
31-50 y	15-80	1:1-3:1	1:1-5:1	2-30	1:1-3:1	0.2-4	4:1-45:1
Pregnancy	24-100	1:1-3:1	1:1-5:1	2-35	1:1-3:1	0.2-5	4:1-45:1
Lactation	24-100	1:1-3:1	1:1-5:1	2-35	1:1-3:1	0.2-5	4:1-45:1
Menopause	15-80	1:1-3:1	1:1-5:1	2-30	1:1-3:1	0.2-4	4:1-45:1

It is of note that in the Parent case the EPO did not find any added matter in this feature in Claim 6(c)(iv) and 6(c)(vii) of AR9-10. See Decision 2015 (pages 14-16). See principles of law recited above.

9.3. Claim 9(b)(v):

[0032] recites, “In certain embodiments, the composition can substitute the unbalanced fats (cooking oils, fats, and the like) that are typically added to various food preparations and/or supplement fats

contained in an individual's diet from other sources", i.e., regardless of "fat calories from the diet". The feature "the formulation supplies 60-90% of a diet's fat calories" "merely represents a reduction of a range [open substitution] to a value already envisaged [60-90%] within the document, i.e. a quantitative choice." T 201/83 (Reason #10)

It is of note that in the Parent case did not find any added matter in this feature in Claim 6(c)(v) and 6(c)(viii) of AR9-10. See Decision 2015 (pages 14-16).

9.4. Examiner acknowledges Claim 8(a), 8(b)(i) and 8(b)(v) (which correspond to new claim 9(a), 9(b)(i) and 9(b)(vi)) are supported by the application as originally filed.

Accordingly, new claim 9 (on file claim 8) does not add subject matter and therefore meets the requirements of Art. 123(2) EPC.

10. On file claim 9 (New claim 10):

10.1. New claim 10(a)(i), 10(a)(ii), 10(a)(iii) represent a logical categorization of nutrients for clarity. There is no issue with separation because paragraph [0022] recites "one or more of" "antioxidants and phytochemicals in general...trace elements". Novelty of each component is destroyed in the context of the disclosure. T 201/83 (Reason #3).

For instance, claim 10(a)(i) recites polyphenols, because polyphenols have been specifically called out throughout the disclosure ([0022], [0025], [0079]); claim 10(a)(ii) recites rest of the phytochemicals recited in [0022]; and claim 10(a)(iii) recites "phytochemicals, antioxidants, vitamins, minerals, and trace elements" in general and specific.

Basis for claim 10(a)(iii):

- "one or more of the following: vitamin A, B9 (folic acid), C, D, E...antioxidants and phytochemicals in general; and trace elements such as Cu, Zn, Mn, Fe, Se and Mg" - [0022].
- "in certain embodiments vitamins and minerals may be added to the compositions" - [0033] lines 8-9.
- "the composition, which contains balanced components of lipids, phytochemicals, antioxidants, vitamins." [0037] line 1-4.

It is not quite clear to the Applicant why the Examiner wishes to remove "folate", which is also known as vitamin B9 or folic acid (see <https://en.wikipedia.org/wiki/Folate>) expressly recited in [0022] and Table 20.

It is of note that in the Parent case the EPO did not find any added matter in this feature in Claim 6(d)(vii)-(ix) and 6(x)-(xii) of AR9-10. See Decision 2015 (pages 14-16).

10.2. Regarding features of new claim 10(a)(iv), basis for this feature has been described above as well as (on file Claim 9(a)(iv)).

New claim 10(a)(iv) also includes preferred ranges from original Claim 36.

It is of note that in the Parent case the EPO did not find any added matter in this feature in Claim 6(d)(x) and 6(d)(xiii) of AR9-10. See Decision 2015 (pages 14-16).

10.3. Examiner alleges that there is no basis for on file claim 9(a)(v) (new claim 10(a)(v)) in the Application, even though Applicant provided paragraph 26, line 2, and Table 20 as support in the table of support.

Even if paragraph 26 is in reference to advantageous properties of sesame seeds, fiber is a phytochemical, which has been repeatedly called out as important component of present compositions, see paragraph [0022], for example.

Additionally, fiber is a component of nutrients in Table 20 at line 6.

In the Parent case the EPO did not find any added matter in this feature in Claim 6(d)(xi) and 6(d)(xiv) of AR9-10. See Decision 2015 (pages 14-16).

10.4. Examiner has alleged that “*no basis could be found for the expression ‘increase effective levels of omega-3’ in claim 9(a)(vi)*”.

Following was cited in the table of support: “disclosure also relates to methods and compositions that deliver omega-6 and omega-3 fatty acids along with other nutrients that optimize the daily delivery and bioavailability of omega-6 and omega-3” [0008] line 6-9.

In addition, [0082] reads:

“It is hypothesized that in this instance, the amount of omega-3 relative to omega-6 in the tissue had exceeded the ratio tolerated by the body. Since the vegetarian diet and nuts contributed plenty of antioxidants and phytochemicals, the subject became deficient in omega-6, despite moderate levels of omega-3.”

Please note that in the Parent case the EPO did not find any added matter in this feature in claim 6(d)(xii) and 6(d)(xv) of AR9-10. See Decision 2015 (pages 14-16).

10.5. The Examiner has alleged that no basis could be found for “*polyphenols effective to increase omega-3 levels*” in a subject in claim 9(a)(vii)”.

Paragraphs [0022] 79 lines 14-17 were cited in the table of support:

“each of these supplements/nutrients [polyphenols] may reduce the requirement/tolerance for omega-3 fatty acids and allow for a higher omega-6 to omega-3 ratio than in the absence of said supplement(s)/nutrient(s)” [0022].

“Olive oil is 75% monounsaturated oil and rich in polyphenols. Since all fatty acids compete for the same enzymes in the metabolic pathway and antioxidants and phytochemicals increase the requirement for omega-6.” Please refer to [0079] lines 14-17.

Please note that in the Parent case the EPO did not find any added matter in this feature in Claim 6(d)(xiii) and 6(d)(xvi) of AR9-10. See Decision 2015 (pages 14-16).

10.6. Examiner alleges that claim 10(b)(i)-(v) (on file claim 9(b)(i)-(v)) add matter because the subject matter has been taken from Table 20 in an alternative manner.

The basis for the nutrients is recited in paragraph 22 and rest of the disclosure, which recite the phytochemicals, antioxidants, vitamins and minerals, and trace elements as “**one or more**”, i.e. even one selection is a legitimate selection. Further, no amount range is specified in paragraph 22 or elsewhere in the disclosure other than Table 20. It is perfectly legitimate for Applicant to select preferred range from Table 20 to add to the open amount of the nutrient recited in paragraph 22. T 201/83 (Reason #10, #12), GL H-IV, 2.4.

Furthermore, “separate features of the original document may be combined without necessarily

generating new subject-matter. If the same document contains instructions as to certain concentrations, proportions and sizes in respect of one or more constituents, it would be within the ordinary skill of the person to select exactly one or more of these numerical values when trying to reproduce an article or process falling within the scope of a general disclosure.” T 201/83 (Reason #11).

Further, “There are some instances where even a very broad field is sufficiently exemplified by a limited number of examples or even one example.” (GL F-III, 1 and F-IV, 6.3). This is such a case. The components in question are nutrients, not toxic new drug. The nutrient ranges recited in Table 20 can be applied generally to nutrients recited in [0022], as preferred ranges.

10.7. It is alleged that new claim 10(c)(i) (on file claim 9(c)(i)) adds matter.

Paragraph [0037] recites, “*meats, poultry, seafood, milk, fruits, vegetables, legumes and grains.*” without the restriction of “calories from...” Even though additional context of “calories from...” is recited in paragraph 58, “expert would treat them as features of the design that could be separately considered... Although such a component contributes to the total effect, it can still be considered separately in view of its specific role on its own.” (T 201/83, Reason #9; G 0001/93, Reason #16).

Please note that in the Parent case the EPO did not find any added matter in this feature in Claim 6(e)(xvii) of AR10. See Decision 2015 (pages 15-16).

10.8. New claim 10(c)(iii) pertaining to carbohydrates finds basis in [0056]. Same logic as in point #9.7 above applies here.

Note that in the Parent case the EPO did not find any added matter in this feature in Claim 6(e)(xix) of AR10. See Decision 2015 (pages 15-16).

10.9. New claim 10(c)(iv) pertaining to proteins finds basis in [0058b].

Please note that in the Parent case the EPO did not find any added matter in this feature in AR 10 Claim 6(e)(xx). See Decision 2015 (pages 15-16).

10.10. New claim 10(d)(i) reciting “full meal **or** a dietary component selected from...” finds support in paragraphs 32, 36, 37, and original claim 11. Examiner alleges that “snack, dairy product, side dish, salad, yogurt, and drink” add matter. Applicant asserts that in context of the overall disclosure there is no added matter. For example, note the following in the disclosure.

“Lipid compositions comprising nuts, seeds, oils, legumes, fruits, grains, and **dairy** useful in specified amounts **as dietary supplements and diet plans** designed around and including the aforementioned for the prophylaxis and treatment of numerous diseases are disclosed.” Abstract.

“In some embodiments, they may be contained in any one or more of, but not limited to...**a nutritional bar; a bakery food product such as a bread, a dessert, a pastry, a truffle, a pudding or cake;** a sealed single dosage packet or resealable packaging containing **a liquid.**” Paragraph 36. The highlighted items are frequently snacks and drinks in context of the disclosure.

“In one embodiment, a dietary component can be a cooking ingredient added to prepared or unprepared food or beverage. In some embodiments, it can also be a finished food product such as a dessert or **side dish**, which are served together with other components of a meal... Again, the administration of the balanced composite nutrients may be achieved through one course in a meal or multiple courses in a meal (e.g., **salad**, main course, and dessert).”. Please see [0037].

“delivery of the desired lipid composition may be achieved through a **one-part or multi-part delivery system**. For example, the desired formulation may be achieved through adding various components to various parts of a meal, including bread, **salad**, main course, and/or dessert.” Paragraph 39.

Please note that in the Parent case the EPO did not find any added matter in this feature in Claims 6(f)(xv) of AR9 and 6(f)(xxii) of AR10. See Decision 2015 (pages 14-16).

10.11. The Examiner had objected to the form “solid” and general form “capsules” in Claim 9(d)(ii) (new claim 10(d)(ii)).

*“In other embodiments the composition is a **solid** formulation. In yet other embodiments the composition is a semi-solid formulation.”* Please see [0032].

*“The compositions as presented in Table 7 were formulated by three different methods: lipid liquid formulation only, a **solid** or semi-solid nut and seed formulation only, or a combination formulation containing oils, nuts and seeds. The compositions were formulated to be administered in a once a day format (combined formulation), or a twice a day format where one administration was of the liquid lipid formation and the other administration was of the **solid** nut and seed composition.”* Please see [0046]. Also see [0047, 0048, 0063, 0064, 0067, 0068], and Tables 16 and 18.

Further, even if paragraph 36 recites three specific types of capsules (controlled release capsule, soft-gel capsule, hard capsule) novelty of “capsule” is destroyed. T 201/83 (Reason #3).

Please note that in the Parent case the EPO did not find any added matter in this feature in Claims 6(f)(xvi) of AR9 and 6(f)(xxiii) of AR10. See Decision 2015 (pages 14-16).

10.12. The Examiner has objected to Claim 9(d)(iv) (new claim 10(d)(iv)).

*“The lipid formulations may be packaged in **one, two, three, four or more mutually complementing daily dosages**... The components of the compositions may be delivered in **one-part or multiple parts** as various **components** of a meal or to complement a meal, for example... In some embodiments a **one-day, one-week, two-week, bi-weekly, bi-monthly, or monthly** diet plan may be formulated comprising various lipid formulations described herein, with varying compositions administered each day”. Please see [0036].*

*“the administration of the balanced composite nutrients may be achieved through **one course in a meal or multiple courses** in a meal.”* Please see [0037].

*“The **delivery of the desired lipid composition may be achieved through a one-part or multi-part delivery system**.”* Please see [0039].

It is clear from the above the one or more “components” are part of the “delivery system,” which can be for multiple days, weeks, or months.

Please note that in the Parent case the EPO did not find any added matter in this feature in Claims 6(f)(xviii) of AR9 and 6(f)(xxv) of AR10. See Decision 2015 (pages 15-16).

10.13. Examiner acknowledges claim 9(c)(ii), 9(c)(v), 9(d)(iii), 9(d)(v) and 9(d)(vi) (new claim 10(c)(ii), 10(c)(v), 10(d)(iii), 10(d)(v) and 10(d)(vi)) find support in applications as filed.

Applicant fails to understand why the Examiner proposes to remove “isoflavones,” which is a term expressly recited in paragraph 22, as filed, see reproduction below:

“monophenols; polyphenols or flavonoids, including flavonols such as quercetin, kaempferol, and resveratrol; flavanones; flavones; flavan-3-ols such as catechins; anthocyanins and anthocyanidins; **isoflavones** or phytoestrogens including...”

Accordingly, new claim 10 (on file claim 9) finds basis in the application as originally filed, does not add subject matter and therefore meets the requirements of Art. 123(2) EPC.

11. On file claim 10 (New claim 11)

Finds basis in at least original claim 1 and claim 16, paragraphs [0029], [0032] and [0033], fifth and sixth sentence of paragraph [0042].

Accordingly, new claim 11 (on file claim 10) finds basis in the application as originally filed, does not add subject matter and therefore meets the requirements of Art. 123(2) EPC.

12. On file claim 11 (New claim 12)

Finds basis in at least original claim 1, paragraphs [0008]-[0012], [0014]-[0018], and paragraphs [0060]-[0063], and Table 13-20, and Examples 11-27.

Accordingly, new claim 12 (on file claim 11) finds basis in the application as originally filed, does not add subject matter and therefore meets the requirements of Art. 123(2) EPC.

13. On file claim 12 (new claim 13):

13.1. Objected medical conditions are most certainly disclosed in context of the claimed compositions as follows:

Example 12. A Case Study on **Hypercholesterolemia (and dyslipidaemia)**, Cardiovascular Disease

Example 13. A Case Study on **Mood Swing**, Mental Function (including **cognitive function**)

Example 16. A Case Study on **Thyroid Disturbances**

Example 18. A Case Study on **Diabetes**

Example 20. A Case Study on Ovulation, **Reproductive Disorders**

Example 27. Case Studies on Immunity, Autoimmune and **Infectious and Inflammatory Diseases** (without limitation to bacterial disease, e.g. yeast infection is neither viral nor bacterial)

Note that the case studies listed above are also encompassed in the medical conditions recited in Table 13. For example, diabetes is an endocrine disorder.

“There are some instances where even a very broad field is sufficiently exemplified by a limited number of examples or even one example.” (GL F-III, 1 and F-IV, 6.3).

In this case, a person or ordinary skill in the art would be aware that improper omega-6 and omega-3 intake is associated numerous medical conditions, because they affect broad range of cellular and physiological functions. Please see paragraphs [0002]-[0006].

The present disclosure corrects the misconception that good health is achieved from a very low ratio intake of omega-6 to omega-3 and from very dosage of omega-6 fatty acids. Rather the present disclosure demonstrates that good health is achieved at higher ratio and amounts of omega-6 fatty acids (e.g. higher than 4:1 O6:O3 ratio and at least 11g/day O6 in Examples 11, 12, 14.2, 15.1, 17, 19, 22, 26, and 27, or at least 5% of calories in Example 11, Table 20).

Combining the common knowledge regarding omega-6, omega-3, and other lipids, with the ratios, the dosages, and the direction in which to proceed taught in the present application, skilled persons would apply the teachings to general health and all medical conditions.

13.2. Examiner’s objection to the term “*gradual*”.

A “gradual” process is disclosed in the application as originally filed and it is a reoccurring theme throughout the disclosure.

By way of example only,

“This disclosure also relates to methods of steady delivery of the bioactive substances, daily, weekly, monthly or longer duration wide and sudden fluctuations of which may be harmful.” (Paragraph [0008])

*“Yet another aspect of the present disclosure is the concept of steady delivery of fatty acids with respect to phytochemicals, based on the observation that each time there is a change in dietary lipid composition, it upsets the body physiology, sometimes with adverse effects such as headaches, muscle and joint pains, digestive and bowel upset, mental confusion, and anxiety; and at other times it may cause short-lived euphoria and general sense of wellness. **Though the body adapts to the change in 2-3 weeks or longer, long-term effects of the change outside the optimal range may be harmful.** Furthermore, sudden large fluctuations in fatty acids can also have acute adverse effects. This steady delivery requires a steady dosage within the optimal range lasting approximately 2 to 3 weeks at a minimum.”* (Paragraph [0041])

*“The subject’s diet was supplemented with a combination of vegetable oils, seed oils, nuts and seeds for a period of 6 weeks. The subject was provided with the twice-daily administration formulation in Example 10. By optimizing omega-6 and omega-3 fatty acids and ratios thereof, it was observed that there was an **adaptation period** over which the intensity of hot flushes gradually diminished... During the **6-week course of treatment**, the subject did improve her posture, which is indicative of greater muscle mass, joint and/or tendon strength and flexibility, and bone density.”* (Paragraph [0069])

*“The host subject experienced hypercholesterolemia on a vegetarian diet low in fat, mostly olive oil (75% monounsaturated fat), a daily fish oil supplement of 1 gram, and a daily total essential fatty acids (EFA) supplement of 1 gram. As part of the treatment, the fish oil and EFA supplements were discontinued. The subject was then administered a daily lipid composition supplement containing 11 grams of omega-6 and 1.2 grams of omega-3, made up primarily from a combination of vegetable oils, and nuts and seeds. Administration of the lipid composition resulted in a reduction of LDL from 160mg to 120mg. Very low levels of blood pressure were observed, 90/55 mmHg, when omega-3 was increased to 1.8 grams; blood pressure levels normalized at 105/70 mmHg at 11 grams of omega-6 and 1.2 grams of omega-3. When omega-3 was reduced from 1.8 grams to 1.2 grams per day, the subject experienced an irregular heartbeat, which **subsided over a period of 2-3 weeks.**”* (Paragraph [0072])

*“It is hypothesized, that **sudden increase in omega-6, when the body is chronically deficient may be harmful.**”* (Paragraph [0074])

*“In a subject host, the inventor observed many musculoskeletal issues appear and disappear in the course omega-6 and omega-3 therapy by administration of lipid compositions. Increases in omega-3 beyond 0.5g, in a vegetarian host with omega-6 at 10-11 grams, yielded better muscular performance, lesser joint pain, lesser joint crackling sounds, and better spatial task performance. But a point of diminishing marginal returns was reached at about 1.2 grams of omega-3. Increases of omega-3 beyond 1.2 grams resulted in weaker muscle tone, posture, and exercise endurance. When the **omega-3 was gradually brought back to 1.2 grams**, the subject experienced leg cramps, lower back pain, burning sensation in the scalp, buckling of knee joints, and joint pains in knees and shoulders. **Over a period of 3-6 weeks these symptoms subsided.**”* (Paragraph [0085])

*“In a vegetarian host subject, it was discovered that there was a band of optimal quantity and ratio of omega-6 and omega-3, beyond which the subject gained weight. At omega-6 of 11 grams and omega-3 of 2 grams, the subject was at 134 lbs. When the inventor **gradually reduced omega-3 to 1.2 grams, the subject initially gained 6 lbs., and then after 6 weeks, lost 12 lbs. for an ending weight of 128 lbs.**” (Paragraph [0091])*

Please note that in the Parent case the EPO did not find any added matter in this feature in claim 10 of AR10. See Decision 2015 (pages 15-16).

Accordingly, new claim 13 (on file claim 12) finds basis in the application as originally filed, does not add subject matter and therefore meets the requirements of Art. 123(2) EPC.

14. On file claim 13 (new claim 14):

14.1. Examiner acknowledges that “one or more mutually complementing daily dosages of fatty acids comprising omega-6 and omega-3 fatty acids, wherein the ratio of omega-6 to omega-3 fatty acids and their amounts are based on the one or more factors” are disclosed in paragraphs 33-36, 39 (A2 version), original claims 1 and 10, and rest of the disclosure. Applicant makes it clear that paragraph 36 expressly recites, “The lipid formulations may be packaged in one, two, three, four or more mutually complementing daily **dosages.**”

14.2. New claim 14 has been amended to recite the features as exactly recited in the corresponding Japanese application JP 2014-099072, which features have been ruled by the Intellectual Property High Court of Japan to be clear and supported by the application as originally filed.

15. On file claim 14 (new claim 15):

New Claim 15 is substantially the same as new claims 2-5 above, therefore supported by the original application as asserted above.

Accordingly, new claim 14 (on file claim 13) finds basis in the application as originally filed, does not add subject matter and therefore meets the requirements of Art. 123(2) EPC.

Article 84 EPC:

The term “% by weight of total lipids” is fully supported by the application as filed, and would be clear to the skilled person. Please see section 1.2 above.

Therefore, requirements of Article 84 EPC are met.

Article 83 EPC:

As a supplement to the argument submitted on 11 October 2018, Examiner’s attention is called to the fact that Claims 1 and 14 recite “dosage of omega-6 and omega-3”, which renders objection to high ratios as being detrimental to health moot, because when “dosage” is practiced as taught, upper limit of the ratio loses significance. For example, if suitable dosage of omega-6 is 20g for a subject, as long as the dosage is less than 20g, it would not matter if the ratio is 400:1.

Such dosages and ratios are taught in Tables 9-13 and 20. Tables 9-13 disclose dosages of omega-6 under the column titled “Range O6-g” and dosages of omega-3 under the column titled “Range O3-g”, wherein ranges as high as 400:1 are evident. For example, in Table 9 under “Males 9-13 y” $O6\ 30 \div O3\ 0.1 = O6:O3\ 300:1$ is evident and in Table 13 under “Obesity” $O6\ 40 \div O3\ 0.1 = O6:O3\ 400:1$ is evident. Omega-6 dosages in Tables 9-13 vary from 1-40 g and omega-3 dosages vary from 0.1-6 g to provide for supplements and entire diet (please see [0019], [0032], [0036]-[0037]) by demographics (e.g. age and gender).

Claimed features recite “dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater.”

Skilled person could derive from the disclosure of the present invention that when the base diet has high omega-3 the supplement may have lower omega-3 and that this may further increase omega-6 to omega-3 ratio in the supplement.

In addition, with regard to use of the claimed formulation, there are described several examples to support the claimed scope for instance: Example 12 represent A Case Study on Hypercholesterolemia (and dyslipidaemia), Cardiovascular Disease; Example 13. A Case Study on Mood Swing, Mental Function (including cognitive function); Example 16. A Case Study on Thyroid Disturbances; Example 18. A Case Study on Diabetes; Example 20. A Case Study on Ovulation, Reproductive Disorders; Example 27. Case Studies on Immunity, Autoimmune and Infectious and Inflammatory Diseases (without limitation to bacterial disease, e.g. yeast infection is neither viral nor bacterial).

Examiner alleges that “claim 11 refers back to the use of the lipid formulations of example 10”. First, it appears the Examiner means Example 11 refers back to Example 10, and second Examiner has missed to read the long Table 20 of Example 11, reciting specific amounts of ~80 nutrients including specific antioxidants and non-fatty acids phytochemicals, and 22 distinct types of fatty acids, and total lipids (see line 3). Further, paragraph [0071] above Table 20 recites, “Nutrients from the total diet (natural sources) including the lipid composition administered were as follows in Table 20.” Therefore, the application discloses precise formulations that were used to provide therapeutic effect.

There is no requirement under EPC to show therapeutic effect in large populations of subjects. Rather, most patents are based on limited examples in handful of subjects. In contrast, subject specification provides not one but more than 20 examples with consistent theme and interrelated findings. For example,

- Examples 7-8 present the ratio ranges and concentrations of polyunsaturated, monounsaturated, saturated, omega-3, omega-6, and omega-9 fats by diet type or medical condition, in one- to multi-component formulations.
- Example 9-10 provide specific concentrations of ingredients, like nuts, seeds, and oils.
- Example 11 provides ranges of ~80 nutrients in RAE to micrograms to grams including 20+ lipids administered to a subject from the entire diet over 6 weeks period.
- Example 12-27 focus on calibration of omega-6/omega-3 and the period of administration.

Thus, clear concise features of the lipid compositions have been provided in addition to direction in which to proceed throughout the specification.

In addition to the examples, the application contains, sufficient information to allow the person skilled in the art, using his common general knowledge, to for example “*use one or more factors selected from: age of the subject, sex of the subject, diet of the subject, the body weight of the subject, physical activity level of the subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and ambient temperature range of the subject's living area as an indicative for preparing a lipid-containing formulation for administration to a subject, comprising one or more mutually complementing daily dosages of fatty acids ...*” and perform the invention over the whole breadth of the claimed scope without undue burden or further unreasonable experimentation (see T 727/95).

Therefore, the requirements of Article 83 EPC have been satisfied.

Articles 54 EPC – Novelty

Principles of Law

A generic disclosure does not usually take away the novelty of any specific example falling within the terms of that disclosure, but that a specific disclosure does take away the novelty of a generic claim embracing that

disclosure, e.g. a disclosure of rivets takes away the novelty of fastening means as a generic concept, but not the novelty of any fastening other than rivets. GL G-IV, 5.

The EPO Enlarged Board has held with respect to patenting of “dosage” regimen “*Such patenting is also not excluded where a dosage regime is the only feature claimed which is not comprised in the state of the art.*” (see G 02/08: Answer to Question 2).

It is not permissible to combine separate items of prior art together. It is also not permissible to combine separate items belonging to different embodiments described in one and the same document, unless such combination has specifically been suggested (see T 305/87). GL G-IV, 1.

It is not correct to interpret the teaching of a document as embracing well-known equivalents which are not disclosed in the documents; this is a matter of obviousness. GL G-IV, 2.

Subject-matter can only be regarded as having been made available to the public, and therefore as comprised in the state of the art pursuant to Art. 54(1), if the information given to the skilled person is sufficient to enable him, at the relevant date (see G-VI, 3) to practice the technical teaching which is the subject of the document, taking into account also the general knowledge at that time in the field to be expected of him (see T 26/85, T 206/83 and T 491/99).

Subject-matter does not necessarily belong to the common general knowledge simply because it has been disclosed in the state of the art: in particular, if the information can only be obtained after a comprehensive search, it cannot be considered to belong to the common general knowledge and cannot be used to complete the disclosure (see T 206/83).

Implicit disclosure can only be alleged if in carrying out the teaching of the prior-art document, the skilled person would inevitably arrive at a result falling within the terms of the claim. An objection of lack of novelty of this kind is raised by the examiner only where there can be no reasonable doubt as to the practical effect of the prior teaching. GL G-IV, 6.

A sub-range selected from a broader numerical range of the prior art is considered novel (see T 198/84 and T 279/89).

In view of the above principles Examiner’s allegation that the claimed subject matter lacks novelty in view of D1 or D5 is improper. Examiner states in exam report dated February 25, 2019, page 7 that compositions “where omega-6 is present at least in amounts four-fold with respect to omega-3, is known from the available prior art. Likewise the amounts of omega-3 in the prior art are generally between 0.1 and 20%” [Emphasis added]. However, present (and pending) claims contain several additional and specific limitations.

New claim 1 is directed to a lipid-containing formulation comprising:

- a *dosage* of omega-6/omega-3 fatty acids, at
- an omega-6 to omega-3 ratio
- of 4:1 or greater; wherein
- omega-6 fatty acids are 4-75% by weight of total lipids;
- omega-3 fatty acids are 0.1-30% by weight of total lipids; or
- dosage of omega-6 fatty acids is not more than 40 grams; or
- polyunsaturated, monounsaturated, and saturated fatty acids, wherein the omega-6 fatty acids are greater than 20% by weight of the total lipids and nutrients comprising one or more polyphenols, or one or more phytochemicals selected from: phytosterols, organosulfides, melatonin, saponins, coumarins, lycopene, lutein, zeaxanthin, and monophenols.

“Generally” is not good enough to make a case of anticipation, prior art must inevitably work as claimed. None of the cited prior art documents disclose let alone suggest, or inevitably lead to a formulation as

presently amended claim 1 and 14, to constitute anticipation. As noted above a generic disclosure does not take away the novelty of a specific disclosure, e.g. a disclosure of fastening means as a generic concept does not take the novelty away of rivets. Similarly, in the present case a disclosure of “concentration” does not take away the novelty of “dosage” and the disclosure of “by weight of fatty acids [or composition]” does not take away the novelty of “by weight of total lipids”. GL G-IV, 5.

Turning to the cited documents:

D1 (WO02/15720)

This document describes compositions for a nutritional supplement and in particular to nutritional supplements as a functional food and more specifically for improving muscle protein synthesis.

This document does not mention or contemplate a formulation comprising all of the features of new claim 1. In particular **D1** does not disclose a formulation comprising a dosage of omega-6 (o-6) and omega-3 (o-3) fatty acids at a ratio of o-6 to o-3 of 4:1 or greater, where the o-6 fatty acids are 4-75% by weight of the total lipids and the o-3 fatty acids are 0.1-30% by weight of total lipids.

In addition, **D1** does not disclose a formulation comprising dosage of omega-6 fatty acids is not more than 40 grams; or polyunsaturated, monounsaturated, and saturated fatty acids, wherein the omega-6 fatty acids are greater than 20% by weight of the total lipids and nutrients comprising one or more polyphenols, or one or more phytochemicals selected from: phytosterols, organosulfides, melatonin, saponins, coumarins, lycopene, lutein, zeaxanthin, and monophenols.

In the Exam Report dated 25 February 2019 at pages 8-9, the Examiner alleges “generally known” compositions of various oils, without evidence, and uses this to allege that based on “generally known” composition of the recited oils D1 inherently discloses the claimed content. However, inherency in D1 cannot be alleged because D1 **does not inevitably** lead a skilled person to the result falling within the terms of the claim 1 or 14.

Applicant has previously submitted evidence on 2 November 2018 that natural products such as nuts, seeds, or their oils are not predictable in lipid content. For example, see R4, *Erickson declaration* (paragraph [003]), and R22, Knowles, “*Variability in Oleic and Linoleic content of Safflower oil*”. Additionally, Applicants submits *Sakhno 2010 “Variability in the Fatty Acid Composition of Rapeseed [Canola] Oil: Classical Breeding and Biotechnology”* (enclosed Annex C) and *Pons 2003 “Heart-Friendly Corn Oil?”* (enclosed – Annex B), which show variability in canola and corn oil also. The following table illustrates the contrast in alleged “generally known” compositions and alternate compositions per *Knowles*, *Sakhno*, and *Pons* of the oils recited in D1.

Evidence Contradicts Examiners Allegation of Standard Lipid Content in Oils

	Safflower Oil	Canola Oil	Corn Oil
Oleic Acid (an omega-9) -Alleged by Examiner -Evidenced by Knowles -Evidenced by Pons, pp 19 -Evidenced by Sakhno, pp 390, 393	-75% -8.9 to 86.8% - -	-62% - - -61 to 90%	-27% - -60 to 70% -
Linoleic Acid (an omega-6) -Alleged by Examiner -Evidenced by Knowles -Evidenced by Pons, pp 19	-13% -8.7 to 84.6% - -	-19% - - -9 to 23%	-58% - -<30 % (if oleic 70%)

-Evidenced by Sakhno, pp 390, 393	-		-
Alpha-Linolenic Acid (an omega-3)	-	-9%	-1%
-Alleged by Examiner	-	-	-
-Evidenced by Knowles	-	-	-
-Evidenced by Pons, pp 19	-	-3 to 24%	-
-Evidenced by Sakhno, pp 390, 393			

As shown by Table 1 of Knowles there are numerous varieties of safflower oil, but D1 does not define what it means by “high oleic”. Therefore, D1 leaves the reader guessing what is meant by “high oleic”, for instance is it high oleic when oleic content exceeds 35% or 50%? Similarly, D1 leaves the reader guessing as to the fatty acid composition of other oils, let alone discuss various other lipids present in the oils.

Therefore, the oils recited in D1 are not standardized in lipid content and cannot be considered to provide dosage of any kind for omega-6, omega-3, or any other lipids.

Moreover, D1 is inoperable due to contradicting directions in Example 1 (in addition to the contradicting ratios in the abstract, pages 2-3, and 8, Example 1, and claim 1). For example, what is meant by “Lipids 2.8g wet weight (% by weight of the total composition)” (see column heading)? Also, D1 states in the paragraph above Example 1 “multiple doses” may be taken “in a single dose.” Such disclosure creates doubt as to the practical effect of D1 teaching; hence it cannot be said that D1 discloses and enables dosage of omega-6/omega-3 for a subject.

Even after “errors” in D1 were asserted on 13 March 2008, i.e. eight years after the D1 priority date (see minutes of the call dated 20 March 2019), D1 does not disclose and enable all the features in the new Claim 1 (or on file). Rather, the Opposition Division did not consider the “error” pertaining to omega-6 to omega-3 ratio to be obvious and the patent was revoked.

Thus, there is no clear teaching and enablement of what constitutes a “dosage of omega-6” “for a subject” in D1, which is explicitly recited in the new claims 1 and 14.

Additionally, neither can D1 Example 1, “Lipids 2.8g wet weight (% by weight of the total composition)” **inevitably** lead a practitioner to omega-6 fatty acids are 4-75% by weight of total lipids and omega-3 fatty acids are 0.1-30% by weight of total lipids” or “omega-6 fatty acids are greater than 20% by weight of the total lipids” explicitly recited in new Claim 1. “Lipids 2.8g wet weight (% by weight of the total composition)” may result in omega-6 less than 4% by weight of total lipids and fail both of the foregoing limitations in present claims.

New claim 14 should also be considered to be novel over **D1** because this document does not contemplate use of one of more factors selected from: age of the subject, sex of the subject, diet recited in Claim 14 as an indicator for selecting a lipid-containing formulation for administering to a subject in accordance with new claim 14, in addition to other limitations in the claim.

Accordingly, new claim 1 and 14 should be considered to be novel over **D1**, and dependent the claims should also considered novel over the disclosure of **D1**.

D5 (WO2008/018147/US2010267681A1)

The purpose of this cited document is to provide a fat or oil composition which has a high content of diacylglycerols (DAG) and high content of conjugated linoleic acid (CLA) and has anti-obesity effect and

stability and improves the storage stability of the fat or oil composition (please see **D5**, for example second sentence of paragraph [0011]). In other words, **D5** describes stabilized compositions of fat or oil where each composition comprises high concentrations of DAG and CLA, e.g. the compositions identified by the Examiner, namely oil F or oil G (see for example **D5**, Table 1 at page 8).

However, D5 does not mention or contemplate the formulation of new claim 1. The compositions disclosed in **D5** and the general teachings of this cited document are completely different from the present invention.

First, note that **D5** Table 1 identifies the fatty acids in the fat or oil compositions A-G by number of carbon atoms and carbon-carbon double bonds in the fatty acids (e.g., C18:1 or C18:3) but without identifying the name of the fatty acids or the position of the double bond, which identifies whether the fatty acid is omega-3, omega-6, or omega-9. See *Ratnayake 2009 "Fat and Fatty Acid Terminology, Methods of Analysis and Fat Digestion and Metabolism: A Background Review Paper,"* pp 12 (enclosed - Annex D). In other words, **D5** identifies fatty acids as C18:1 or C18:3, which is insufficient to identify the specific fatty acids in the compositions. The following table notes some of the ambiguities in Table 1 of **D5**.

Ambiguities in Identification of Fatty Acids in Table 1 of D5

	Possible Fatty acids	Evidence
C18:1	omega-7 (or n-7) vaccenic acid (C18:1n-7), or omega-9 (or n-9) oleic acid (C18:1n-9)	<i>Ratnayake 2009</i> , Table 3, pp28
C18:3	omega-3 (or n-3) alpha-linolenic acid (C18:3n-3), or omega-6 (or n-6) linolenic acid (aka gamma-linolenic acid) (C18:3n-6)	<i>Ratnayake 2009</i> , Tables 4 and 5 Figure 8
C20:1	omega-7 (or n-7) paullinic acid (C20:1n-7), or omega-9 (or n-9) gadoleic (aka eicosenoic) acid (C20:1n-9)	<i>Avato "Seed oil composition of Paullinia cupana var. sorbilis (Mart.) Ducke" Lipids. 2003 Jul;38(7):773-80</i> <i>Ratnayake 2009</i> , Table 3, pp28

Therefore, one cannot be certain of omega-3, omega-6, or omega-9 concentrations or the ratio of omega-6 to omega-3, or omega-9 to omega-6 in the compositions in Table 1 of D5.

Note that all of the fatty acids in the table above are contemplated for use in D5 compositions (see paragraphs [0014], [0028], and [0061]), including both alpha-linolenic acid (C18:3n-3) (see paragraph [0018]) and linolenic acid (C18:3n-6) (see paragraph [0038]). Also note that the oils in composition E, G, and F are known to contain linolenic acid (C18:3n-6), for example see *Wainwright et al., Lipids. 2003 Feb;38(2):171-8*.

Second, one cannot calculate omega-3, omega-6, or omega-9 concentrations by weight of total lipids in the compositions in Table 1 of D5, because the table only recites fatty acid components, not other lipids which are certainly present in these composition because they comprise oils and additional lipids (see paragraphs [0082]-[0084]) without closing the possibility of presence of more lipids.

Third, D5 does not disclose and enable a suitable dosage of omega-6/omega-3 for a subject; most certainly, since D5 Table 1 fails to even specify omega-3 or omega-6 concentrations.

Therefore, **D5** does not disclose and enable a dosage of omega-6 (o-6) and omega-3 (o-3) fatty acids at a ratio of o-6 to o-3 of 4:1 or greater, where the o-6 fatty acids are 4-75% by weight of the total lipids and the o-3 fatty acids are 0.1-30% by weight of total lipids.

In addition, **D5** does not disclose and enable a formulation comprising dosage of omega-6 fatty acids is not more than 40 grams; or polyunsaturated, monounsaturated, and saturated fatty acids, wherein the omega-6 fatty acids are greater than 20% by weight of the total lipids and nutrients comprising one or more polyphenols, or one or more phytochemicals selected from: phytosterols, organosulfides, melatonin, saponins, coumarins, lycopene, lutein, zeaxanthin, and monophenols.

Note the principles of law above that the prior art must **inevitably** lead the skilled person to the result as claimed to constitute anticipation.

Accordingly, new claim 1 should be considered to be novel over **D5**.

New claim 14 should also be considered to be novel over **D5** because this document does not contemplate or enable the use of one of more factors selected from: age of the subject, sex of the subject, diet as an indicative for selecting a lipid-containing formulation for administering to a subject, in addition to other limitations in the claim.

It follows that the claims dependent on claims 1 and 14 should also be considered to be novel over **D5**. In view of the above, new claims 1 to 15 should be recognised to be novel over each one of the cited documents i.e. **D1** or **D5**.

In view of the above, the claims should be regarded to meet the requirements of Art. 54 EPC.

Articles 56 EPC – Inventive Step

The Examiner has previously alleged that the claimed invention lacks inventive step in view of D2 in combination with D1 and has now also alleged that D5 could be considered as a possible closest prior art in combination with documents such as D3 and/or D8.

Applicant submitted arguments and **twenty-four evidence documents**, R1-R24 on 02 November 2018, including testimony from skilled persons evidencing **unexpected results** and that the subject matter is poorly understood and **evidencing numerous obstructive factors** in the prior art, therefore, lack of inventive step objection cannot be made.

Yet, the Examiner has raised a new objection under inventive step and alleged lack of inventive step in view of a further possible closest prior art document, namely **D5** when in combination with other documents such as **D3** or **D8**. Additionally, in the results of the phone call held on 12 March 2019 and dispatched on 20 March 2019, the Examiner stated at page 2, “*The concept of providing nutritional fatty acids in which there are (much) more n6- than n3-fatty acids appears to be known. The currently available prior art, not to mention prior art that is currently coming to the examiner’s attention (as related to D1* [WO9942001 and WO9716079] and as provided by the applicant** [Simopolous 1999]), makes it necessary to reduce the scope of the claims enough to arrive at subject matter that is not anticipated or made obvious by the prior art.*”

However, these statements are improper because in making these statements examiner has disregarded many limitations from the claims and many factual and legal points, and improperly obliged the Applicant to reduce the scope of the claims.

Disregarded Factual and Legal Points

Examiner has disregarded at least the following points.

In selecting the closest prior art, the first consideration is that it must be directed to a similar purpose or effect as the invention.... The closest prior art must be assessed from the skilled person's point of view on the day before the filing or priority date valid for the claimed invention. GL, G-VII, 5.1.

Identify the technical effect resulting from the distinguishing features. GL, G-VII, 5.2.

The point is not whether the skilled person could have arrived at the invention by adapting or modifying the closest prior art, but whether he **would have done** so because the prior art incited him to do so in the hope of solving the objective technical problem or in expectation of some improvement or advantage (see T 2/83). GL, G-VII, 5.3.

The interactions of the individual features to produce a synergistic effect is evidence of inventive step. GL, G-VII, 7.

Using hindsight is not permissible when assessing patentability of claims and therefore making conclusions from abstract documents which are not related to the present invention should be discouraged. GL, G-VII, 8.

An unexpected technical effect based on the characterising features of the invention, in combination with the known features of the claim, is regarded as an indication of inventive step. GL, G-VII, 10.2.

Where the invention solves a technical problem which workers in the art have been attempting to solve for a long time, or otherwise fulfils a long-felt need, this is regarded as an indication of inventive step. GL, G-VII, 10.3.

The very basis for the present disclosure identified in paragraph [0006]-[0007] is to overcome the **obstructive factors** in the prior art with respect to absolute (one-time dosage and daily dosage) and relative (to other lipids) intake of omega-6 fatty acids. Inventive step is present because the invention is based on (i) the devising of a solution to a known problem; and (ii) the arrival at an insight into the cause of an observed phenomenon in accordance with GL, G-VII, 9.

Present inventions do not **solely** reside in the discovery that high n6 to n3 ratios are beneficial for health. They reside in the high ratios **combined with and in synergy with** the following main discoveries reflected in the claims that the prior art has failed to understand. The interactions of the individual features to produce a synergistic effect is evidence of inventive step. GL, G-VII, 7.

- a. Prior art held that stepwise increase in n6 was harmful (e.g., see R10 abstract; R11 pp192). In contrast here the inventor finds that n6 has a peculiar dose-effect wherein adverse symptoms may be produced when n6 intake is increased from low habitual intake, but over time higher n6 dosage is better for health (see paragraph 41 and examples 11-27), which is the arrival of an insight (GL, G-VII, 9) and an unexpected technical effect (GL, G-VII, 10.2). **This finding is reflected in present claim 1 and 14 as “dosage of omega-6”, and upper limit of “40g”, and in claim 14 as “wherein increase of omega-6 is gradual and/or withdrawal of omega-3 is gradual and the dosage of omega-6 is not more than 40 grams”.**
- b. Prior art has taught very low dosages of n6, for example 1g/day (e.g., see R11 pp192; R13 pp183; also see D2 pp8) and up to 6.67g/day by international scientists (e.g., R12 Table 1). In contrast here the inventor finds at least 11g/ n6 per day is required for an adult (see Examples 11-27), which is an unexpected technical effect (GL, G-VII, 10.2). **This finding is reflected in present claims 1 and 14 as “dosage of omega-6 fatty acids is not more than 40 grams.”** (The

claimed formulations can be entire diet or complement the base diet; lower limit is left open to accommodate for gradual increase and the base diet (e.g., see paragraphs [0032] and [0040]).

- c. Prior art has taught use of antioxidants and phytochemicals (which tend to be lipids) to suppress the activity of n6 (e.g., see R7-R9, paragraph [0018]). In contrast here the inventor finds antioxidants and phytochemicals can reduce the requirement of n3 and increase the requirement of n6. **This finding is reflected in the present claims 1 in the recitation, “by weight of total lipids” and in claim 14 in “selection” based on “diet of the subject” and “based on amount of antioxidants, phytochemicals, and seafood”.**
- d. Prior art has taught low omega-6 intake, such as less than 10% in a composition and high monounsaturated fatty acids intake, such as above 70% of fatty acids (e.g., see EP1510133A1 paragraphs [002] and claims 2-4, and R12 Table 1). In contrast here the inventor finds monounsaturated fatty acids can be harmful, and **n6 intake should be greater than 20% by weight of total lipids including monounsaturated fatty acids, reflected in present claim 1, which is an unexpected technical effect (GL, G-VII, 10.2).**

Examiner has mis-constructed the differences between alleged closest prior art versus present invention.

D2 (WO 2006/007818) with D1(WO02/15720)

Examiner states at page 10 of the Exam Report dated 25 February 2019, that the problem to be solved in **D2** is to provide lipid-containing compositions that optimize the delivery of omega-6 and omega-3 fatty acids and antioxidants, notably Vitamin E and C, to improve or maintain health related to metabolism, specially linked to lipid imbalance.

However, **D2** discloses at page 8,

“An essential part of the invention is that the conversion of the energy gain of the cell is fixed through regular supply of Omega-3 and Omega-6 fatty acids, antioxidants and essential amino acids. Preferably be fed **1-2 g fatty acids per day**, preferably special 1.5 g / day. An **optimal** ratio of Omega-3 fatty acid to Omega-6 fatty acid is 1: 1 to 1: 7, with a ratio of 1: 5 is preferred. As antioxidants are vitamin E and vitamin C...” [From English translation] [Emphasis added].

D2 discloses at page 3 “a series of unsaturated fatty acids **such as** Omega-3 and Omega-6.” [From English translation] [Emphasis added]. In other words, D2 recitation “1-2 g fatty acids per day” can include other fatty acids.

The D2 and D1 disclosure would not lead a skilled person to the claimed inventions for the following reasons:

- i. There is no explicit disclosure or enablement of dosage of omega-6/omega-3 in D2. In other words, D2 is not directed to similar purpose or effect as the claimed invention and does not qualify as CPA. GL, G-VII, 5.1.
- ii. D2 recitation “1-2 g fatty acids per day” irrespective of the subject type, does not overcome the prejudice in the art with respect to low omega-6 dosage (point #2.a-b above). D2 does not identify the technical or synergistic effect resulting from the distinguishing or synergistic features. GL, G-VII, 5.2., and GL, G-VII, 7.
- iii. The present disclosure reveals unexpected results in that at least 11g/day of omega-6 was required for an adult see Examples 11, 12, 14.2, 15.1, 17, 19, 22, 26, and 27, which is indicative of inventive step; see GL, G-VII, 10.2.
- iv. Further, D2 has neither taught gradual increase nor complementing the omega-6 in the base diet. Consequently, from D2 skilled person's point of view on the priority date for the claimed invention is to practice the same low intake of omega-6 taught in the prior art. GL, G-VII, 5.1. There is nothing in D2 inciting the reader to increase the omega-6

dosage in expectation of some improvement or advantage (see T 2/83; GL, G-VII, 5.3) rather they might encounter adverse symptoms on stepwise increase and reduce the dosage (point #2.a above).

- v. There is nothing in D2 that would incite skilled persons to obtain omega-3/omega-6 concentrations by weight of total lipids, let alone “greater than 20% by weight of total lipids including monounsaturated fatty acids.” The mere inclusion of vitamin in the formulations where the concentration or dosage of vitamin E is not even mentioned cannot be construed as “by weight of total lipids.”
- vi. The deficiencies in D1 have been discussed above in detail and the same issues apply here: namely D1 has not disclosed “dosage of omega-6/omega-3” and their concentrations by “weight of total lipids”, and D1 may result in omega-6 less than 4% by weight of total lipids and fail the limitations in present Claim 1(a)(i) and 1(b), and that D1 is inoperable due to ambiguous recitation “Lipids 2.8g wet weight (% by weight of the total composition).” Nor has D1 taught selection of formulations based upon subject’s demographic factors.

Therefore, D1 and D2 in combination have neither disclosed nor enabled nor motivated/incited a skilled person to practice the claimed inventions as taught in the present claims and specification. Rather, based on D1 and D2 disclosure skilled person would be incited to practice the same low omega-6 to omega-3 ratios and low omega-6 intake taught in the prior art (irrespective of the amount of antioxidants and phytochemicals in the subject’s diet).

D5 (WO2008/018147/ US2010267681A1) with D3 (WO 2006/065735 A1) and/or D8 (DE 10347970 A1)

The main problem that **D5** was trying to address was that of poor stability of compositions comprising conjugated linoleic acid (CLA) (one of the o-6 fatty acids) and diglycerides (DAG). **D5** solved this problem by discovering “the above-described problems can be overcome by controlling each of the diacylglycerol content in the fat or oil composition, and the conjugated linoleic acid content and tocopherol content in the diacylglycerol to fall within a specific range.” See **D5**, paragraph [0012].

In other words, **D5** describes known stabilized compositions comprising high concentrations of CLA and DAG. See for Example 1, Table 1 at pages 8-9.

D5 does not disclose a formulation according to new claim 1 or claim 14.

Moreover, **D5** does not contemplate optimized or correct delivery of o-6. **D5** does not even disclose the amount of total omega-6 in its compositions, as noted above **D5** does not even specify if C18:3 used in the compositions in Table 1 is omega-6 or omega-3.

It is impossible for the Applicant to envisage the circumstances under which a skilled person would consider this document relevant to the patentability of the claimed subject matter let alone regard this as a possible closest prior art document. This document, at best, belongs to a neighbouring field of the present invention. There will be no motivation for a skilled person to combine D3 (which teaches preferred omega-6 to omega-3 ratio 2.6:1, paragraph [0011]) and/or D8 (which teaches preferred omega-6 to omega-3 ratio 3:1, paragraph [0044]) with D5 because D5 is not in the same field.

WO9942001 (Possible prior art mentioned in 20 March 2019 communication)

This document addresses the problem of providing “compositions for use in metabolically stressed patients who need food restriction, but who do not necessarily need increased contents of protein or special nutrients.”

The document does not disclose a formulation according to new claim 1 or claim 14.

The document does not contemplate optimized or correct dosage of o-6. It does not even disclose any amount of omega-6 in its compositions or any daily amount. See table at pages 9-10.

It is impossible for the Applicant to envisage the circumstances under which a skilled person would consider this document relevant to the patentability of the claimed subject matter.

WO9716079 (Possible prior art mentioned in 20 March 2019 communication)

This document addresses the problem of providing “a nutritional formula designed to meet the nutritional needs of a larger base of paediatric patients as well as paediatric patients recovering from trauma, post-surgical and moderate traumatic injuries and burns.” Page 1.

The document does not disclose and enable a formulation according to new claim 1 or claim 14.

The document does not contemplate optimized or correct dosage of o-6.

- Omega-6 to omega-3 ratios recited at page 2 lines 19-20, 29-30, page 3 line 6, and page 5, line 15, **contradict** the ratios recited at page 4 lines 33-35, page 8.
- Also note that the table at page 8 is also in **contradiction**. “linolenic (N6)” is “11.7” and “linoleic (N3) is “2.35”. This is not only contrary to the naming convention (See Ratnayake), but also leaves the reader confused as to what is being taught: Is it “linoleic” which would be N6 2.35 or is it really N3 2.35.
- The statement at pages 4 line 36 to page 5 lines 1-3, “the source of omega-6 fatty acids preferably provides about 4 to about 12% of the total calories. The omega-3 fatty acid source is preferably present in the range of approximately 0.8-3.0%” is meaningless because source is defined at page 4 lines 31-32 as, “canola oil, soy oil, residual milk fat, and soy lecithin,” which can have both omega-6 and omega-3.

Therefore, this document is unable to teach anything and overcome the prejudice against omega-6 in the prior art.

Simopolous 1999 (Possible prior art mentioned in 20 March 2019 communication)

This document addresses the problem of recommended omega-6 and omega-3 for dietary intake (page 127) developed by international scientists from academia, government, international organizations, and industry, from Australia, Canada, Denmark, France, Italy, Japan, Norway, Switzerland, United Kingdom, and the United States.

The document states at page 128,

“After much discussion consensus was reached on the importance of reducing the omega-6 polyunsaturated fatty acids (PUFAs) even as the omega-3 PUFAs are increased in the diet of adults and newborns for optimal brain and cardiovascular health and function. This is necessary to reduce adverse effects of excesses of arachidonic acid and its eicosanoid products. Such excesses can occur when too much LA and AA are present in the diet and an adequate supply of dietary omega-3 fatty acids is not available.”

The document discloses the recommended amounts of some fatty acids for adults at page 129, Table 1, wherein one of the omega-6 fatty acids, LA, is disclosed to be less than 6.67g/day and less than 3% of energy; and three of the omega-3 fatty acids LNA, DHA, and EPA are disclosed to be 2.87g/day. Omega-6 and omega-3 fatty acids include several other fatty acids (see Ratnayake Tables 4-5, and present specification paragraph [0029]), the recommendations for which are not provided in the table. Based on the partial disclosure, the omega-6 to omega-3 ratio recommended is 2.32:1 for adults wherein omega-6 dosage is less than 6.67g/day.

Further, Table 2 of this document *only* discloses “Percent of Fatty Acids” “for infant formula/diet” for LA and AA (two of the omega-6 fatty acids), and LNA, DHA, and EPA (three of the omega-3 fatty acids) and

neither other omega-6 and omega-3 nor other lipids/nutrients present in the “infant formula/diet” are disclosed (see footnote #1), nor is the dosage of any of the fatty acids disclosed. Therefore, the dosage and ratio of total omega-6 to omega-3 cannot be calculated from this table.

Therefore, the disclosure in Tables 1 and 2 of this document does not meet the limitation of total “omega-6 to omega-3 ratio of 4:1 or greater” in Claim 1(a) and Claim 14. Further, the tables do not disclose total amounts of lipids or the full composition, nor is there any disclosure of total lipids or antioxidants and phytochemicals in this document. Therefore, the disclosure in this document does not meet the limitations recited in present Claims 1(a), 1(b), and 14.

Further, there are obstructive factors in the prior art as evidenced by the cited art itself and references R1-R19 submitted on 02 November 2018, in particular see R7-R9 paragraphs [0014]-[0025], due to which there would be poor expectation of success from prior art. Additionally, skilled persons have testified that the claimed inventions solve a long-felt critical unmet public health need (see R7-R9 paragraphs [0026]-[0028]), which is an indication of inventive step. GL, G-VII, 10.3.

In view of the above, the claims should be regarded to meet the requirements of Art. 56 EPC.

Final comments

This application has a priority date of April 2008. It is directed to solving the critical persistent unmet public health problem of incorrect omega-6 intake plaguing the society for at least the last 100 years, the problem that the society has failed to solve despite numerous repeated attempts. Applicant has repeatedly called this to EPO’s attention and that patent policy favoring patent grants to restricted patents is causing the problem rather than solving the problem. See enclosed Formal Complaint filed in the parent case on 30 January 2018, pages 1-6 and 32-34.

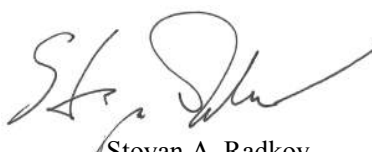
In view of the state of the prior art and that even after the publication of the present application confusion and mayhem in the art has persisted (see Exhibit E. “Omega-6 fatty acid” Wikipedia, accessed January 29, 2018 to the enclosed Formal Complaint and that competitors have sought patents teaching the opposite e.g., US Patent 7,759,507 B2 granted in 2010) neither lack of novelty nor lack of inventiveness objection is proper.

The claimed scope of the patent is necessary to rise above the noise in the art. It is not appropriate for EPO to oblige the applicant to reduce the scope of the claims in the absence of a legitimate anticipatory prior art.

Therefore, the patent should be granted without further loss of time and harm to the applicant and public.

Oral proceedings pursuant to Art 116 EPC are requested should the Examiner consider refusing the application without giving the applicant the opportunity to address any further concerns.

Your faithfully



Stoyan A. Radkov
Authorised Representative
European Patent Attorney

Encl:

- Amended claims 1 to 15; Annex A; Annex B; Annex C; Annex D; Exhibit E – Formal Complaint; AR10; Decision for patent case - EP09735962.4 – see pages 15-16.

Attachment J:

Applicant's Letter to the Congress of the United States of America dated 10 August 2019,
regarding related US Applications
(Attachments omitted, which are available at <https://portal.uspto.gov/pair/PublicPair>
Application no. 12/426,034)



August 10, 2019

BY EMAIL

SUBJECT:
**PATENT SYSTEM IS OBSTRUCTING ADVANCEMENT IN
NUTRITION, KEEPING PUBLIC ON DRUGS AND DEVICES, AND
PROMOTING THE NATIONAL DISEASE BURDEN AND
HEALTH CARE COSTS**

The President

The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

The Honorable Nancy Pelosi

Speaker, United States House of Representatives
1236 Longworth House Office Building
Washington, DC 20515

The Honorable Lindsey Graham

Chairman, Committee on the Judiciary
United States Senate
290 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Lamar Alexander

Chairman, Committee on Health, Education, Labor & Pensions
United States Senate
455 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Jerrold Nadler

Chairman, Committee on the Judiciary
United States House of Representatives
2132 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Frank Pallone

Chairman, Committee on Energy and Commerce
United States House of Representatives
2107 Rayburn House Office Building Washington, DC20515

The Honorable Dianne Feinstein

Ranking Member, Committee on the Judiciary
United States Senate

331 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Patty Murray

Ranking Member, Committee on Health, Education, Labor & Pensions
United States Senate
154 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Doug Collins

Ranking Member, Committee on the Judiciary
United States House of Representatives
1504 Longworth House Office Building
Washington, D.C. 20515

The Honorable Greg Walden

Ranking Member, Committee on Energy and Commerce
United States House of Representatives
2185 Rayburn House Office Building
Washington, DC 20515

The Honorable Thom Tillis

Chairman, Subcommittee on Intellectual Property
United States Senate
113 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Henry C. Johnson

Chairman, Subcommittee on Courts, Intellectual Property, and the Internet
United States House of Representatives
2240 Rayburn House Office Building
Washington, DC 20515

The Honorable Ben Sasse

Chairman, Subcommittee on Oversight, Agency Action, Federal Rights and
Federal Courts
United States Senate
107 Russell Senate Office Building
Washington, DC 20510

The Honorable Martha Roby

Ranking Member, Subcommittee on Courts, Intellectual Property, and Internet
United States House of Representatives
504 Cannon House Office Building

Washington, DC 20515

The Honorable Michael B. Enzi

Chairman, Subcommittee on Primary Health and Retirement Security
United States Senate
379A Senate Russell Office Building
Washington, DC 20510

The Honorable Christopher Coons

Ranking member, Subcommittee on Intellectual Property
United States Senate
218 Russell Senate Office Building
Washington, DC 20510

The Honorable Richard Blumenthal

Ranking member, Subcommittee on Oversight, Agency Action, Federal Rights
and Federal Courts
United States Senate
706 Hart Senate Office Bldg.
Washington, DC, 20510

The Honorable Bernie Sanders

Ranking Member, Subcommittee on Primary Health and Retirement Security
United States Senate
332 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Anna Eshoo

Chairwoman Subcommittee on Health
United States House of Representatives
202 Cannon House Office Building
Washington, DC 20515

cc.

The Honorable Wilbur Ross
Secretary of Commerce
U.S. Department of Commerce
1401 Constitution Ave NW
Washington, DC 20230

The Honorable Andre Iancu
Director
United States Patent and
Trademark Office
Madison Building
600 Dulany Street
Alexandria, VA 22314

Subject Recap:
**Patent System is Obstructing Advancement in Nutrition,
Keeping Public on Drugs and Devices, and
Promoting the National Disease Burden
and Health Care Costs**

Case in Point:

**The Disdainful Treatment of Asha Nutrition Sciences' Patent Applications
(12/426,034 (pending since 2009), 13/332,251 (granted after 8 years of pendency),
and 13/877,847 (pending since 2013))
by the United States Patent and Trademark Office, and
the United States Court of Appeals for the Federal Circuit, and
The Worldwide Consequences of the Same**

Dear Mr. President, Madam Speaker, Honorable Congress Members:

We the public and the United States Government have rallied, caucused, campaigned, complained, and grumbled about our over \$3 trillion annual healthcare costs and associated social burden. Rather it is a national obsession to lament about the health care system. Yet when our small company, Asha Nutrition Sciences, in 2008 presented the Government (USPTO) with an innovative inexpensive solution to significantly solve the problem at the base via tailored lipid nutrition (a fitting complement to Government sponsored healthcare), it was snubbed by the Government (USPTO, the US Court of Appeals for the Federal Circuit, and the US Supreme Court) rather apathetically, and the Government declined to grant us proper and timely patent rights to properly nurture the innovation to bring about leaps of advancement for future generations.

The legislature does not restrict patent grant to nutritional innovations, but in practice the patent system disfavors such patent grants, and when nutritional patents are granted, they are severely restricted or dragged in prosecution robbing off proper scope and term for effective implementation, *neutering* the innovation. *Tragically if our innovations were drawn to drug candidates similarly differentiated over prior art, the patents would have been granted many years ago.* Narrow patents in the nutrition arts and favorable patent grant to drugs have created *patent-practice-made humanitarian crises* by perpetuating misinformation, taking us farther away from solving nutritional problems and sustainability, fostering stagnation in the nutrition art, and making us dependent on drugs and devices.

Of note is the disdainful treatment of our patent applications, particularly the application no. 12/426,034 by the US Government and its worldwide effects. We request you to intervene in this *extraordinary case and abrogate the holdings of the USPTO and the Federal Circuit that mutilate Title 35 of the United States Code.*

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¹ Almost all the references/publication cited in this paper are on record at USPTO and have been submitted to the Federal Circuit, with the exception of petitions and briefs submitted to the Supreme Court, which were added to the record at the USPTO but not at the Federal Circuit. For the sake of brevity, only a subset of documents from the Joint Appendix submitted to the Federal Circuit is included here, additional documents are available upon request.

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Annex AB: The World’s Healthiest Foods (WHFoods.com) The George Mateljan Foundation (non-profit) “ <i>A New Way of Looking at Proteins, Fats and Carbohydrates</i> ” published January 2007. http://web.archive.org/web/20070104020351/http://whfoods.com/genpage.php?tname=faq&dbid=7#polyun	532-541
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I. Prosecution Summary of the '034 Application

Application no. 12/426,034 (the '034 application (Annex A)) was filed on April 17, 2009 and has April 2008 priority. The inventions pertain to tailored delivery of dosages of omega-6 fatty acids relative to other lipids (fatty acids, antioxidants, and phytochemicals), because of continuing *mass miseducation in the art that omega-6 fatty acids are unhealthy* and that intake and activity of omega-6 should be suppressed using other nutrients, and grave consequences of this mass miseducation on public health.

Due to its bias against nutrition the USPTO issued a dozen improper rejections, citing remotely related art as anticipatory under 35 USC § 102 and applying obviousness rejections under 35 USC § 103 despite opposite teachings in the prior art. None of the rejections could not be sustained. The obviousness rejections were particularly improper since the '034 Application itself evidences that the subject matter is poorly understood, that there are opposite teachings in the prior art, and that the long-felt critical public health need remains unmet (e.g., see Annex A paragraphs [0006]-[0007]). Furthermore, even the art cited by the USPTO teaches the opposite of the claimed subject matter (discussed below).

However, then the USPTO resorted to *excising limitations* from the claims, *mutilating* the law, and *reconstructing* the prior art and products of nature to allege anticipation by nature under § 101—applied for the first time in 7th Office Action in October 2013. The Examiner issued final rejection on September 22, 2015, ***rejecting all 55 claims² under § 101*** over alleged anticipation by *alleged* “products of nature”, *individual oils*, olive oil (Annex B) and walnut oil (Annex C), each separately, and ***rejecting 52 claims (except Claims 102, 107, and 119) under § 102*** over alleged anticipation by *individual fruits/nuts*, olives (Annex D) and walnuts (Annex E), each separately.

Some claims were also rejected over alleged anticipation by U.S. Patent No. 5,549,905 (“Mark”) (Annex F). Applicant³ submitted reams of arguments and evidence including skilled person’s testimony that Mark does not anticipate, however, Mark is not dispositive in any case since most claims (e.g. independent Claim 91 and dependent claims, and dependent claim 82 which can replace claim 65) are not rejected under Mark.

Patent Trial and Appeal Board affirmed Examiner’s rejections on April 15, 2016 (Annex G) and denied Rehearing on June 21, 2016.

² See full claim chapter of the rejected claims at the end of Annex A.

³ “Applicant” refers to Asha Nutrition Sciences, the assignee of the application, and “inventor” and “I” refers to Urvashi Bhagat, the undersigned throughout this paper.

Independent Claim 65 rejected under § 101 (allegedly anticipated by olive oil) and under § 102 (allegedly anticipated by olives) recites:

A lipid-containing formulation, comprising a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater, contained in one or more complementing casings providing controlled delivery of the formulation to a subject, wherein at least one casing comprises an intermixture of lipids from different sources, and wherein

- (1) omega-6 fatty acids are 4-75% by weight of total lipids and omega-3 fatty acids are 0.1-30% by weight of total lipids; or
- (2) omega-6 fatty acids are not more than 40 grams.

Dependent Claim 102 *solely* rejected under § 101 (i.e., not anticipated by any product of nature, including olives or walnuts or their oils but allegedly still a product of nature because it is obtained by mixing naturally occurring omega-6, omega-3, and omega-9 fatty acids) recites:

The formulation of claim 65, wherein the dosage of total fat is 10-100 grams, the dosage of omega-6 fatty acids is from 1 to 40 grams; the dosage of omega-3 fatty acids is from 0.1 to 5 grams, the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 1:1 to 3:1, the ratio of monounsaturated fatty acids to saturated fatty acids is 1:1 to 5:1, the ratio of omega-9 to omega-6 fatty acids is in the range of 1:1-3:1, and the ratio of omega-6 to omega-3 fatty acids is in the range of 4:1 to 45:1.

Independent Claim 91 rejected under § 101 (allegedly anticipated by walnut oil) and under § 102 (allegedly anticipated by walnuts) recites:

A lipid-containing formulation, comprising a dosage of omega-6 fatty acids, wherein the omega-6 fatty acids are greater than 20% by weight of the total lipids, contained in one or more complementing casings providing controlled delivery of the formulation to a subject, wherein at least one casing comprises an intermixture of lipids from different sources, the formulation comprising polyunsaturated, monounsaturated, and saturated fatty acids, and wherein the formulation includes at least

- (i) one or more polyunsaturated fatty acids selected from [omitted], and
- (ii) nutrients including at least
 - (a) one or more polyphenols, or
 - (b) one or more phytochemicals,
 the one or more phytochemicals being selected from [omitted].

Thus, USPTO obstructed *critical innovation* directed to specific *formulations* comprising *intermixtures in casings* and *dosages of lipids*—that is “*composition of matter*” and “*manufacture*” and “*process*”—over individual foods contrary to 35 USC § 101. Critical does not mean unpatentable or “product of nature;” further, nature being highly unpredictable in nutrient (lipid) content is incapable of providing “dosage” of anything, let alone tailor it for subjects (discussed below).

Further, § 102 was applied though *identical* invention as claimed is not disclosed and enabled in either of olives, walnuts, or their oils, or Mark, and a competitor could *not* obtain the claimed subject matter from the prior art and that the prior art does *not necessarily* function as claimed. Congress created § 103 in the 1952 Patent Act for such rejections, but USPTO applied the rejections under § 102 because § 103 rejections could not be sustained due to unexpected results and opposite teachings in the prior art, i.e. USPTO circumvented the law. The impropriety of the rejections is discussed further in Sections III.5 and IV.1-2.

United States Court of Appeals for the Federal Circuit rubberstamped USPTO on March 16, 2018, contrary to Title 35 USC and a large body of its own and Supreme Court precedents without a meaningful review, as required by Administrative Procedure Act, issuing a non-precedential opinion (Annex H) so as to not affect the case law *singling out this case for injustice*, and denied the Petition for Rehearing and Hearing En Banc (Annex I) on June 1, 2018, heedless to the Amicus Brief submitted on May 9, 2018, and despite the opinions of well-known patent lawyers that the case was improperly decided (see Addendums to Annex I). Applicant submitted an Open Letter to Director Andrei Iancu at USPTO and Chief Judge Sharon Prost at the Federal Circuit, on April 27, 2018 asserting that USPTO's and the Federal Circuit's actions were improper (Annex J).

Petition for a Writ of Certiorari was submitted to the Supreme Court of the United States on August 29, 2018 (Annex K) (case no. 18-277) supported with an amicus brief submitted on October 5, 2018 (Annex L), and a Supplemental Brief on October 22, 2018 (Annex M). The Supreme Court denied the acceptance of the amicus brief for being one day late and the Petition on October 29, 2018.

In view of extreme abuse of discretion in examination and appeal review, Petition for a Writ of Mandamus was submitted to the Supreme Court on March 30, 2019 (Annex N) (case no. 18-1274). An amicus brief was submitted on May 3, 2019 (Annex O). The Supreme Court denied the Petition on May 13, 2019. Petition for Rehearing for Writ of Mandamus was submitted on June 7, 2019 (Annex P), which was denied on July 15, 2019.

In view of intervening circumstances in the form of the US Senate's recently published proposed language to reform Title 35 U.S.C. § 101 based on problematic behavior of the USPTO and the lower courts⁴, Petition for Rehearing for the Writ of Certiorari (case no. 18-277) was submitted to the Supreme Court on July 11, 2019 (Annex Q), which is currently pending.

⁴ <https://www.tillis.senate.gov/services/files/E8ED2188-DC15-4876-8F51-A03CF4A63E26>

II. The Claimed Inexpensive Innovative Solution— *Formulations of Tailored Lipid Dosages!*

The claimed inexpensive innovative solution is *formulations of tailored lipid dosages*, particularly of omega-6 fatty acids—**more critical for health than milk at any age and more crucial for protecting and enhancing public health than the most effective healthcare plan**, whether we call it “universal health care”, “Medicare for all”, or by any other name, particularly in view of the mass chaos in the art.

Chronic diseases and preventable medical conditions cost about \$3.7 trillion annually in the United States⁵. Almost all chronic diseases are associated with improper intake of lipids (fatty acids, certain vitamins like A, E, D, K, and certain phytochemicals like sterols and polyphenols) evidenced by 100s of studies conducted in past 100 years⁶. This is because lipids are crucial components of cell membranes in animal body and play critical role in many physiological functions. For example, they are involved in gene regulation, and their derivatives are important hormones and biological messengers, affecting functions such as blood vessel dilation, platelets aggregation, pain modulation, inflammation, and cell growth. Therefore, when lipid intake is corrected by delivery of tailored lipid dosages by subject type, the foundation of health is corrected, hormonal balance is corrected, and immunity is strengthened and susceptibility to infections is reduced.

Therefore, *the claimed inventions can substantially reduce the suffering of 117 million Americans from chronic diseases and of 80% of women from hormonal issues and can complement Government sponsored healthcare.*

Americans are literally put under a knife in cardiovascular surgery and subjected to drugs and devices (treatments) in diabetes, because *treatments are made more financially rewarding by preferentially giving them patents/exclusive markets*, and *preventative solutions such as claimed tailored lipid dosages are denied patent protection and therefore effective implementation*. For example, why are we throwing medications on people who have mild depression or on young women suffering from premenstrual syndrome, which can be significantly abated with correct lipid delivery? Same with,

- 90 million people suffering from diabetes or pre-diabetes,
- 54 million people with arthritis,
- 26 million people with asthma, and so on...

If a business is paid \$10,000 or like for treatments favored by the patent system, why would they provide lipid dosages for \$100 or like? It is basic economics!

⁵ Milken Institute, “The Cost of Chronic Disease in the U.S.,” May 2018.

⁶ E.g., see Baum et al., “Fatty acids in cardiovascular health and disease: A comprehensive update” *Journal of Clinical Lipidology* (2012) 6, 216–234; Bhagat U. Das UN. “Potential role of dietary lipids in the prophylaxis of some clinical conditions” *Arch Med Sci* 2015; 11, 4: 807–818 (Annex Y).

However, when preventative solutions such as tailored lipid dosages are given patent protection, the limited exclusivity allows higher product margins and a protected period to recover investment in the required novel infrastructure for the novel product platform.

Ultimately, we all win by implementing such critical preventative solutions:

- when prevention is in full gear, we can reallocate resources (currently usurped in treatment) to find cure to ailments that cannot be prevented, potentially benefiting “treatment businesses”;
- reduction in suffering from disease increases productivity and per capita income;
- reduction in suffering from disease increases productivity and Gross Domestic Product; and
- reduction in suffering from disease increases productivity and per capita income and in turn increases taxes earned by the Government.

Patents for Humanity Application was submitted to USPTO on November 8, 2015 (Annex R) asserting the importance of the innovation particularly for the impoverished populations. Additionally, eleven testimonies from esteemed scientists are on record testifying that the claimed solutions are extremely important for public health (a subset of which is included as Annexes S-X).

In his testimony of September 29, 2014 (Annex U), Dr. Rustagi testified:

“Thus, the art recognized in 1929 that the problem existed as noted in paragraph [0019]. However, the art has failed to solve the long-felt, critical and unmet need until the April 2008 priority date of the subject patent application, i.e. for ~80 years. There have been many persistent attempts as evidenced by the references cited above (e.g. Mark et al., whfoods.com, Lands 1986 and 2005; Simopoulos 1999; Hamazaki et al., 2003 supra), but the problem has not been solved. Lipid art has been struggling to find what are the right combinations of omega-6 and omega-3 and other lipids for consumption, how to keep the fatty acids stable on shelf (without formation of toxic compounds) but bio-available in-vivo (Chen and Chaiyasit supra). Inventions of instant claims 65, 91, 98, 122, 129, and 130 have devised the solutions. Thus, the invention of the subject patent application solves a long-felt critical persistent unmet need, and has great potential to protect and improve public health.” See para [0019]-[0023].

“[The technologies]... are well-reasoned and directed at much needed lipid solutions, particularly in light of mass erroneous teachings and confusion in the lipid art.” See para [0026].”

Drs. Robert Rucker and Undurti Das have given similar testimony, which is on record at USPTO and was submitted to the Federal Circuit in the Joint Appendix.

III. Why Are Tailored Lipid Dosages Not Implemented Given the Momentous National Importance?

It is self-evident from our daily lives and the prosecution history at USPTO (discussed above and below) that the innovation described above has not been implemented despite the momentous national implications.

The reasons include:

1. Certain aspects of the science are not well understood.
2. Misconception that teaching and publication of tables listing lipid content in common foods is sufficient.
3. Tailored lipid dosages are difficult to implement.
4. Tailored lipid dosages are economically infeasible business without sufficient patent scope.
5. The patent system disfavors proper patent grant to nutritional solutions
6. Special interest groups including the patent system thwart preventative efforts.

Each of the above points is further elaborated below.

1. Certain Aspects of the Science are Not Well Understood

There is mass misinformation both in the popular and scientific media as to what constitutes proper lipid intake.

Prior to 2008 (the priority date of '034 application) scientists understood that lipids are important for health, but they failed to understand the relative importance of various lipid classes and total lipid intake. For example, prior to 2008, scientists overwhelmingly taught to reduce intake of omega-6 family of fatty acids and increase the intake of omega-3 family of fatty acids, because omega-6 was widely believed to cause inflammation and numerous diseases and omega-3 was believed to be anti-inflammatory and counter the effects omega-6⁷. Prior to 2008, low omega-6 to omega-3 ratios like 1:1 or 2:1 were widely taught and very low dosages, for example *less than 1g* (less than 1% of calories) were taught⁸. Moreover, whenever prior art found another nutrient that inhibited the activity of omega-6 fatty acids, they recommended increased intake of such a nutrient⁹.

⁷ Simopoulos et al., "Essentiality of and Recommended Dietary Intakes for Omega-6 and Omega-3 Fatty Acids" *Ann Nutr Metab* 1999;43:127-130 (Annex Z).

⁸ *Lands WE. "Dietary Fat and Health: The Evidence and the Politics of Prevention"* *Ann. N.Y. Acad. Sci.* 1055: 179-192 (2005), (page 183, para 4) (Annex AA).

⁹ Wu D. et al., *Am J Physiol Cell Physiol* 275:661-668, 1998; Shah et al., *Biochemical Pharmacology*, Vol. 58, pp. 1167-1172, 1999; O'Leary et al., *Mutation Research* 551 (2004) 245-254.

Such teachings were reported in numerous scientific publications, numerous patents were issued to high omega-3 containing formulations and methods of treatment¹⁰, and many mainstream publications advocated high use of omega-3¹¹. Many companies marketed and profited from such products containing high amounts of omega-3. For example, Lovaza (omega-3) was marketed by Reliant Pharmaceuticals (sold to GlaxoSmithKline for \$1.6 billion in 2007).

In early 2000s, motivated by my own mother's suffering from neural disease and premature death, I investigated the effect of relative intake of various lipids in live subjects and was astonished to find that such a large body of scientists had been incorrect and that they had endangered public health at such a large scale¹². I found dosage of omega-6 to be most important for health, dependent on age, gender, bodyweight (e.g., greater than 5% of calories, noting that % of calories is not synonymous with dosage) and that omega-3 requirement for health was very low and its benefits were ephemeral, that long-term effects of fatty acids were different from short-term, that ratios of omega-6 to omega-3 should be at least 4:1 and could be very high such as 50:1, that the dosage was the most important factor. For example, if we kept the dosage of omega-6 for an adult female below 20g/day, the ratio became less relevant, but that high relative amounts of omega-3 interfered with omega-6 actions. I also found that initial increase in omega-6 from deficient state caused unfavorable symptoms but that health improved after the body adjusted to higher dosage of omega-6.¹³ This explained the prior art had failed to understand the dose-effect of omega-6.

Understanding the dose-effect was an important finding, which the prior art had failed to understand. The prior art held that there was a proportional increase in adverse health with step-wise increase in omega-6 in the range of 0.5 to 4.4% of calories¹⁴, therefore "ingestion of about 1 percent of daily calories" or even "0.5-1.0% of calories"—0.9-1.9g/day based on 1700-calorie diet—met the omega-6 requirements¹⁵.

However, my experiments demonstrated that omega-6 greater than 11g/day (for adults) was required to overcome adverse health, and that the deficiency of omega-6

¹⁰ US Patent 7759507 (Jul 2010), teaching "omega-6 to omega-3 LCPUFAs of about 0.25:1 to about 3:1" (col 3).

¹¹ "A New Way of Looking at Proteins, Fats and Carbohydrates"

<http://web.archive.org/web/20070104020351/http://whfoods.com/genpage.php?tname=faq&dbid=7#polyun> mainstream public education website, The World's Healthiest Foods (WHFoods.com), run by The George Mateljan Foundation (non-profit) teaching, "ideal ratio of omega-3 to omega-6...is estimated to be around 1:2" (Annex AB).

¹² Bhagat U, "Denying Patents on Applications of Discoveries Puts Public Health at Risk" published online at <https://www.ipwatchdog.com/2018/10/04/denying-patents-discoveries-puts-public-health-risk/id=101994> October 4, 2018 (Annex M)

¹³ The'034 Application, Examples 11-27 (Annex A).

¹⁴ Ip et al., "Requirement of Essential Fatty Acid for Mammary Tumorigenesis in the Rat"; Cancer Research 45, 1997-2001, May 1985.

¹⁵ Lands, Nutrition Reviews 1986:44-6:189-95; and Lands WE. "Dietary Fat and Health: The Evidence and the Politics of Prevention" Ann. N.Y. Acad. Sci. 1055: 179-192 (2005)

potentiates certain mechanisms, such that sudden increases in omega-6 have an overflow effect which can lead to myocardial infarction, strokes, infections, and physiological disturbances¹⁶. Later publications corroborated my findings.¹⁷

Thus, prior art was motivated to reduce subject's omega-6 intake because increases in omega-6 produced undesirable health effects. Skilled persons could not predict that higher levels of omega-6 fatty acids would produce desirable health effects, therefore, skilled person in prior art could not determine and practice the suitable dosages of omega-6 and omega-3 fatty acids for a subject taught in the subject applications.

I also found high amounts of omega-9 (monounsaturated fatty acids) to lead to adverse health, and phytochemicals and antioxidants to increase requirement for omega-6 and reduce requirements/tolerance for omega-3.

These discoveries were momentous because they set the stage for many more discoveries. Based on my discoveries I filed for patents in April 2008. The discoveries are explained in the above referenced applications (e.g., Annex A). The subject applications are intentionally written in layperson terms to raise awareness among the general public.

In his testimony of October 7, 2012 (Annex S), Dr. Erickson testified:

“The subject application contains very important focal points that were not understood prior to this disclosure. Most important of those as discussed above is that the prior art failed to fully understand the importance of omega-6 for health. Human and animal tissue contains many times omega-6 as compared to omega-3. Omega-3 can be preferentially metabolized. However, omega-6 has a shorter in-vivo life, possibly due to myriad of critical metabolites for which it is a precursor. Therefore, a lot more omega-6 is usually required as compared to omega-3. This disclosure indicates that deficiency of omega-6 is a greater problem. The disclosure focuses on the fact that certain nutrients including antioxidants and phytochemicals can effectively enhance omega-3 bioactivity in-vivo but inhibit the metabolism of omega-6. The risks of sudden increase of omega-6 or withdrawal of omega-3 have been explained, which was not previously appreciated or incorporated into dietary strategy. Prior dogma held that omega-6 causes disease, whereas this disclosure explains that the deficiency of omega-6 potentiates certain mechanisms, such that sudden increases in omega-6 have an overflow effect which can lead to myocardial infarction, strokes, infections, and physiological disturbances. Several examples have been given to manage menopause, sleep disorders, neural disease, mental function, musculoskeletal disorders, obesity, diabetes, digestive, reproductive, pulmonary, ophthalmologic, dermatologic, and immune functions. These are

¹⁶ The'034 Application, Examples 11-27 (Annex A).

¹⁷ Lu et al., Lipids in Health and Disease 2010:9:106.

multiple significant discoveries. Novel methods of treatment, administration, use, and tailored preparation are also disclosed. Because omega-6 and omega-3 significantly impact the structure and function of multiple physiological processes, correct delivery has a beneficial effect on many diseases. Sufficient directions are provided for the practitioner in the disclosure.” Para [0023].

Subsequent to April 2008 priority date of the subject application the state of the art started to change. American Heart Association issued an advisory in 2009 to correct the perception that omega-6 are unhealthy¹⁸. In 2010, the US Department of Health and Human Services increased the recommended omega-6 intake in its Dietary Guidelines for Americans. Yet they did not teach all features in our applications and claims. Further, teaching is not sufficient as explained below.

2. Misconception That Teaching and Publication of Tables Listing Lipids in Foods Is Sufficient

Though the disclosure in our applications can be followed by general public, it is extremely difficult for public to obtain suitable dosages of lipids.

First, the public continues to be *mised* to believe that foods come with set nutrient (lipid) content as published in various tables listing nutrients in foods, such as olives and walnuts in Annexes B-E. In reality, nutrient content in foods varies based on genetics and epigenetics, and cultivating conditions, such as soil used, fertilizer used, hours of sunlight, and water composition, and from production batch to batch¹⁹. For example, olives have been found to have 3.5-21% omega-6 fatty acids content,²⁰ walnuts similarly vary in lipid content²¹. Therefore, all the published nutrient tables are giving us is nutrient content in the *tested batch* of the type of food, such as olives or walnuts.

Second, less than 1% of public can even name lipids—in a survey less than 1% of Americans correctly named six fats considered to be solid.²² How can we expect them to consider minor lipids such as vitamins like A, E, D, K, sterols, and polyphenols present in foods that are potent in micrograms²³, particularly from oils because they are absorbed differently than whole foods?

Finally, it is too complex for the public to formulate lipid dosages for different family members on a daily basis.²⁴

¹⁸ Harris *et al.*, *Circulation* 200, 119:902-907.

¹⁹ Erickson testimony, January 31, 2014, para [003] (Annex T).

²⁰ The Olive Oil Source, <https://www.oliveoilsource.com/page/chemical-characteristics#Fatty>

²¹ Tsao *et al.*, “Fatty Acid Profiles, Tocopherol Contents, and Antioxidant Activities of Heartnut (*Juglans ailanthifolia* Var. *cordiformis*) and Persian Walnut (*Juglans regia* L.)” *J. Agric. Food Chem.* 2007, 55, 1164-1169.

²² International Food Information Council Foundation, 2011 Food & Health Survey.

²³ Tsao *et al.*, *supra*.

²⁴ Bhagat and Das (Annex Y).

3. Tailored Lipid Dosages are Difficult to Implement

Tailored lipid dosages are difficult to implement because of the points made above in Section III.2. For example, how to tailor lipid dosages despite unpredictability in food sources, how to control dosages of minor lipids such as vitamins like A, E, D, K, sterols, and polyphenols, how to create a spectrum of products keeping total lipid intake in check, giving consumers a regimen but with variations to maintain flexibility and gastronomic appeal, and how to make it work in daily life?

The complexity of the products necessitates a novel commercial structure under the direction of skilled persons.

4. Tailored Lipid Dosages are Economically Infeasible Business Without Sufficient Patent Scope

The complexities described in Sections III.2 and III.3 in formulating and implementing tailored lipids dosages make implementing these solutions economically infeasible without sufficient patent scope. The profit margins in food products are too thin to support recovery of investment in specialized products necessitating novel infrastructure and public teaching to rise above the noise created by 1000s of oils, oil mixtures, nut mixtures, and supplements on the market.

However, when the innovative tailored lipid dosages are given sufficient patent protection, the limited exclusivity allows marketing the products at higher margins, making it feasible to invest in the novel infrastructure and public teaching.

5. The Patent System Disfavors Proper Patent Grant to Nutritional Solutions

There is a most definite bias against nutrition in the patent system evidenced by the prosecution history of the '034 Application at USPTO, the appeal review at the Federal Circuit, and the refusal of the Supreme Court to accept the petitions for review despite clear violations of the law and abuse of discretion.

USPTO's unwillingness to grant proper patent protection to nutrition solutions is evidenced by the following in the subject applications:

1. Despite the fact that claims were drawn to linking features—dosages fatty acids for ingestion by a subject—numerous restrictions were placed on the claimed subject matter forcing divisional application filing.²⁵
2. Alleged that claims are not patentable being drawn to recipes²⁶, though they are drawn to mixtures comprising determined dosages of lipids based upon subjects.

²⁵ USPA 12/426,034 Office action dated October 14, 2010, p. 2.

²⁶ Office Action of October 11, 2013, p. 15.

3. Arbitrarily selected *only* the narrowest embodiments of oil mixtures for patent grant²⁷
4. Several limitations were excised or discounted from the claims in order to limit the allowable subject matter to certain oil mixtures.²⁸ (See Section IV).
5. Arbitrary §§ 101 and 102 rejections were forced and maintained despite strong rebuttals with arguments and evidence.²⁹ (See Section IV).

Additional pressure was placed upon the Applicant during interviews in form of the following statements from USPTO, in order to force narrow position:

- The subject claims are inherent in nutrition.
- Patents on omega-6 and omega-3 have to be restricted because many people work with them.

However, inherency can only be alleged if the prior art (nutrition) necessarily functions as claimed, which it does not. Rather the art overwhelmingly teaches the opposite, including in the cited references, as demonstrated above in Section III.1 and below in Section IV.1.

Further, restricting patents on omega-6 and omega-3 because many people work with them all but ensures that there will never be any meaningful advancement in this art. Many people work with restricted formulations is precisely why there is so much confusion and so much noise in the art. Everybody enters the market place and sells products based on the artificially patent-created boundaries, marketing to masses with conflicting marketing messages. This is how omega-3 got out of hand and hyped out of context in the first place, because many restricted patents on omega-3 have been issued.

The restrictions are in part because of USPTO's revenue maximization drive. Higher number filings, restricted patent grants, and divisional applications, all increase revenue to USPTO. Therefore, USPTO is happy to give composition A to Party-1, composition B to Party-2... and composition ZZZ to Party-nnn. These restrictions especially are applied to nutrition patents. This keeps revenue rolling in to USPTO and inventors given token patents and some revenue stream, but public confused, ill, and on drugs, because nobody truly gets the head or the tail and a system is set that perpetuates confusion.

Most important goal of USPTO is advancement for the betterment of human condition, revenue comes second. If USPTO inhibits advancement for revenue, then USPTO is failing its goal.

²⁷ USPA 12/426,034 Interview Summary mailed by USPTO on January 31, 2014, finding only narrow oil mixtures (3) and (4) in then claim 91 to be allowable.

²⁸ USPA 12/426,034 Office action dated March 10, 2015, p. 4-6.

²⁹ USPA 12/426,034 Office actions dated September 22, 2015 and PTAB Decision dated April 15, 2016 (Annex G).

This unfavorable treatment of nutrition patents is also evident from the Federal Circuit's review of the appeal in case of the '034 Application. For example, the Federal Circuit Opinion (Annex H) states at middle of page 5,

The Board found that the "casing" and "dosage" terms do not impart patentability to the claimed compositions, and we agree, for the specification states that these claim elements are not limiting, and does not describe any assertedly novel characteristics of these components or their formulations.

The allegation that the limitations "casing" and "dosage" are "not limiting" is in violation of a large body of the Federal Circuit's own and Supreme Court's precedents and ruthlessly obliterates the Specification. For example, in *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-81 (Fed. Cir. 1995) (en banc) the Federal Circuit stated,

"Both this court and the Supreme Court have made clear that all elements of a patent claim are material, with no single part of a claim being more important or "essential" than another. See *Fay v. Cordesman*, 109 U.S. 408, 420-21, 3 S.Ct. 36, 243-45, 27 L.Ed. 979 (1883); *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 936 (Fed.Cir.1987) (in banc)."

Further, the Specification never said that "these claim elements are not limiting". The importance of "dosage of omega-6" is the most important feature in the Specification, emphasized throughout, especially in tables 10-14 and 21, Examples 11-27 and original claim 3. Specification paragraph [00106] specifically states, "It is intended that the following claims define the scope of the disclosure."

Then on what basis did the Federal Circuit decide that "casings providing controlled delivery of the formulation to a subject" and "dosage" recited in the claims is not limiting?

Additionally, the Federal Circuit itself has ruled in a large number of cases (see Section IV.1.iii-ix below) that the prior art must necessarily function as claimed and a competitor must be able to obtain the claimed subject matter from the prior art to be considered anticipatory.

Then on what basis did the Federal Circuit opine contrary to its own holdings?

Furthermore, in *Berkheimer v. HP, Inc.*, 881 F.3d 1360 on February 8, 2018, in case of a software patent (one month before issuing the problematic opinion in case of the '034 Application), the Federal Circuit held,

"The question of whether a claim element or combination of elements is well understood, routine and conventional to a skilled artisan in the relevant field is a question of fact. Any fact, such as this one, that is

pertinent to the invalidity conclusion must be proven by clear and convincing evidence. *See Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011)...Whether a particular technology is well-understood, routine, and conventional goes beyond what was simply known in the prior art. The mere fact that something is disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional.”

Yet in case of '034 Application, which repeatedly asserts that the subject matter is poorly understood (e.g., see paragraphs [006]-[007], Annex A) and despite eleven testimonies from skilled persons to this effect (see subset in Annexes S-X) and numerous publications (Annexes Y-AB), and the cited art itself teaching the opposite, the Federal Circuit uttered not even a single word about this in its opinion (Annex H). In face of all the evidence, the Federal Circuit rather apathetically stated, “claims are directed to the omega-6 and omega-3 fatty acids that occur in nature” (Annex H, p. 12), disregarding the numeric limitations in the claims.

Further, *exactly one day* after the Federal Circuit affirmed *Berkheimer v. HP, Inc.*, refusing to rehear the case by a near-unanimous *en banc* decision (May 31, 2018), the Federal Circuit refused to reconsider its *exact opposite ruling* in the present case upon the Petition for Rehearing and Rehearing En Banc on June 1, 2018 (Annex I).

These violations of the USPTO and the Federal Circuit have been repeatedly called to the attention of the Supreme Court in several petitions (see Annexes K-Q). The Supreme Court has turned a deaf ear, thus far.

Thus, the entire US patent system disfavors patent grant to nutritional solutions, which the rest of the world follows, creating unfavorable economics for prevention and grave patent-practice-made humanitarian crises. See discussion below in Section V.

6. Special Interest Groups Including the Patent System Thwart Preventative Efforts

It is self-evident that the treatment industry, the sellers of drugs and devices and the providers of surgical and other procedures, work against preventative efforts such as tailored lipid dosages, but that the patent system run by the Government of the United States would thwart such efforts, as evidenced above and below is most disturbing. Significant patent scope is not only necessary to rise above the noise in the art, but also to fend off the efforts of those who undermine such efforts. Therefore, at least the Government should not compromise the effort by unnecessarily restricting the nutrition patents.

IV. Mutilation of Title 35 USC in Examination and Appeal Review of the '034 Application

1. USPTO Mutilated Title 35 of the United States Code and a Large Body of Case Law to Sustain Rejections

USPTO mutilated the law and wiped out the separation between 35 USC §§ 101, 102, and 103, usurping Congress' power and purpose behind those separations to an extreme that has never been done before.

In *six Office actions* over several years USPTO was unable to sustain § 102 rejections because no prior art taught identical claimed features, and § 103 rejections could not be sustained because of new insights presented, disadvantages predicted in the prior art, unexpected results, and opposite teachings in the prior art and critical unmet public health need. Thereafter, in the *7th Office action* in October 2013 and onwards USPTO mutilated the claims and the law and *forced* §§ 101 and 102 rejections.

As evidenced in Section III.1 above, prior to April 2008 the art overwhelmingly taught the opposite of the claimed inventions: low intake of omega-6 and low omega-6 to omega-3 ratios, and high intake of omega-9 (monounsaturated fatty acids), and failed to understand peculiar dose-effect of omega-6. A prior art teaching the claimed combinations has not surfaced in 10 years of worldwide prosecution of the corresponding applications. This bears out in *all* of the citations by USPTO.

For example:

- Cited arts under § 101: Olive Oil (Annex B) and Walnut Oil (Annex C) are interactive webpages describing nutrient content in a batch of each oil in capacity measures ranging from 1 tsp to 1 cup, and 4g to 100g. That is neither are the references teaching “dosage [amount determined for administration]” of omega-6 and omega-3, nor are the references teaching “intermixtures of lipids” in “casings” to control lipid content/delivery or provide daily variety as taught in Specification (Annex A, e.g., paragraph [0030] and Table 3).
- Cited arts under § 102: Olives (Annex D) and Walnuts (Annex E) found on archives of whfoods.com webpages also describe nutrient content, specifically reciting “Nutritional Profile” on each of the main pages of Olives and Walnuts and “In depth nutrient analysis” on the associated pages. Furthermore, under “How to Enjoy” each of the Olives and Walnuts pages teach mixing olives/ walnuts with other foods and the website teaches “ratio of omega-3 to omega-6...around 1:2...decrease the

amount of omega-6 fatty acids in your diet, while increasing the amount of omega-3 fatty acids” (Annex AB).

- Cited art under § 102: Mark (Annex F) is inoperable and it teaches little of relevance to current claims because it teaches contradicting omega-6 to omega-3 ratios in col.2.ll.37-38 versus col.4.ll.21-25; it teaches incomplete lipid profile in the table in column 4 (86% of fatty acids in line 60); it gives an inoperable table in column 6 (“whey” is 100% yet other ingredients are present); it does not teach dosage of omega-6; and it does not teach the effect of other lipids on the requirements of omega-6. Skilled persons have testified to Mark’s inoperability and their inability to arrive at the claimed inventions from Mark. See Annex T para [004], Annex U para [005] and [0022], Annex V para [0010] and [0013], Annex W para [009]-[0017], and Annex X para [3.3.10., and 3.4].

In order to support the rejections, USPTO gave no weight to the limitations “formulation”, “dosage”, and “casings providing controlled delivery of the formulation to a subject, wherein at least one casing comprises an intermixture of lipids from different sources” and alleged that “intermixture of lipids from different sources” is a product-by-process limitation.³⁰ Similarly, many limitations were written out of the claims, for example, “daily amounts of fatty acids for the subject based on one or more factors selected from...” from Claim 98.

Further, even after *admitting* that the combination of ratios recited in Claim 102, 107, and 119 does not occur in nature, USPTO rejected the claims under § 101 for *combining* fatty acids that occur in nature into the formulation of the claims.³¹

Furthermore, not only did USPTO erroneously treat oils as “products of nature”³² but they also improperly treated the man-made instructions on the webpages as “product of nature.” All 55 claims were ruthlessly rejected as being drawn to “products of nature,” and patent ineligible under § 101. (See claims at the end of Annex A and USPTO Decision at Annex G).

After excising limitations, USPTO alleged that Applicant had not demonstrated marked structural differences or transformation over Olive Oil or Walnut Oil, citing *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948) and *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.* 133 S. Ct. 2107 (2013).³³

³⁰ PTAB Decision dated April 15, 2016, pp. 7—9 (Annex G).

³¹ Final Office action dated September 22, 2015, p. 36.

³² Oils are not products of nature; they are made from nuts/seeds and have different properties and nutrient content from nuts/seeds. Extensive arguments and evidence to this effect are on record.

³³ PTAB Decision dated April 15, 2016 pp. 9-14 (Annex G).

Both the citations of Funk Bros. and Myriad under § 101 were contrary to 35 USC § 101 and Congress' intent!

Funk Bros. was decided under the now obsolete 35 USC § 31 (1946) that governed both patent-eligibility and novelty, which described “Inventions Patentable” as:

“Any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvements thereof...not known or used by others in this country, before his invention or discovery thereof, and not patented or described in any printed publication in this or any foreign country, before his invention or discovery thereof...”

Congress using *its authority* had revamped Title 35 USC via the 1952 Patent Act, setting up separate standards for eligibility under § 101 and for novelty under § 102, and introducing new standards for non-obviousness under § 103. The 1952 act was enacted precisely because having eligibility and novelty decided together under one section was problematic, and because there was great ambiguity in what it means to “invent.” Congress after great deliberations decided that among conditions for patentability non-obviousness was the correct statutory standard rather than “invention” because “invention” is meaningless and lacks clarity³⁴ and accordingly set the standards in § 103.

Congress set the test for patent eligibility under Title 35 USC §101 of the 1952 Patent Act as:

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

Noticeably missing from §101 are the word “structural difference” or “transformation” as a precondition to “obtain a patent therefor”, as required by USPTO. Also, what standard of “structural difference” or “transformation” is sufficient for patent-eligibility. As with “invention,” there is no standard of “structural difference” or “transformation.”

Thus, USPTO improperly applied *Funk Bros.* where alleged want of “invention” was the issue, which was overruled by Congress via the 1952 Patent Act. Further, USPTO improperly applied *Myriad*, where the claims were drawn to isolated DNA

³⁴ “Efforts to Establish a Statutory Standard of Invention: Study of the Subcommittee of Patents, Trademarks, and Copyrights of the Committee on the Judiciary” United States Senate; Eighty-fifth Congress, First Session Pursuant to Senate Resolution 55, Study No. 7 (published 1958)

and not expressed in terms of chemical composition. Even then the Supreme Court did find man-made cDNA to be patent-ineligible in *Myriad*.

In contrast, the subject claims are most clearly drawn to man-made composites of omega-6, omega-3, and/or other lipids “from different sources,” and thus without a doubt the claimed formulations clearly fall within the ordinary, contemporary and common meaning of a “composition of matter” under § 101.

Further, the “casing” limitation also falls within the definition of a “manufacture” according to the common meaning of “manufacture” as in § 101.

Still further, the claims represent an important new and useful discovery in nutrition, and the USPTO de facto removed the word “discovers” from § 101.

USPTO usurped Congress’ power and rewrote 35 USC § 101 as follows:

“Whoever invents ~~or discovers~~ any new and useful ~~process transformation, machine, manufacture, or composition of matter,~~ or any new and useful improvement thereof, may obtain a patent therefor...”

This re-write of § 101 is an instance of extraordinary usurpation of judicial powers from interpreting statutes to completely redrafting them. It is most disturbing that the USPTO unlawfully abrogated the “discovery,” “process,” “composition of matter,” and “manufacture” language actually found in 35 U.S.C. § 101 from numerous claims at issue in favor of vague concepts “structurally different” or “transformation” or “invention” that the Congress has expressly rejected in deliberations for the 1952 Patent Act.

USPTO also usurped Congress’ power and rewrote 35 USC § 102. The rejections under § 102 are contrary to 35 USC § 102 and Congress’ intent!

The legal requirements for anticipation rejection under § 102 are very strict and rightly so. In order to anticipate the applicable prior art must disclose and enable the exact same invention with every single element as recited in the claims. The underlying principle of anticipation rejection is that public—skilled persons including competitors—has been fully informed of the exact solutions and how to practice them and there can be no doubt about this. This is built into Title 35 USC.

§ 102 states,

*“Novelty; Prior Art.—A person shall be entitled to a patent unless—
(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention...”* [Emphasis added].

In contrast § 103 states,

*“A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not **identically disclosed as set forth in section 102**, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.”* [Emphasis added].

Specificity in patent law has always been held as not anticipated by general prior art disclosure, and neither the USPTO nor the courts have had any difficulty in examining and upholding specific disclosure and enablement as not anticipated by general prior art. See representative jurisprudence below:

- i. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).
- ii. A reference disclosing “alkaline chlorine or bromine solution” embraces a large number of species and cannot be said to anticipate claims to “alkali metal hypochlorite.” *In re Meyer*, 599 F.2d 1026, 202 USPQ 175 (CCPA 1979).
- iii. Anticipation law does not permit to fill in missing limitations simply because a skilled artisan would immediately envision them. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 851 F.3d 1270, 1274 (Fed. Cir. 2017).
- iv. “Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981).
- v. The anticipation analysis asks solely whether the prior art reference discloses and enables the claimed invention.” “Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claim limitations, it anticipates.” *Perricone v. Medicis Pharm. Corp.* 432 F.3d 1368, 1376 (Fed. Cir. 2005). [Emphasis added].
- vi. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art).

- vii. In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with “sufficient specificity to constitute an anticipation under the statute.” What constitutes a “sufficient specificity” is fact dependent. If the claims are directed to a narrow range, and the reference teaches a broader range, other facts of the case, must be considered when determining whether the narrow range is disclosed with “sufficient specificity” to constitute an anticipation of the claims. Compare *ClearValue Inc. v. Pearl River Polymers Inc.*, 668 F.3d 1340, 101 USPQ2d 1773 (Fed. Cir. 2012) with *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006).
- viii. If little is known in the prior art about the nature of the invention and the art is unpredictable, the disclosure would need more detail as to how to make and use the invention in order to be enabling. *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004) (“the public’s end of the bargain struck by the patent system is a full enabling disclosure of the claimed technology.”)
- ix. “[A]nticipation under § 102 can be found only when the reference discloses exactly what is claimed and that where there are differences between the reference disclosure and the claim, the rejection must be based on § 103 which takes differences into account.” *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

Thus, there is clear and *purposeful* distinction between lack of novelty and obviousness, in that the law recognizes that in order to destroy novelty a prior art document must disclose and teach how to practice the *identical* invention then only it can be said that this is in possession of the public. Furthermore, a selected range from a broader numerical range is considered novel.

For instance, if there were a reference that exactly described and enabled a formulation to cure common cold permanently, then common cold would be cured. It would defy every conceivable logic if there is a reference that exactly describes and enables the formulation to cure common cold (e.g., dosage of compound A above X g/day), yet billions of humans repeatedly suffer the misery of common cold. Therefore, it is flawless if a reference *exactly* describes and enables claimed limitations, then such claims are not novel.

However, if exact same formulation is *not* described in the prior art, it is *not* clear what aspect of the prior formulation is problematic (e.g., how much compound A in absolute and relative to compound B), and there are *opposite teachings* to the claimed formulation (e.g., dosage of compound A below X g/day) and the public continues to suffer from the misery (like common cold), then the claimed formulation (ratio of compound A to compound B Y:1 and compound A above X g/day) can neither lack novelty nor be obvious.

Thus, § 102 requires *identical* disclosure of the claimed subject matter, which requirement is not met by Olives, Walnuts, or Mark.

USPTO excised the specific differentiating features “dosages”, “casings providing controlled delivery” and “intermixtures of lipids from different sources,” in order to force rejections under § 102 because claims were non-obvious under § 103 because of new insights presented, disadvantages predicted in the prior art, unexpected results, and opposite teachings in the prior art and critical unmet public health need.

Furthermore, USPTO reconstructed Mark that gives *no* teaching about “dosage of omega-6 fatty acids” *no* teaching of how other lipids affect the activity of omega-6 under § 102. Because Mark recited contradicting omega-6 to omega-3 ratios in col.2.ll.37-38 versus col.4.ll.21-25, and gave inoperable tables in columns 4 and 6, USPTO reconstructed Mark’s recitation “the source of omega-6 fatty acids is present in the range of approximately 4-6% of the total calories. The omega-3 fatty acid source preferably present in the range of approximately 0.8-1.2% of calories”³⁵ into ratio of omega-6 to omega-3, though same source can be source of omega-6 and omega-3 (e.g., canola oil) rendering the recitation meaningless; and USPTO reconstructed concentration (g/1000 ml) into dosage. Mark also does not *necessarily* function as an “intermixture of lipids from different sources,” reciting “a lipid source” in claim 1, 9, and 15. (See Annex F). Thus, USPTO cherry-picked Mark recitations and combined as convenient to sustain rejections.

Olives, Walnuts, and Mark rejections, which would have been applied under § 103 were applied under § 102 because § 103 could not be sustained due to opposite teachings in the art—including in Olives, Walnuts, and Mark.

In any case, Mark is not dispositive because subject Claim 91 and dependent claims, and subject Claim 82, which can replace independent Claim 65, are not rejected under Mark.

Thus, this is an *extreme case of improper rejections by USPTO* of an extremely important invention directed to “composition of matter” “dosages” and “controlled delivery” over *individual foods* under §§ 101 and 102 despite opposite teachings in the art as a whole including the cited art. Though tables describing possible content of *some* nutrients in *individual foods* are in public domain, but popular media, international scientists, various governments, and industry overwhelmingly teach to mix these foods to achieve low absolute and relative intake of omega-6 fatty acids³⁶? *In other words, the individual foods in the prior art have neither disclosed nor enabled the solutions nor solved the public suffering.*

³⁵ PTAB Decision dated April 15, 2016, pp. 19-20 (Annex G).

³⁶ Ip et al. 1985 supra; Lands 1986 supra; Simopoulos et al. 1999 supra (Annex Z); Lands 2005 supra (Annex AA); WHFoods.com (Annex AB); Wikipedia (Annex AC).

Neither would an individual food composition enable a skilled person to inevitably practice omega-6 dosages as taught in the subject disclosure based on state of the art at the time of the disclosure, nor would it be immediately apparent to skilled person to practice the dosages as taught and consider omega-6 concentration in relation to total lipids from individual foods, nor is it proper to interpret equivalents not disclosed in the references, that is a matter of obviousness. Furthermore, as evident from Annex AC, there is still debate in the art on the claimed subject matter. Therefore, at least lack of enablement in the cited art is a dispositive point to ruling non-anticipation.

Holding scope of the inventions against the Applicant USPTO rejected all claims under the pretext of §§ 101 and 102 because rejections under § 103 could not be sustained, and USPTO wiped out the separation between §§ 101, 102, and 103 and usurped Congress' power and purpose behind the separations.

2. US Court of Appeals for the Federal Circuit Rubberstamped USPTO Without Meaningful Review as Required by Administrative Procedure Act

The Federal Circuit affirmed the USPTO in March 2016, without giving a meaningful review, and issued an evasive disjointed opinion. See Annex H.

The case demonstrates astounding breadth of abuse of discretion by the Federal Circuit at least on the following eight counts:

- i. Condoned USPTO's mutilation of the claims by excising limitations,
- ii. Condoned USPTO's rewriting of §101 to strike, "composition of matter", "manufacture", and "process" from the statute,
- iii. Condoned USPTO's requirement of "structurally different" or "transformation" under §101,
- iv. Failed to cite eligibility and anticipation law based upon which the case is decided,
- v. Failed to meaningfully review §102 rejections,
- vi. Acknowledged prosecution disclaimer of single source like olives/walnuts, then disregarded it and affirmed §102 rejection over olives/walnuts anyway,
- vii. Failed to review many claims including independent claims 91,
- viii. Dismissed eleven expert testimonies, without a word in the opinion.

The opinion jumps from one context to another inexplicably; one doesn't know which claim is being reviewed and what law is being applied. For example, at page 10 opinion states,

"The Applicant also argues that claim 128 is distinguished from natural products, and is not anticipated based on the limitation

that the compositions contain “nuts or their oils” obtained from “almonds, peanuts, and/or coconut meat.” The Board held that admixture with other natural products of known composition was not shown or stated to change the nature of the compositions, citing *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948)...The Board correctly held that claim 128 does not avoid the rejection on the ground that the claims are directed to known natural products.”

However, Claim 128 is dependent on Claim 91, which the Federal Circuit *never reviewed*. How can Federal Circuit opine upon a dependent claim without reviewing the elements of the independent claim first? Further, Funk Bros. citation against Claim 128 is the only citation under § 101 by Federal Circuit, there is no other citation even under §102. So one is left guessing as to what principles of law are being applied?

Further, at page 11 the opinion states,

Claim 102 recites specific ratios of **polyunsaturated, monounsaturated**, and saturated fatty acids. Claims 107 and 119 present the fatty acid content recited in claims 98 and 91, respectively, in Tables in the specification. The Board observed that the servings of olive oil and walnut oil shown in the references contain **omega-6 and omega-3 fatty acids in amounts within the Applicant’s claimed ranges**. Thus the Board held that the “intermixture of lipids from different sources” does not distinguish the claims from natural products because the Applicant “has not provided adequate evidence that an oil from different sources would necessarily have a composition that is different from one from the same source, nor that a different source would necessarily impart characteristics to the formulation which were absent when a single source was used.” Board Op. at *8. [Emphasis added].

However, the Federal Circuit comments above pertain to Claim 65 not claims 102, 107, and 119. For example, what do “omega-6 and omega-3 fatty acids in amounts within the Applicant’s claimed ranges” have to do with “ratio of monounsaturated fatty acids to polyunsaturated fatty acids?” The Federal Circuit *failed to answer* the argument that claims 102, 107, and 119 expressly recite numeric limitations directed “**ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 1:1 to 3:1**”³⁷, which is *not* met by olive oil or walnut oil.

³⁷ Appeal Brief p. 34, 58-59, 77-78.

It is well established that failure to answer an argument is tantamount to conceding that there is no answer. The opinion was intentionally written evasively and in a disjointed manner to evade justice, because the Federal Circuit had no answer. There is not one instance of impropriety but improprieties on all counts. The Federal Circuit's improprieties were also established above in Section III.5.

The whole point of the claimed inventions is that nature does not provide the required nutrients in desired combinations and restrictions and is unpredictable. The allegation that the claimed products occur in nature is an oxymoron. The Federal Circuit's actions demonstrate the system's bias against nutrition.

One does not expect such travesty of justice from the Federal Circuit, the second highest court in the nation. This is extremely demoralizing for the citizens, above and beyond the public health consequences.

3. Reticence of the Supreme Court of the United States

The Supreme Court has not accepted the Petition for a Writ of Certiorari (Annexes K-M) (case no. 18-277) and the Supreme Court has overlooked the extreme abuse of discretion in examination and appeal review and denied the Petition for a Writ of Mandamus (Annexes N-P) (case no. 18-1274).

In view of intervening circumstances in the form of the US Senate's recently published proposed language to reform Title 35 U.S.C. § 101 based on problematic behavior of the USPTO and the lower courts³⁸, Petition for Rehearing for the Writ of Certiorari (case no. 18-277) was submitted to the Supreme Court on July 11, 2019 (Annex Q), which is currently pending.

It is disturbing that the Supreme Court considers it more important to protect the constitutional rights of heinous criminals, see *Kennedy v. Louisiana*, 554 U.S. 407 (2008) under the 8th Amendment to not be subjected to "cruel and unusual punishment" than protecting the same rights of general public to not be put under the knife or subjected to drugs and devices unnecessarily, which happens when patent system favors patent grants to drugs over nutrition.

Additionally, the Supreme Court disregards constitutional rights of inventors to due process and equal protection of laws under the 14th Amendment. Supreme Court should have afforded the same protection of laws to the Applicant and Inventors, such as to *Dickenson v. Zurko*, 527 U. S. 150 (1999) holding "the importance of not simply rubber-stamping agency fact-finding." Id 162., and to *Myriad* finding cDNA to be patent eligible.

The Supreme Court's declinations are further travesty of justice.

³⁸ <https://www.tillis.senate.gov/services/files/E8ED2188-DC15-4876-8F51-A03CF4A63E26>

V. Patent Practice-made Humanitarian Crises

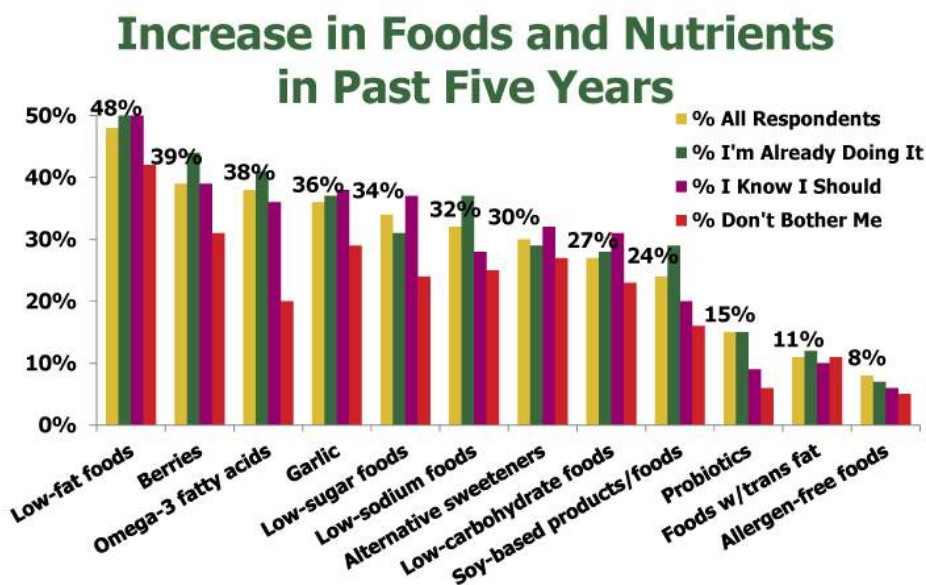
The dubious patent practices discussed above have created at least two kinds of humanitarian crises, first towards the public at large, and second towards independent inventors and small entities.

1. Humanitarian Rights Violations of Public at large

Though Title 35 USC does not differentiate patent grant to nutrition versus drugs, but as evidenced above patent practice does. If Applicant's claims were directed to a drug candidate similarly differentiated over the prior art, the patent would have been granted many years ago.

When patents are favourably granted to drugs and devices it makes them more financially rewarding, enabled by the large profit margins from prompt and strong monopoly. Then, investors, marketers, and providers heavily fund and tout drugs and devices and make public dependent on drugs and devices.

When nutrition patents are granted, they are severely restricted which causes confusion and makes the problem worse, as USPTO has done in the subject case under the pretext of §§ 101 and 102. Piecemeal patents do not solve problems and cannot advance nutritional arts. Rather, they create more confusion and excesses/ imbalances of certain foods and nutrients in the nutrition supply and individual consumption, as evidenced by Nutrition and You: Trends 2008; Survey by American Dietetic Association.³⁹



³⁹

http://www.eatrightpro.org/~media/eatrightpro%20files/media/trends%20and%20reviews/nutrition%20and%20you/trends_2008_presentation.ashx; slide 37.

For example, Applicant pointed out in examination of USPA 13/877,847 that Examiner is improperly restricting the claims to small amount in the package, rather than dosage customarily indicated on product packaging, allowing multi-dose packaging, and that the restrictions will force the pricing of the claimed consumer product out of the market and multiply packaging and create waste and burden the environment and humanity. Examiner responded that it was not her problem and forced the restriction under the pretext of clarity.⁴⁰

Thus, thousands of patents are granted on very restricted formulations and methods leading to advertising campaigns that cancel each other out and cause mass misinformation. This leads to total confusion and public stops believing everything.

Therefore, the patent system is obstructing advancement in nutrition.

The misdirected patent policy is why public has been paying for lipid patents since 1870s⁴¹ but the problem has not gone away. The very issue is that patent protection is not provided to formulated lipid dosages for subjects, which is the necessary foundation, but patent protection is provided to a restricted amount in a package, or different oil mixtures, or structurally altered molecules, or designing new oil varieties, which is of limited value because lipid content will still depend on where and how a species is cultivated.

Such missteps take us farther and farther from genuine solutions, in the meantime more harm is caused to public health. For example, it was a German patent of structurally altered fats⁴² that gave us hydrogenated fats and caused worldwide diseases for 100 years⁴³, which activity is still ongoing⁴⁴ despite damage caused previously.

Thus, occasionally, some oils, mixtures, molecules are promoted but then they realize it does not solve the problem or causes more problems and come back to square one. The result is lipid delivery to public has not substantially advanced in 6000 years, since invention of oils. Though oil manufacturing has advanced, but to date random oils are randomly added to foods.

Thus, the patent practice is skewing the marketplace in favor of drugs and devices and taking public farther from prevention, while the public continues to suffer. As noted above 117 million Americans from suffer from chronic diseases and 80% of women suffer from hormonal issues, which can be abated by tailored lipids.

This is a humanitarian crisis from which public has been suffering for at least 100 years, since industrialization of nutrition started to prevail. If patents were equitably granted to nutrition and drugs, then at least nutrition and prevention

⁴⁰ USPA 13/877,847 Office action dated August 13, 2018, p. 20-21.

⁴¹ <https://en.wikipedia.org/wiki/Margarine>

⁴² https://en.wikipedia.org/wiki/Wilhelm_Normann

⁴³ <https://en.wikipedia.org/wiki/Crisco>

⁴⁴ E.g., U.S. Patent 9,351,502 "Oxidized and partially hydrogenated oil or fat" issued May 31, 2016

have a fair chance. However, in the current scenario, where the patent system has compromised and sabotaged efforts such as ours with undue restrictions and 10 years of delay in patent grant, nutrition has little chance and the crisis may get more severe.

Net effect is that the patent system is not only obstructing advancement in nutrition, but it is promoting stagnation in nutrition. By obstructing advancement in nutrition, the system is obstructing advancement in medicine also, because we as a society are so consumed in treating what can be prevented that we are not making true downstream advancements in medicine that address issues beyond what can be prevented.

2. Humanitarian Violations of Independent Inventors and Small Entities and Worldwide Consequences of Actions of the USPTO and the Federal Circuit

The patent system neutered our innovation with obstruction and delays because of its bias against nutrition and because they are programmed to restrict. Although, USPA 13/332,251 was granted in May 2019 (US Patent 10292958), it is 10 years after the parent application was filed and after numerous Office actions and appeals and enormous prosecution costs and business setbacks to the Applicant.

It is extremely arduous for small entities and independent inventors to sustain such long prosecution (10 years in the present case). We have had lawyers prosecuting for us off and on, but as a small company we cannot keep that up for 10 years. As a result, we had to self-prosecute before the Appeal Board at USPTO and the Federal Circuit, which apparently was held against us as evident from the impropriety of the decisions discussed above. In other words, first they compromise small companies with improper objections and delays, and then when small companies are forced to self-prosecute, they hold self-prosecution against the applicants.

This case also illustrates that *pro se* inventors cannot get fair treatment at USPTO or the Courts. As evidenced above in Section III.5, the Federal Circuit gave a favorable treatment to Berkheimer and exactly opposite to us even though the issue of poorly understood factors is stronger in our case than the Berkheimer case. Further, why is the Berkheimer case getting Supreme Court's attention⁴⁵ and not ours, though our case has 1000 times more national significance? Only because HP Inc., a big business, filed the petition.

Furthermore, in this case there is evidence of EPO (European Patent Office) copying USPTO's improprieties⁴⁶, and many other jurisdictions in turn have copied

⁴⁵ <https://www.supremecourt.gov/search.aspx?filename=/docket/docketfiles/html/public/18-415.html>

⁴⁶ Alleged anticipation by individual oils was brought up for the first time by EPO at the Oral Proceedings held on 11 February 2015, following USPTO's allegation of anticipation by individual oils as alleged "products of nature" in the

August 10, 2019

Subject: Patent System is Obstructing Advancement in Nutrition
and Promoting the Disease Burden

EPO's and USPTO's improper actions. **That is *the Governments are violating independent inventors/small entities (and the public) in collusion with each other.*** Because of this collusion Applicant has had to file scores of extra responses to repeated improper objections and over dozen appeals and lawsuits in various jurisdictions.

Thankfully, some governing bodies in some other jurisdictions have demonstrated greater sense of responsibility, duty, and justice than the United States of America and EPO⁴⁷ thus far. For example, Intellectual Property High Court of Japan (in case of Japanese Patent application 2014-099072) and Intellectual Property Trial and Appeal Board of South Korea (in case of Korean Patent Application 10-2010-7026029) have reversed the decisions of their respective patent offices. South Korea has issued a Notice of Allowance, which patent covers claims similar to *both* the '034 Application and the recently granted US Patent 10292958.

However, imagine the burden all these actions have placed on the small company and its proprietors, and how this has obstructed innovation and reduced the time window to implement the critical innovation.

The prosecution delays impede implementation of innovation because investors and strategic partners do not come forward until patent scope is clear. By the time the patent is granted so little patent term is left that the necessary window to nurture the innovation in protected environment is gone.

It should be noted that disclosure or teaching is not always enough to solve a problem. In cases such the present one, the complex innovation will not take hold in the absence of a sufficient scope and protected term. Just like a tree sapling needs a fence around it to protect from cattle to allow growth, similarly such inventions need the twenty-year patent term for proper implementation. Therefore, the view that the patent system's objective is to induce disclosure, would be misplaced.

Such US practices (in collusion with other jurisdictions) have put human rights and sustainable development in jeopardy.

Office action of 18 August 2014 p. 14-20, in case of corresponding US patent application number 12/426,034. Additionally, EPO had raised some far-fetched objections copying the USPTO Examiner, such as referring to "different sources" as "different producer" or "different supplier." See Annex AD.

⁴⁷ The injustice at EPO has been called to the attention of the Administrative Council of EPO. See Annex AD.

VI. Conclusion and Remedy Requested

Since USPTO rejection in 2015 in the '034 application, over four years have been lost in appeals at the expense of innovation and public health. USPTO and the Courts successfully obstructed the innovation and public well-being and failed to render justice.

They defeated the very purpose of patents, innovation for betterment of the human condition, the very reason for USPTO's and the patent system's existence!

The Federal Circuit should have shown grave concern upon such violations happening at USPTO that are abusive to inventors, applicants, and are sabotaging implementation of innovation for public benefit. Under the circumstances the Federal Circuit should have reversed the USPTO.

These actions are extremely detrimental to innovation, public benefit, and the USPTO's charter.

We request the Congress to take action to stop this malfeasance and request the following remedies:

1. Abrogate the USPTO's and the Federal Circuit's Decisions in case of the '034 Application.
2. Due to the extraordinary case of malfeasance on part of the USPTO and the Federal Circuit, adjust the patent term such that the 20 years patent term is counted from the date of allowance of the '034 Application. In the worst case, no more than three years may be deducted from the 20-year patent term for prosecution as per 35 U.S.C. § 154.
3. Reconsider revenue and reward at USPTO, removing incentives for unnecessary restrictions that compromise innovation, and place burden on humanity.

Unless the Congress fully supports this endeavor the current stagnation in the lipid nutrition and the associated public suffering will likely continue for 1000s of years to come.

Respectfully,



Urvashi Bhagat
Chief Executive Officer

Attachment K:

Translation of the Decision of Intellectual Property High Court of Japan and the
pending claims in corresponding application

Rendition of Judgement: April 12, 2019, the Original
Received on the Same Date, Court Clerk
Case No. 2018 (Gyo-Ke) 10117 Demand for Cancellation of
Trial Decision
Conclusion of Oral Argument: March 13, 2019

Judgement

P.O. Box 1000, Palo Alto, California, the United
States

Plaintiff: Asha Nutrition Sciences Inc.

Representative of the same: Bhagat Urvashi

Advocating attorney of the same: SONODA Yoshitaka
ISHIOKA Toshiyasu
NAKATA Hiroko

3-4-3, Kasumigaseki, Chiyoda-ku, Tokyo

Defendant: Commissioner of the Patent Office,
MUNAKATA Naoko

Designated agent of the same: KIMOTO Takashi
YAMAZAKI Masashi
INOUE Tetsuo
HANDA Masato
HARA Ken-ichi

Main Text

1. The trial decision made by the Patent Office on
April 3, 2018 with respect to the Dissatisfaction Case No.
2016-5871 is canceled.

2. Litigation costs shall be borne by the defendant.

Facts and Reasons

I. Demand

The same as item 1 of the Main Text.

II. Summary of the Case

1. Procedural History in the Patent Office

(1) The plaintiff filed a patent application (JP Appl. No. 2014-99072, Ko-1) on May 12, 2014 which is titled as "lipid-containing composition and method for using the same" (a divisional application from JP Appl. No. 2011-506377 which was filed on April 20, 2009 (claimed priority: April 21, 2008, US; June 25, 2008, and US; November 5, 2008, US)).

(2) The plaintiff received a Decision of Final Rejection (hereinbelow, referred to as "the decision of final rejection") as of December 17, 2015, against which the plaintiff demanded a Dissatisfaction Trial on April 20, 2016, and kept the case pending as Dissatisfaction case No. 2016-5871 (Ko-4 and Ko-5).

(3) The Patent Office notified Reasons for Rejection dated April 17, 2017 (hereinbelow, referred to as "the reasons for rejection". Ko-11).

(4) The plaintiff amended the Claims by a Written Amendment dated November 9, 2017 to revise content of claim

1, newly add claims 19-47, etc. (hereinbelow, referred to as "the amendment". Number of claims: 47. Ko-13).

(5) The Patent Office made a trial decision that "the present demand for trial does not hold true" as presented in the annexed Written Trial Decision (copy) (hereinbelow, referred to as "the trial decision") on April 3, 2018, and the original document was delivered to the plaintiff on April 17, 2018. As a term for action, 90 days was given.

(6) The plaintiff instituted the present lawsuit which demands cancellation of the trial decision on August 15, 2018.

2. Recitations of the Claims

Recitation of claim 1 of the Claims after the amendment is as follows. Hereinbelow, the invention according to this claim is referred to as "the invention" and the Specification thereof (Ko-1) is referred to as "the specification".

Notes

A use of one or more factors of a subject as an indicator for selecting a lipid-containing formulation for administration to the subject, the one or more factors of the subject being selected from the following group: age of the subject, sex of the subject, diet of the subject, body weight of the subject, physical activity level of the subject, lipid tolerance level of the subject,

medical condition of the subject, family medical history of the subject, and temperature range around the subject's living area, wherein:

the formulation comprises a fatty acid comprising one or more mutually complementing daily dosages of omega-6 and omega-3 fatty acids, a ratio of omega-6 fatty acid to omega-3 fatty acid and their amounts being based on the one or more factors, a ratio of omega-6 to omega-3 being

4:1 or more, with the dosage of omega-6 being 40 g or less, or

1:1 to 50:1 according to an amount of antioxidant, phytochemical, and seafood in diet of the subject and/or in the formulation;

an increase in omega-6 is gentle and/or a discontinuation of omega-3 is gentle, with a dosage of omega-6 being 40 g or less; or

a content of the fatty acid suits Table 6 below

[Table 1]

Table 6 Unsaturated Fatty Acid Contents According to Climate

% by Weight Ranges by Temperature (inc °F.)	HOT 90°-135°	WARM 70°-99°	COOL 50°-75°	COLD 33°-55°	BELOW FREEZING 0°-37°	ARCTIC 50°-5°	POLAR -100° - -45°
	Low/High	Low/High	Low/High	Low/High	Low/High	Low/High	Low/High
Omega-9 Fats	20/90	20/90	20/90	10/80	10/80	10/80	10/80
Omega-6 Fats	4/60	4/60	6/60	10/60	12/70	13/70	15/73
Omega-3 Fats	0.3/5	0.5/6	0.8/7	1/8	1.5/12	1.8/15	2/20

3. Gist of Reasons of the Trial Decision

Reasons of the trial decision are as in the annexed Written Trial Decision (copy). In summary, i) the invention is not definite and recitation of the Claims does not comply with the requirements prescribed in Article 36(6) (ii) of the Patent Law (hereinbelow, referred to as "definiteness requirement"), and ii) the invention is not described in the Detailed Description of Invention of the specification, and recitation of the Claims does not comply with the requirements prescribed in Article 36(6) (i) of the Patent Law (hereinbelow, referred to as "support requirement"), and thus, should not be granted a patent.

4. Reasons for Cancellation

(1) Procedural contravention (Cancellation Reason 1)

(2) Misjudgment of definiteness requirement

(Cancellation Reason 2)

(3) Misjudgment of support requirement (Cancellation Reason 3)

III. Argument of Adversary

1. Regarding Cancellation Reason 1 (Procedural Contravention)

[Argument of the Plaintiff]

(1) Inexecution of examination

The plaintiff filed the amendment to add claims 19-47. However, the defendant did not notify new reason for

rejection with respect to the claims added by the amendment, and did not judge the claims either in the trial decision.

At the time of filing the amendment after the Demand for Trial, the plaintiff paid the fee for demand for trial (¥159,500) and the fee for request for examination (¥116,000) corresponding to the addition of the claims, under Article 195(2) of the Patent Law. Even provided that, as for the fee for demand for trial, the price of the fee reflects a benefit of the demandant of trial to argue in the trial, it has to be said that the fee for request for examination is a groundless unilaterally imposed compulsory service.

Therefore, the trial decision should be cancelled, for having a procedural violation which is substantially in contravention of the regulation of Article 47 of the Patent Law.

(2) Insufficient trial examination

The present case cannot be regarded as having been substantially examined. That is to say, in spite that the decision of final rejection notified every contravention of the novelty requirement, the inventive step requirement, and the definiteness requirement as the reason for rejection, the notice of reason for rejection judged only a part of the invention on definiteness requirement and made

a corresponding judgment on the support requirement. The trial decision substantially judged only a definiteness in expression of the invention according to claim 1. The Manual of Trial stipulates that any reasons for rejection discovered should be notified, etc. It cannot be considered that the collegial body of trial has tried to appropriately grasp technical recognition of a person skilled in the art, on the basis thereof, tried to judge whether or not the decision of final rejection held, and tried to notify any reasons for rejection discovered.

Moreover, in spite that the present case is a case in which a technical recognition of a person skilled in the art is important, the trial examination was made only by trial examiners in a field completely different from the technical field of the invention, even without studying a correct technical recognition through a prior art search, or the like.

Therefore, the trial decision contravenes Article 153(1) of the Patent Law, since the reasons alleged by the adversary have not been examined. Furthermore, the trial decision contravenes Article 156(1) of the same law, since in spite that the case was not matured for receiving a trial decision, a conclusion of a trial examination was notified and a trial decision was made. Thus, the trial decision is illegal and should be cancelled.

[Argument of Defendant]

(1) Inexecution of examination

Since the amendment was made in the trial stage, it is natural that the inventions according to claims 19-47 added in this stage have not undergone an examination.

The Patent Law is premised on such a basic structure that a patent grant decision or a patent trial decision is made as an administrative disposition on a patent application, and a patent is granted on the basis of this decision. A patent is not granted individually on each claim. When an invention according to a part of claims has a reason for which a patent cannot be granted, the patent application as a whole should receive a decision of final rejection, regardless of judgement on invention according to other claims.

As long as the trial decision has judged that the invention cannot be granted a patent for the reasons of the definiteness requirement contravention and the support requirement contravention, it is clear that the present application should be rejected as a whole, for falling under Article 49(4) of the Patent Law, without a need of judgement of the invention according to other claims.

(2) Insufficient trial examination

The trial decision introduced the conclusion that a patent could not be granted, on the basis of a judgement of

the trial examination that recitations of the Claims of the present application did not meet the definiteness requirement and the support requirement.

The lack of judgement on the other reasons for rejection presented in the original decision does not constitute any insufficient trial examination. Moreover, since the present application has indefinite recitations of the claims, it is impossible to recognize the invention as a basis of judgement on novelty and inventive step. Incidentally, the trial examination of the trial decision was made by a collegial body of a department in charge of the technical field of the invention. Originally, an argument concerning difference of technical field of trial examiners is irrelevant to any procedural illegality.

Therefore, in the trial decision, there is no illegality for insufficient trial examination.

2. Regarding Cancellation Reason 2 (Misjudgment of Definiteness Requirement)

[Argument of Plaintiff]

(1) Regarding the recitation of "a use of one or more factors of a subject as an indicator for selecting a lipid-containing formulation for administration to the subject"

i) The Invention is an invention related to a "use as an indicator for selecting a lipid-containing formulation" of factors of "age, sex of the subject, diet of the

subject, body weight of the subject, physical activity level of the subject, lipid tolerance level of the subject, medical condition of the subject, family medical history of the subject, and temperature range around the subject's living area".

(i) First, the invention is definite, because whether or not a method is included in the range of the invention is determined on whether or not any of the factors is used (in any form) as an index for selecting a lipid-containing formulation.

To the contrary, even if the invention is recited as a superordinate concept, such a recitation is not unallowable. The Invention is related to a use of at least one of the factors listed in claim 1 as an index (a mark for judgement) for selecting a lipid-containing formulation. For example, if "an age" is used as "an index (a mark for judgement)", even in any form, to select a lipid-containing formulation within a range which meet the quantitative limitation of the invention, even if it is prima facie common action, it is clear that such action is within the technical range of the invention naturally, with no room for doubt.

(ii) The invention limits the use by the characteristic that "the formulation comprises a fatty acid comprising one or more mutually complementing daily dosages

of omega-6 and omega-3 fatty acids, a ratio of omega-6 to omega-3 and their amounts being based on the one or more factors". It is definite whether or not a method is included in the range of the invention, because it is determined on whether or not a "ratio of omega-6 to omega-3 fatty acids and their amounts" are determined on the basis of a "factor" (in any form).

Further, in connection with the use, the invention limits a dosage or a ratio of omega-6 or omega-3 by a technical characteristic, in a kind of numerical manner, to be in any of four modes of "4:1 or more... 40 g or less", "diet of the subject... to 50:1", "wherein... of omega-6 is 40 g or less", or "wherein... content of the fatty acid suits...". Since these are also merely numerical limitations principally, it is definite whether or not a method is included in the technical range of the invention. From a viewpoint of definiteness, it is not necessary that claims recite all "patterns of basing".

In general, claims recite characteristics in order from a broader abstract characteristic to a narrower specific characteristic. Therefore, when the four modes are recited subsequently to the recitation "a ratio of omega-6 to omega-3 fatty acids and their amounts being based on the one or more factors", such recitation cannot be judged as a recitation to specify how the "ratio of

omega-6 to omega-3 fatty acids" and "their amounts" is based on the "one or more factors", in light of such order of recitations.

In addition, although the four modes are punctuated with ";", as long as all the characteristics of the invention are recited with being punctuated with ";", it cannot be judged that only the ";" in "wherein the formulation... being based on the one or more factors;" has a different meaning.

Furthermore, there is no description in the specification, on the basis of which the invention should be construed with a limitation, such that the "ratio of omega-6 to omega-3 fatty acids" and "their amounts" are based on "one or more factors". It is clear that the four modes are limitations to quantitative ranges within which omega-6 and omega-3 can be, in the invention.

ii) As such, the invention relates to a use of a specific factor as an indicator for selecting a lipid-containing formulation, which bases a ratio of omega-6 to omega-3 fatty acids and their amounts on the factor in any form, and further limits an amount of omega-6 or omega-3. Thus, the technical range of the invention is definite.

iii) The trial decision has judged that the "one or more factors of a subject" other than the "temperature range around the subject's living area" (climate) are not

specified at all as to in what manner the "one or more factors" are used "as an indicator for selecting a lipid-containing formulation", and as a result, content of the method of using the "one or more factors of a subject" "as an indicator for selecting a lipid-containing formulation" is not definite.

However, there is no reason that a content is judged as indefinite for a lack of a specific subordinate mode thereof recited in claims. A specific subordinate method of use is a matter which should be suitably determined by a person skilled in the art on the basis of a technical common knowledge or description of a specification or claims. How the invention can be implemented is a problem of the enablement requirement. If the invention is judged to coincide with a prior art, for being too broad as a technical idea, it is a problem of novelty or inventive step.

(2) Regarding the recitation of "wherein the formulation comprises a fatty acid comprising one or more mutually complementing daily dosages of omega-6 and omega-3 fatty acids"

i) The recitation was made by the amendment filed to revise the recitation "daily amount of the fatty acid comprising omega-6 and omega-3 fatty acids are put

together", which was judged as indefinite in the reasons for rejection, to be in more definite form.

It is clear that the term "mutually complementing daily dosage" means a daily dosage divided into two or more. The specification sets forth in [0037] that "the lipid formulations may be packaged in one, two, three, four or more mutually complementing daily dosages". This indicates a mode in which the lipid formulation of the invention (which is blended with a plural number of fatty acids. The "fatty acids" in the description above) is packaged in one or more dosages, and means that a plural number of the packaged dosages make a daily dosage in a mutually complementing manner. Such mode is shown as "the delivery of the desired lipid composition may be achieved through a one-part or multi-part mutually complementing delivery system" ([0040]), as also specifically shown in [0065], [0071], and [0072]. Many relevant descriptions are also found, such as "multiple parts" ([0037]), "daily administration (one or more components)" ([0063]), and "one or more daily administration (e.g., 1, 2 or 3 component daily formulation) ([0072])".

Accordingly, the description of "wherein the formulation comprises a fatty acid comprising one or more mutually complementing daily dosages of omega-6 and omega-3 fatty acids" indicates a characteristic that daily amount

of fatty acids (comprising omega-6 and omega-3 fatty acids) are totalized to consider whether the limitation recited in the claim is met, in a mode where the fatty acid is administered in two or more times. Therefore, it is clear that the recitation means "a daily dosage of fatty acid in a form divided into one-part or multi-part which necessarily comprises omega-6 and omega-3 fatty acids (and may further comprise another fatty acid)".

ii) Reversely the trial decision has judged that it is not definite whether the "daily dosage" indicates an amount of "omega-6 and omega-3 fatty acids" or an amount of the "fatty acid" which comprises them. As set forth above, it is clear that the daily dosage refers a daily dosage of the "fatty acid" from the recitation of the claim before the amendment, and from the description in [0037] of the specification.

In addition, the trial decision sets forth that the recitation can be construed as a mode in which "a dosage of omega-6 fatty acid and a dosage of omega-3 fatty acid are mutually complementing", as a mode in which "dosages of various fatty acids contained in the formulation are mutually complementing", or as it indicates "a dosage which complements fatty acid taken from meals, relative to a daily dosage which should be taken by a subject". However, any of the modes are not directly described in the

specification in connection with the "mutually complementing daily dosage". Moreover, it is unreasonable to construe the recitation as "a dosage of omega-6 fatty acid and a dosage of omega-3 fatty acid are mutually complementing", since relationship of omega-6 and omega-3 fatty acids is separately recited in the claims. In addition, it is unreasonable to construe the daily dosage as "a dosage which complements fatty acid taken from meals, relative to a daily dosage which should be taken by a subject", since it is a further limitation identical to the mode in which the factor of the invention is "diet of the subject".

(3) Thus, the recitations of the Claims corresponding to the invention comply with the definiteness requirement.

[Argument of Defendant]

(1) Regarding the recitation of "a use of one or more factors of a subject as an indicator for selecting a lipid-containing formulation for administration to the subject"

i) The Invention is not only specified as "a use of one or more factors of a subject as an indicator for selecting a lipid-containing formulation for administration to the subject, the one or more factors of the subject being selected from ... temperature range of the subject's ... area,", but further specified as "the use..., wherein the formulation... one or more... suits". It

cannot be said that the invention relates to "a use of a specific factor as an indicator for selecting a lipid-containing formulation" or that "a determination of whether or not included in the range of the invention is made by whether or not a factor is used as an indicator for selecting a lipid-containing formulation (in any form)", as argued by the plaintiff.

In addition, it is not possible to definitely tell "whether or not a factor was used as an indicator for selecting a lipid-containing formulation (in any form)". That is to say, in the invention, the recitation "a use of one or more factors of a subject as an indicator for selecting a lipid-containing formulation for administration to the subject, the one or more factors of the subject being selected from ... temperature range of the subject's ... area," indicates a method of using an attribute such as "age" or "sex" as an indicator for selecting a common oil. However, the recitation of "as an indicator" is abstract, and it is not definite to what extent of actions the action of using "as an indicator" includes, in actions of using an attribute such as "age" or "sex". Therefore, extension of the invention is not definite.

ii) In the invention, "the formulation comprises a fatty acid comprising one or more mutually complementing

daily dosages of omega-6 and omega-3 fatty acids, a ratio of omega-6 to omega-3 fatty acids and their amounts being based on the one or more factors". Therefore, it can be said that the "ratio of omega-6 to omega-3 fatty acids" contained in the "lipid-containing formulation" and "their amounts" are based on the "one or more factors".

Then, the recitation of "a ratio of omega-6 fatty acid to omega-3 fatty acid and their amounts being based on the one or more factors" is followed by the invention-specifying matters of "4:1 or more... 40 g or less" and "diet of the subject... to 50:1" with respect to the "ratio of omega-6 fatty acid to omega-3 fatty acid"; and the invention-specifying matters of "4:1 or more... 40 g or less", "wherein... of omega-6 is 40 g or less", and "wherein... content of the fatty acid suits..." with respect to "their amounts", each punctuated with ";" as an alternative. Therefore, the recitation of "the use, wherein ratio of omega-6 to omega-3 being... suits..." should be understood as a recitation to specify the invention how the "ratio of omega-6 fatty acid to omega-3 fatty acid" and the "amount thereof" are based on the "one or more factors". Since the four invention-specifying matters are recitations to specify the invention how the ratio and the amount is based on, it cannot be said that the ratio and the amount only have to be determined on the

basis of a factor (in any form), and in addition, "on the basis" (in any form) is abstract by itself, from which it is not possible to tell what case is "based".

As such, the recitation of "the use, wherein ratio of omega-6 to omega-3 being... suits..." of the invention is a recitation to specify the invention how the "ratio of omega-6 fatty acid to omega-3 fatty acid" and "their amount" are based on the "one or more factors". On the other hand, the invention-specifying matters of "4:1 or more... 40 g or less" and "wherein... of omega-6 is 40 g or less" do not include any recitation in connection with the "one or more factors". In addition, the four invention-specifying matters do not have any recitation in connection with "age", "sex", "body weight", "physical activity level", "lipid tolerance level", "medical conditions", and "family medical history" among the "one or more factors". Accordingly, in spite that the "ratio of omega-6 fatty acid to omega-3 fatty acid" and "their amount" are to be based on the "one or more factors" (age, sex, etc.), it is utterly unclear as to how those are based thereon.

iii) Furthermore, even with referring to descriptions of the specification and technical common knowledge, it is not definite that what extent of actions can be included in the "use of one or more factors of a subject as an

indicator for selecting a lipid-containing formulation for administration to the subject".

That is to say, although the specification describes the "factors" in [0010], [0011], and [0035], these descriptions do not disclose any method of using the "factors". The specification does not include any other description which explains a method of using the "factors", nor is a method of using the "factors" technical common knowledge. Although an action of selecting a lipid-containing formulation by referring to an Example of the specification can be understood to be included in the "use of one or more factors of a subject as an indicator for selecting a lipid-containing formulation for administration to the subject", it is not definite whether an action of simply providing a lipid-containing formulation which meets the conditions listed in a Table corresponding to the Example is included in the use.

iv) As above, since it is impossible to tell what actions are included in the "use" from the recitation of "use of one or more factors of a subject as an indicator for selecting a lipid-containing formulation for administration to the subject", the technical range of the invention is indefinite.

(2) Regarding the recitation of "wherein the formulation comprises a fatty acid comprising one or more

mutually complementing daily dosages of omega-6 and omega-3 fatty acids"

i) The recitation of "wherein the formulation comprises a fatty acid comprising one or more mutually complementing daily dosages of omega-6 and omega-3 fatty acids" can be construed in many ways, and therefore is indefinite in its meaning.

That is to say, the "daily dosage" can be construed as a daily dosage of the "omega-6 and omega-3 fatty acids" or as a daily dosage of the "fatty acid". The "mutually complementing daily dosage" can be construed as indicating that a dosage of omega-6 fatty acid and a dosage of omega-3 fatty acid are mutually complementing, or as indicating that dosages of various fatty acids contained in the formulation are mutually complementing, or as it indicates "a dosage which complements fatty acid taken from meals, relative to a daily dosage which should be taken by a subject". Thus, it is not definite which of those the recitation should be construed as.

In this connection, since claim 1 is considered to have an intension to specify dosage or ratio of omega-6 and omega-3 fatty acids, it is reasonable to construe the recitation as "a dosage of omega-6 fatty acid and a dosage of omega-3 fatty acid are mutually complementing". In addition, since claim 1 shows a content of omega-9 fatty

acid as "wherein... content of the fatty acid suits...", it is also reasonable to construe the recitation as "dosages of various fatty acids contained in the formulation are mutually complementing", without limiting the fatty acids to omega-6 and omega-3. Further, according to [0037] and [0040] of the specification, it cannot be said unreasonable to construe the recitation as "referring to a dosage which complements fatty acid taken from meals, relative to a daily dosage which should be taken by a subject".

ii) Reversely, the plaintiff asserts that the daily dosage is a daily dosage of the "fatty acid", indicating that packages constitute the daily dosage (in total), in a mutually complementing manner.

However, the description in [0037] of the specification does not mention a daily dosage of the "fatty acid", but describes the point that the "lipid formulation" may be packaged in daily dosages. From the recitation above, it is not possible to determine whether the "daily dosage" is a daily dosage of the "omega-6 and omega-3 fatty acids" or a daily dosage of the "fatty acid", since both of the "fatty acid" and the "omega-6 and omega-3 fatty acids" are component included in the "lipid formulation". In addition, since claim 1 does not mention "package" at all,

claim 1 should not be construed on the premise that the formulation is "packaged".

As for the description in [0040] of the specification, it does not mean that each of the packages mutually complements, but merely describes the "mutual complementing" as it means a mutual complementing occurred in a "delivery system" including meals such as "bread, salad, main course, and/or dessert".

iii) As above, the recitation of "wherein the formulation comprises a fatty acid comprising one or more mutually complementing daily dosages of omega-6 and omega-3 fatty acids" cannot be construed in a single meaning, even with referring to the specification.

(3) Thus, the recitations of the Claims corresponding to the invention do not comply with the definiteness requirement.

3. Regarding Cancellation Reason 3 (Misjudgment of Support Requirement)

[Argument of Plaintiff]

(1) The trial decision has judged that the following technical matter is not described in the Detailed Description of Invention of the specification: "an increase in omega-6 is gentle and/or a discontinuation of omega-3 is gentle, with a dosage of omega-6 being 40 g or less".

(2) However, the invention in a superordinate concept described in the specification does not limit amount of omega-6 or omega-3 ([0009], etc.).

Then, the mode in which "an increase in omega-6 is gentle and/or a discontinuation of omega-3 is gentle" is described in the specification ([0042], [0079], [0090], and [0096]). The mode in which "a dosage of omega-6 is 40 g or less" is described in the specification (Table 9, Table 11, and Table 13), and a bad effect which may be brought about by a high dosage of omega-6 is described in the specification ([0081], [0093], [0098], [0103], [0106], and [0111]).

These two limitations are basically independent two limitations from a viewpoint of each, and can be said to be a kind of preferred mode of the invention described in the specification. It is clear that the limitation relating to each of the preferred modes is not to be applied only to a specific subordinate mode of the invention, but is a general limitation, from the context of [0042], or the contexts of Tables 9 to 13 in light of [0081], [0093], [0098], [0103], [0106], and [0111]. Therefore, having both of these two limitations is a matter described in the specification, or in a range of matters obvious therefrom.

Incidentally, although these two limitations are basically independent from each other, the limitations

share a broad purpose, in the point that both are limitation to amount of fatty acid (in particular, limitation to amount of omega-6 fatty acid) to prevent occurrence of harmful action.

Therefore, the technical matter of "an increase in omega-6 is gentle and/or a discontinuation of omega-3 is gentle, with a dosage of omega-6 being 40 g or less" is described in the Detailed Description of Invention of the specification, or is obvious from the described matters.

(3) Thus, the recitations of the Claims corresponding to the invention comply with the support requirement.

[Argument of Defendant]

The Invention can be said to be an invention of a method of using "one or more factors of a subject" "as an indicator for selecting a lipid-containing formulation for administration to the subject", in which "ratio of omega-6 fatty acid to omega-3 fatty acid" contained in the "lipid-containing formulation" and "their amounts" are determined according to the "one or more factors".

Accordingly, it is natural to understand that "an increase in omega-6 is gentle and/or a discontinuation of omega-3 is gentle" and "a dosage of omega-6 being 40 g or less" were determined on the basis of an identical factor of the same subject. If it cannot be said that the specification determines the limitation corresponding to

"an increase in omega-6 is gentle and/or a discontinuation of omega-3 is gentle" and the limitation corresponding to "a dosage of omega-6 being 40 g or less" on the basis of a factor of the same subject, it cannot be said that the specification describes a lipid-containing formulation which simultaneously meets the two limitation, namely, the technical matters of "an increase in omega-6 is gentle and/or a discontinuation of omega-3 is gentle, with a dosage of omega-6 being 40 g or less".

In the specification, these two limitations are described in connection with factors of subjects different from each other. Although Tables 9, 11, and 13 of the specification which are bases of "a dosage of omega-6 being 40 g or less" specify factors of a subject, paragraph [0042] which is a basis of "an increase in omega-6 is gentle and/or a discontinuation of omega-3 is gentle" does not describe a relationship with a factor of a subject, and paragraphs [0079], [0090], and [0096] just describe specific "host subject" in individual case study. Therefore, it cannot be said that the specification describes a lipid-containing formulation which meets these two limitations, simultaneously.

Thus, the recitations of the Claims corresponding to the invention do not comply with the support requirement.

IV. Judgement of the Court

1. Regarding the Invention

(1) While recitations of the Claims corresponding to the invention are as claim 1 referred in II. 2. above, the specification (Ko-1) includes the following description. Incidentally, the specification shows Tables 9 to 13, as in the annexed listing of tables of the specification.

i) Background art

Fatty acids perform important physiological functions. ... ([0002])

Human and animal bodies synthesize many kinds of fatty acids of various length of the carbon chain, with various numbers and locations of double bonds. The addition of double bonds into a fatty acid chain converts it into an unsaturated fatty acid, which play significant roles in physiological functions. ...([0003])

... Linoleic acid (LA) and α -linolenic acid (ALA) are the precursors for all omega-6 and omega-3 fatty acids. It is well established that LA and ALA are "essential" fatty acids. LA and ALA must be supplied in the diet because the human and other mammals cannot synthesize LA and ALA from other sources. Dietary deficiency or excess of the two essential fatty acids may cause many illnesses. ... ([0004])

ii) Problem to be solved by the invention

The traditional emphasis on increasing omega-3 fatty acid and reducing omega-6 fatty acid consumption often does not result in satisfactory relieves because of the uncertainties introduced by dietary and demographic factors. Accordingly, improved methods and treatments, using improved lipid compositions, for medical conditions and prophylaxis are still needed. ... The current methodologies are confusing for the consumer, hence lead to over consumption or under consumption of critical nutrients with major health consequences. ([0008])

iii) Means for solving problem

The present disclosure relates to compositions and methods for prophylaxis and/or treatment of medical conditions linked with an imbalance in one or more lipids within context of other factors. ... ([0009])

iv) Best mode

(i) Lipid formulation

In one aspect, the present disclosure incorporates relatively high ratio of omega-6 to omega-3 fatty acid, while maintaining optimal daily delivery of both omega-6 and omega-3 fatty acids. ... ([0022])

In some embodiments, the compositions of the present disclosure include the following optimally balanced fatty acids and combinations thereof. Saturated fatty acids: butyric acid...; monounsaturated fatty acids: myristoleic

acid ... omega-9 oleic acid ...; and polyunsaturated fatty acids: omega-6 linoleic acid ... omega-3 alpha-linolenic acid ([0030])

(ii) Administration

In some embodiments, the compositions comprising the lipid formulation disclosed in the specification may be administered to an individual in any orally accepted form. The lipid formulations may be packaged in one, two, three, four or more mutually complementing daily dosages. ... ([0037])

The delivery of the desired lipid composition may be achieved through a one-part or multi-part mutually complementing delivery system. For example, the desired formulation may be achieved through adding various components to various parts of a meal, including bread, salad, main course, and/or dessert. ([0040])

One aspect of the disclosure is to deliver fatty acids in such a way that the total daily delivery of omega-6 and omega-3 from the lipid composition and the rest of the diet are optimal with respect to daily recommendations. ([0041])

... Though the body adapts to the change in 2-3 weeks or longer, long-term effects of the change/consumption outside the optimal range may be harmful. Furthermore, sudden large fluctuations in fatty acids ingestion can also

have acute adverse effects. A sudden stop of a habitual large amount of supply of a long chain omega-3 fatty acid or an immunosuppressive phytochemicals/nutrient, or a sudden increase of an omega-6 fatty acid to a host sometimes cause a cytokine storm response accompanied with a severe consequences, including systemic inflammatory responses (capillary leak, fever, tachycardia, tachypnea), multi-organ failures (digestive organ, lung, liver, kidney, heart), and damages to connective tissue of arthron. ... ([0042])

v) Example

(i) Examples 1 to 10 of the specification describe Examples in connection with preparation of the formulations, as follows.

a. Example 1 ([0043] to [0045])

Formulations with various lipid ratios

... The formulations may provide a balanced fatty acid composition of approximately 10-100 grams of total daily fat. ...

b. Example 2 ([0045] to [0050])

Lipid compositions according to climate

c. Example 3 ([0050] to [0053])

Lipid compositions based on age, sex, and diet

... Table 9 below provides dose ranges for total fatty acid content (unit: gram), the ratio range of

monounsaturated fatty acid to polyunsaturated fatty acid, and the ratio range of monounsaturated fatty acid to saturated fatty acid, range of omega-6 fatty acid content (unit: gram), ratio range of omega-9 fatty acid to omega-6 fatty acid, range of omega-3 fatty acid content (unit: gram), and the ratio range of omega-6 fatty acid to omega-3 fatty acid for vegetarian or high antioxidant and/or high phytochemical consuming non-vegetarian subjects ... by gender and age group...

... Table 10 provides dose ranges for total fatty acid content (unit: gram), the ratio range of monounsaturated fatty acid to polyunsaturated fatty acid, and the ratio range of monounsaturated fatty acid to saturated fatty acid, range of omega-6 fatty acid content (unit: gram), ratio range of omega-9 fatty acid to omega-6 fatty acid, range of omega-3 fatty acid content (unit: gram), and the ratio range of omega-6 fatty acid to omega-3 fatty acid for non-vegetarian (i.e., omnivorous human) or low antioxidant and/or low phytochemical consuming vegetarian subjects ... by gender and age group...

... Table 11 provides dose ranges for total fatty acid content (unit: gram), the ratio range of monounsaturated fatty acid to polyunsaturated fatty acid, and the ratio range of monounsaturated fatty acid to saturated fatty acid, range of omega-6 fatty acid content

(unit: gram), ratio range of omega-9 fatty acid to omega-6 fatty acid, range of omega-3 fatty acid content (unit: gram), and the ratio range of omega-6 fatty acid to omega-3 fatty acid for high-seafood consumers ... by gender and age group...

d. Example 4 ([0053] to [0060])

Diet formulations

e. Example 5 ([0060] to [0061])

Formulation with varied omega-3 fatty acid content

Table 12 provides dose ranges for total fatty acid content (unit: gram), the ratio range of monounsaturated fatty acid to polyunsaturated fatty acid, and the ratio range of monounsaturated fatty acid to saturated fatty acid, range of omega-6 fatty acid content (unit: gram), ratio range of omega-9 fatty acid to omega-6 fatty acid, ratio range of omega-6 fatty acid to omega-3 fatty acid, range of omega-3 fatty acid content (unit: gram), designed by age and gender with increasing strength of omega-3, low, medium, and high, such that a human subject may choose the composition most agreeable to his/her diet ...

f. Example 6 ([0061] to [0063])

Formulation Based on Medical Conditions

Table 13 provides dose ranges for total fatty acid content (unit: gram), the ratio range of monounsaturated fatty acid to polyunsaturated fatty acid, and the ratio

range of monounsaturated fatty acid to saturated fatty acid, range of omega-6 fatty acid content (unit: gram), ratio range of omega-9 fatty acid to omega-6 fatty acid, range of omega-3 fatty acid content (unit: gram), and ratio range of omega-6 fatty acid to omega-3 fatty acid, for subjects with medical indications ...

g. Example 7 ([0063] to [0065])

Lipid Composition according to diet and medical condition

h. Example 8 ([0065] to [0069])

Two-component lipid formulation according to diet and medical condition

In one example liquid lipid and solid lipid composition parameters were established per diet or medical condition, intended for twice-a-day administration. ...

i. Example 9 ([0069] to [0070])

Special formulations based on diet

In this example one liquid lipid composition parameters was established and one formulation was prepared, intended for once, twice, or thrice or more a day administration to an individual whose diet is high in antioxidants/phytochemicals and/or is a vegetarian and to an individual who does not favor, or cannot tolerate nuts and seeds. ...

j. Example 10 ([0071] to [0072])

Daily formulations

Liquid lipid and solid lipid composition parameters were established for a twice-daily administration. ...

(ii) Examples 11 to 27 of the specification describe individual case studies, for example, in which a specific lipid-containing formulation is administered to a person with a disorder in a physiological function, and a result thereof is analyzed, as Examples.

(2) According to (1) above, it is considered that the specification discloses at least the following matters on the subject of the invention.

i) Background art

Fatty acids play important role in physiological functions of human. While human must obtain omega-3 and omega-6 fatty acids by being supplied with a precursor thereof from diet, deficiency or excess of supply amount thereof may cause many illnesses. ([0002] to [0004])

ii) Problem to be solved by the invention

The conventional intake method in which omega-3 fatty acid is increased and omega-6 fatty acid is decreased has had a possibility of having an adverse influence on health. Therefore, improved methods and treatments, using improved lipid compositions are still needed. ([0008])

iii) Means for solving problem

The Invention relates to compositions and methods for prophylaxis and/or treatment of medical conditions brought about by an imbalance in lipids, within context of other factors.

([0009])

2. Regarding Cancellation Reason 1 (Procedural Contravention)

(1) The plaintiff argues that despite the plaintiff filed the amendment which newly added claims 19-47, in response to the notice of reason for rejection which he received in the case of dissatisfaction trial against decision of final rejection, the collegial body of trial neither newly notified a Reason for Rejection for the claims added by the amendment, nor made any judgement thereon in the trial decision, which substantially contravenes Article 47 of the Patent Law.

However, the patent law is premised on a basic structure that a patent grant decision or a patent trial decision is made on a patent application as an administrative disposition, on the basis of which a patent is granted, and a patent right occurs, and a patent is not granted individually on each claim. On the basis of such structure, even a patent application involving a plurality of claims has no other way but receiving a decision of patent grant or a decision of final rejection as an

integral and inseparable total of the patent application, unless a divisional application is filed from the patent application. Therefore, a separate handling, such that a patent is granted on a patent application involving a part of claims while a decision of final rejection is made on a patent application involving the other claims, is not expected. This is clear from the sentence of Article 49 and Article 51 of the Patent Law, or in light of the presence of the system of divisional application of a patent application (see the first petty bench judgment upon Case Number 2007 (Gyo Hi) No. 318 of Supreme Court, decided on July 10 of the same year, Civil Law Report Vol. 62, No. 7, p. 1905).

Accordingly, in a dissatisfaction trial against a decision of final rejection, once a single claim is judged to have a reason for rejection, a collegial body of trial can make a trial decision of rejecting the demand only on the basis thereof, and it should be said that the lack of judgement on other claims added by the amendment is not illegal.

In this connection, in filing an amendment which increases number of claims, a patent applicant should pay a fee at the time of filing a Written Amendment (Article 11(4) of the Patent Law Implementing Regulations). In a case of an amendment to increase number of claims after

demanding a dissatisfaction trial against decision of final rejection, it can be said that the filing of the Written Amendment makes the added claim pending latently in the trial procedure that is a continued examination.

Accordingly, it cannot be said to be unreasonable that the fee which should be paid at the time is attributed to a fee required in requesting an examination of an application, and to a fee required in demanding a trial. The provision of the regulation which rules that a payment time of the fee should be a time point of filing a Written Amendment should be said to be a problem of legislation policy.

In the present case, the collegial body of trial made the notice of reason for rejection (Ko-11) which judges that recitation of claim 1 of the Claims does not comply with the definiteness requirement and the support requirement, and made the trial decision which judges that recitation of the claim amended by the amendment does not comply with the definiteness requirement and the support requirement, either. It cannot be said that there is an illegality in the trial procedure, for the reason that the collegial body of trial neither newly notified a reason for rejection for the claims added by the amendment, nor made a judgment thereon in the trial decision.

(2) The plaintiff argues that there is an illegality of insufficient trial examination, since the present case

cannot be said to have substantially been gone through a trial examination, for the reason that the collegial body of trial has judged only a part of the reasons of the Present Notice of Final Rejection, or the reason that the trial examiner was specialized in a technical field different from the technical field of the invention.

However, the collegial body of trial made the notice of reason for rejection which judges that recitation of claim 1 of the Claims does not comply with the definiteness requirement and the support requirement, and made the trial decision which judges that recitation of the claim amended by the amendment does not comply with the definiteness requirement and the support requirement, either. In a dissatisfaction trial against decision of final rejection, a collegial body of trial is not required to judge all reasons pointed out in a decision of final rejection. In addition, there is no evidence which suggests that there was a cause of exclusion or challenge of a trial examiner who made the trial decision. Nor is any sufficient evidence for which it is admitted that the collegial body of trial has not substantially made a trial examination of the present case.

Therefore, it is not possible to adopt the argument of the plaintiff that there is an illegality of insufficient trial examination in the present case.

(3) Thus, the cancellation reason 1 has no reasonability.

3. Regarding Cancellation Reason 2 (Misjudgment of Definiteness Requirement)

(1) A judgement on whether or not an invention sought to be patented is definite should be made considering not only recitations of Claims but also descriptions of a specification and drawings attached to the application request, and from a view point of whether or not a recitation of Claims is so indefinite that it unfairly harms interest of a third person, on the basis of a technical common knowledge of a person skilled in the art at time of filing.

Thus, below is a discussion on whether or not the recitations of the Claims corresponding to the invention are so indefinite that it unfairly harms interest of a third person. Hereinbelow, invention-specifying matters of the invention are discussed separately, each sometimes being referred to as "Specifying Matter A" to "Specifying Matter I".

A. A use of one or more factors of a subject as an indicator for selecting a lipid-containing formulation for administration to the subject,

B. the one or more factors of the subject being selected from the following group: age of the subject, sex

of the subject, diet of the subject, body weight of the subject, physical activity level of the subject, lipid tolerance level of the subject, medical condition of the subject, family medical history of the subject, and temperature range around the subject's living area,

C. wherein the formulation comprises a fatty acid comprising one or more mutually complementing daily dosages of omega-6 and omega-3 fatty acids,

D. wherein a ratio of omega-6 fatty acid to omega-3 fatty acid, and their amounts are based on the one or more factors;

E. wherein a ratio of omega-6 to omega-3 is 4.1 or more, with the dosage of omega-6 being 40 g or less;

F. or 1:1 to 50:1 according to an amount of antioxidant, phytochemical, and seafood in diet of the subject and/or in the formulation;

G. or wherein an increase in omega-6 is gentle and/or a discontinuation of omega-3 is gentle, with a dosage of omega-6 being 40 g or less;

H. or wherein a content of the fatty acid suits Table 6 below (the table is omitted),

I. the use.

(2) Definiteness of the recitation "a use of one or more factors of a subject as an indicator for selecting a

lipid-containing formulation for administration to the subject" (Specifying Matter A)

i) Specifying Matters A and B

The Invention is specified as "a use of one or more factors of a subject as an indicator for selecting a lipid-containing formulation for administration to the subject" (Specifying Matter A), and then specified as "the one or more factors of a subject being selected from the following group: age of the subject, sex of the subject, diet of the subject, body weight of the subject, physical activity level of the subject, lipid tolerance level of the subject, medical condition of the subject, family medical history of the subject, and temperature range around the subject's living area" (Specifying Matter B).

Accordingly, it is reasonable to understand that Specifying Matters A and B specify the invention at least as the method as described below.

Notes

A method of using one or more of "factors" of a subject, namely, age, sex, diet, body weight, physical activity level, lipid tolerance level, medical condition, family medical history, and temperature range around the subject's living area as an "indicator" for selecting a lipid-containing formulation, in administrating the lipid-containing formulation to the subject.

ii) Specifying Matter C

The Invention is specified as "wherein the formulation comprises a fatty acid comprising one or more mutually complementing daily dosages of omega-6 and omega-3 fatty acids," (Specifying Matter C). Here, "wherein the formulation" indicates the "lipid-containing formulation" which is the object to be selected by the method specified by Specifying Matters A and B.

Accordingly, it can be said that Specifying Matter C specifies a structure of the object to be selected by the method of the invention, such that a lipid-containing formulation which is an object to be selected by the method of the invention comprises a fatty acid comprising omega-6 and omega-3 fatty acids.

iii) Object to be specified by Specifying Matters D to H

Specifying Matters D to H specify a dosage ratio of omega-6 and omega-3 fatty acids (Specifying Matters D, E, and F), specify dosage of omega-6 fatty acid and/or omega-3 fatty acid (Specifying Matters D, E, and G), specify percent by weight of omega-6 and omega-3 fatty acids, or omega-9 fatty acid included in the fatty acid (Specifying Matter H), or specify a chronological change of consumption amount of omega-6 fatty acid and/or omega-3 fatty acid (Specifying Matter G).

Accordingly, it can be said that Specifying Matters D to H further specifies the structure of an object to be selected by the method of the invention specified by Specifying Matter C, namely, the structure in which the lipid-containing formulation that is the object comprises a fatty acid comprising omega-6 and omega-3 fatty acids, by focusing on ratio, dosage, percent by weight, or chronological change in consumption amount of omega-6 fatty acid, omega-3 fatty acid, or omega-9 fatty acid included in the fatty acid.

iv) Relationship of Specifying Matters D to H

(i) Specifying Matters D to H are each punctuated with ";", and therefore, should be understood such that every invention-specifying matter has individual technical significance.

(ii) Moreover, Specifying Matter D starts with "wherein", Specifying Matter E starts with "wherein", Specifying Matters F to H are connected with "or", and therefore, Specifying Matters D to H are further separated into Specifying Matter D and Specifying Matters E to H, and the Specifying Matters E to H are in an alternative relationship.

(iii) The relationship of Specifying Matter D and Specifying Matters E to H are discussed.

These specifying matters further specify the structure of an object to be selected by the method of the invention specified by Specifying Matter C, by focusing on ratio, dosage, percent by weight, or chronological change in consumption amount of omega-6 fatty acid, omega-3 fatty acid, or omega-9 fatty acid included in the fatty acid.

Specifying Matter D is to specify the structure of an object to be selected by the method of the invention specified by Specifying Matter C, on the basis of a "factor" of the subject to which the lipid-containing formulation is administered, namely, one or more of age, sex, diet, body weight, physical activity level, lipid tolerance level, medical conditions, family medical history, and temperature range around the subject's living area.

On the other hand, Specifying Matters E to H are to specify the structure of an object to be selected by the method of the invention specified by Specifying Matter C, on the basis of an objective ratio, dosage, percent by weight, or chronological change in consumption amount.

As such, Specifying Matter D and Specifying Matters E to H both further specify the structure of an object to be selected by the method of the invention specified by Specifying Matter C. For difference in way of specifying, no inconsistency occurs between the specification by

Specifying Matter D and specification by Specifying Matters E to H. Therefore, it should be said that Specifying Matter D and Specifying Matters E to H are to be applied in a superposed manner.

v) Specifying Matter I

While Specifying Matters A and B specify the invention as a method of using one or more of "factors" of a subject as an "indicator" for selecting a lipid-containing formulation, when administering the lipid-containing formulation to the subject, Specifying Matter C specifies structure of the lipid-containing composition that is an object to be selected by the method of the invention, and Specifying Matter D and Specifying Matters E to H further specifies the structure in a superposed manner.

Accordingly, it can be said that Specifying Matter I further specifies the method of using one or more of "factors" of a subject as an "indicator" for selecting a lipid-containing formulation when administering the lipid-containing formulation to the subject, as it is a method of selecting a lipid-containing formulation when administering a lipid-containing formulation having a structure specified by Specifying Matters C to H to the subject.

vi) Definiteness of Specifying Matter A

In light of the above, it can be said that it is reasonable to understand that Specifying Matter A is "a method of using one or more of "factors" of a subject as an "indicator" for selecting a lipid-containing formulation, when the lipid-containing formulation is administered to the subject", and it can be said that such understanding of Specifying Matter A is consistent with understanding of the other Specifying Matters.

vii) Regarding the argument of the defendant

(i) The defendant argues that while the invention is a method of using an attribute such as "age" or "sex" as an indicator for selecting a common oil, the recitation of "as an indicator" is abstract, and it is not definite to what extent of actions the action of using "as an indicator" includes, and therefore, extension of the invention is not definite, and it is not possible to definitely tell whether or not the factor was used as an indicator for selecting the lipid-containing formulation in any form.

However, when a lipid-containing formulation is administered to a subject, if a structure of the lipid-containing formulation was determined according to a factor of a subject such as age or sex as a merkmal, it can be said that a factor was used "as an indicator". In addition, even if a structure of a lipid-containing formulation determined by the factor was a common

structure, the invention is not evaluated as having an indefinite extension, for the reason that the structure is common. Accordingly, it cannot be said that the recitation of "as an indicator" is so indefinite that it unfairly harms interest of a third person.

A judgement on whether or not a target method belongs to the technical range of the invention is made by comparing and discussing the technical range of the invention and the target method, after distinguishing the technical range of the invention and certifying the target method. The problem of whether or not the factors of the invention was used as a merkmal as an indicator for selecting a lipid-containing formulation is not a problem of distinction of the technical range of the invention or the definiteness requirement, but is a problem of certifying of a target method.

Therefore, the defendant's argument cannot be adopted.

(ii) The defendant argues that the Specifying Matters E to I should be understood to be recitations to specify in what manner the "ratio of omega-6 fatty acid to omega-3 fatty acid" and "their amount" in Specifying Matter D are based on the "one or more factors".

However, both of Specifying Matter D and Specifying Matters E to H are to further specify the structure of an

object to be selected by the method of the invention specified by Specifying Matter C, from viewpoints different from one another. As long as there is no recitation concerning "one or more factors" in Specifying Matters E and G, it cannot be said that a technical significance of Specifying Matter D should be understood from a relationship thereof with Specifying Matters E to H which are in an alternative relationship with Specifying Matters E and G.

Therefore, the defendant's argument cannot be adopted.

(iii) The defendant argues that the method of using the "factors" is neither clarified in the specification, nor is a technical common knowledge.

The defendant's argument is premised on an understanding that the invention relates to a method which specifies how to use the "factors" to select a lipid-containing formulation for administration to a subject.

However, although the recitations of the Claims corresponding to Specifying Matters F and H specify how to use a diet and a temperature range of living area which are the "factors", Specifying Matters E and G which are in an alternative relationship with these specifying matters have no recitation concerning method of using the "factors". Specifying Matters F and H should be understood to merely

specify a structure of a lipid-containing composition which is the object to be selected by the method of the invention. The other recitations of the Claims corresponding to the invention have no description on a method of using the "factors".

Therefore, the defendant's argument cannot be adopted, for being premised on an understanding of the invention beyond recitations of the Claims. In this connection, if the inventions recited in the Claims merely specify methods of using the specific "factors" in selecting lipid-containing formulation, in spite that it is necessary for solving the problem of the invention to specify to an extent how to use the specific "factor" in selecting a lipid-containing formulation, it is not a problem of the definiteness requirement, but a problem of the support requirement. The definiteness requirement is not for a judgement on whether or not a technical range sought to be patented through an application by an applicant is sufficient as a structure or as a method for solving a problem of the invention, but for a judgement on whether or not the technical range is definite.

viii) Summary

In light of the above, Specifying Matter A specifies that the invention is a method of using one or more of "factors" of a subject as an "indicator" for selecting a

lipid-containing formulation, when a lipid-containing formulation is administered to the subject. It cannot be said that recitation of the Claims corresponding to Specifying Matter A is so indefinite that it unfairly harms interest of a third person.

(3) Definiteness of the recitation "wherein the formulation comprises a fatty acid comprising one or more mutually complementing daily dosages of omega-6 and omega-3 fatty acids" (Specifying Matter C)

i) Significance of Specifying Matter C

Specifying Matter C specifies that the formulation, namely, the lipid-containing formulation administered to a subject comprises a fatty acid comprising one or more "mutually complementing" "daily dosage" of omega-6 and omega-3 fatty acids.

Specifying Matter C specifies that the lipid-containing formulation for administration to a subject comprises a fatty acid, and specifies a structure of the fatty acid.

ii) Regarding the "mutual complement"

(i) A structure of the fatty acid as specified by Specifying Matter C is "mutually complementing". However, it is not clear only from the recitation of the Claims corresponding to Specifying Matter C, as a single meaning, as to whether (1) one or more fatty acids in a subordinate

concept included in the lipid-containing formulation "mutually complement" to form a daily dosage of fatty acid in a superordinate concept, or (2) fatty acids included in one or more parts of the lipid-containing formulation "mutually complement" to form a daily dosage of fatty acid included in total of the lipid-containing formulation.

(ii) Thus, descriptions of the specification are considered.

a. The specification includes the following descriptions: "the lipid formulations may be packaged in one, two, three, four or more mutually complementing daily dosages." ([0037]); "the delivery of the desired lipid composition may be achieved through a one-part or multi-part mutually complementing delivery system" ([0040]); "in one example, liquid lipid and solid lipid composition parameters were established per diet or medical condition, intended for twice-a-day administration." ([0065]); "one formulation was prepared, intended for once, twice, or thrice or more a day administration." ([0069]); "liquid lipid and solid lipid composition parameters were established for a twice-daily administration." ([0071]); "Some parameters were also established for one or more daily administration." ([0072]).

Accordingly, it can be said that the specification discloses that the lipid-containing formulation can be

administered separately, and parameters included in each of the administration parts are controlled within a range of daily dosage, premised on (2) above.

b. On the other hand, the specification does not include a description which shows that fatty acids in a subordinate concept are in a mutually complementing relationship, and thus, does not include a disclosure premised on (1) above.

(iii) As such, it can be said that Specifying Matter C specifies that (2) fatty acids included in one or more parts of the lipid-containing formulation "mutually complement" to form a daily dosage of fatty acids included in total of the lipid-containing formulation, considering the descriptions of the specification, in addition to the recitation of the Claims corresponding to Specifying Matter C.

iii. Regarding "daily dosage"

(i) A structure of the fatty acid included in the lipid-containing formulation as specified by Specifying Matter C comprises a "daily dosage" of fatty acid. However, it is not clear only from the recitation of the Claims corresponding to Specifying Matter C, as a single meaning, as to whether (1) the lipid-containing formulation comprises "omega-6 and omega-3 fatty acids" corresponding to the "daily dosage" and may further comprise another

fatty acid, or (2) the lipid-containing formulation comprises "fatty acid" corresponding to the "daily dosage" and the "fatty acid" comprises "omega-6 and omega-3 fatty acids".

(ii) Thus, descriptions of the specification are considered.

a. In the specification, descriptions specifically illustrating amount of the fatty acid included in the lipid-containing formulation for administration to a subject are only in Examples 1, 3, 5, and 6.

Example 1 sets forth that "the formulations may provide a balanced fatty acid composition of approximately 10-100 grams of total daily fat", to thus describe a "daily dosage" of the "fatty acid" included in the lipid-containing formulation. On the other hand, the example has no description on "daily dosage" of "omega-6 fatty acid" and "omega-3 fatty acid".

Examples 3, 5, and 6 show Table 9 to Table 13, and explain that each of the Tables "provides dose ranges for total fatty acid content (unit: gram), the ratio range of monounsaturated fatty acid to polyunsaturated fatty acid, and the ratio range of monounsaturated fatty acid to saturated fatty acid, range of omega-6 fatty acid content (unit: gram), ratio range of omega-9 fatty acid to omega-6 fatty acid, range of omega-3 fatty acid content (unit:

gram), and the ratio range of omega-6 fatty acid to omega-3 fatty acid, by gender and age group. Each of the Tables of Examples 3, 5, and 6 shows a "daily dosage" of "fatty acid" included in the lipid-containing formulation, and then shows, as a specification of the "fatty acid", amount of monounsaturated fatty acid, polyunsaturated fatty acid, saturated fatty acid, omega-6 fatty acid, omega-9 fatty acid, and omega-3 fatty acid.

b. On the other hand, the specification discloses a "lipid formulation" as an embodiment for implementing the invention ([0022] to [0036]). Although the disclosure describes "optimal daily delivery of both omega-6 fatty acid and omega-3 fatty acid", the description is disclosed as one aspect ([0022]), and the disclosure also includes "embodiments" which mention balance of "fatty acids" other than "omega-6 fatty acid" and "omega-3 fatty acid" ([0030]).

In addition, each Table of Examples 3, 5, and 6 which shows dosages of "omega-6 fatty acid" and "omega-3 fatty acid" included in the lipid-containing formulation also shows dosages of other fatty acids.

Accordingly, these descriptions of the specification which disclose dosages of omega-6 fatty acid and omega-3 fatty acid do not allow dosages of other fatty acids to be

determined appropriately, and therefore, it should be said that the descriptions are not premised on (1) above.

c. Therefore, the specification explains amount of fatty acid included in the lipid-containing formulation after focusing on "daily dosage" of "fatty acid", and therefore, can be said to be premised on (2) above.

(iii) As such, it can be said that Specifying Matter C specifies that (2) the lipid-containing formulation comprises "fatty acid" corresponding to a "daily dosage" and the "fatty acid" comprises "omega-6 and omega-3 fatty acids", considering the descriptions of the specification, in addition to the recitation of the Claims.

iv. Regarding defendant's argument

(i) The defendant argues that it is possible to construe "mutually complementing" as omega-6 and omega-3 fatty acids "mutually complement", and also as various fatty acids "mutually complement".

However, there is no description in the specification which indicates that omega-6 and omega-3 fatty acids included in a lipid-containing formulation are in a mutually complementing relationship, or that various fatty acids are in a mutually complementing relationship. Although some of the invention-specifying matters of the invention specify amount or ratio of omega-6 and omega-3

fatty acids or amount of omega-9 fatty acid, complementing relationship of these fatty acids is not specified.

(ii) The defendant argues that it is also possible to construe "mutually complementing" as complementing fatty acid taken from meals.

However, it is clear that Specifying Matter C does not specify a relationship with fatty acid included in meals which is not included in lipid-containing formulation administered to a subject, but specifies structure of fatty acid included in a lipid-containing formulation administered to a subject, on the basis of recitations of the Claims corresponding thereto. Although [0041] of the specification describes the latter relationship, the description does not deny the interpretation clearly led from the recitation of the Claims corresponding to Specifying Matter C.

(iii) The defendant argues that it is also possible to construe "daily dosage" as "daily dosage" of "omega-6 and omega-3 fatty acids".

However, since the specification includes descriptions which focus on amounts of fatty acids other than "omega-6 and omega-3 fatty acids", including daily dosage of "fatty acid", it cannot be said that Specifying Matter C limits the daily dosage to only daily dosage of "omega-6 and omega-3 fatty acids".

(iv) Therefore, any of the interpretations argued by the defendant cannot be adopted.

v) Summary

In light of the above, Specifying Matter C specifies that the lipid-containing formulation administered to a subject comprises fatty acid; the fatty acid specifically may include, in addition to omega-6 and omega-3 fatty acids, another fatty acid; total amount of these fatty acids corresponds to a daily dosage of fatty acids; and these fatty acids are included in one or more parts of lipid-containing formulations. It cannot be said that recitation of the Claims corresponding to Specifying Matter C is so indefinite that it unfairly harms interest of a third person.

(4) Thus, the Cancellation Reason 2 is reasonable, and it cannot be said that the invention should be rejected for definiteness requirement contravention.

4 Regarding Cancellation Reason 3 (Misjudgment of Support Requirement)

(1) Relating to the support requirement, the trial decision has judged that recitation of the Claims of the invention does not comply with the support requirement, since the technical matter of "an increase in omega-6 is gentle and/or a discontinuation of omega-3 is gentle, with

a dosage of omega-6 being 40 g or less" is not described in the Detailed Description of Invention of the specification.

In the trial decision, neither discussed nor judged on whether or not the invention is in a range where a person skilled in the art can solve the problem of the invention on the basis of descriptions of the Detailed Description of Invention, or whether or not the invention is in a range where a person skilled in the art can recognize that the problem of the invention can be solved, in light of a technical common knowledge at the time of filing, even without a description or a suggestion in the Detailed Description of Invention.

(2) However, a judgement on whether or not a recitation of Claims complies with the support requirement should be made contrasting the recitation of the Claims with descriptions of the Detailed Description of Invention, to discuss whether or not an invention recited in the Claims is an invention described in the Detailed Description of Invention and in a range where a person skilled in the art can solve the problem of the invention on the basis of the descriptions of the Detailed Description of Invention, or whether or not the invention is in a range where a person skilled in the art can recognize that the problem of the invention can be solved, in light of a technical common knowledge at a time of

filing, even without a description or a suggestion in the Detailed Description of Invention.

Accordingly, the trial decision is a Misjudgment, for judging that the invention does not comply with the support requirement, only from a fact that the Detailed Description of Invention does not describe the technical matter of Specifying Matter G "an increase in omega-6 is gentle and/or a discontinuation of omega-3 is gentle, with a dosage of omega-6 being 40 g or less", among Specifying Matters E to H which are in an alternative relationship, without having any discussion on whether or not the invention is in a range where a person skilled in the art can solve the problem of the invention on the basis of the descriptions of the Detailed Description of Invention, or whether or not the invention is in a range where a person skilled in the art can recognize that the problem of the invention can be solved, in light of a technical common knowledge at the time of filing, even without a description or a suggestion in the Detailed Description of Invention.

(3) Moreover, the technical matter of Specifying Matter G "an increase in omega-6 is gentle and/or a discontinuation of omega-3 is gentle, with a dosage of omega-6 being 40 g or less" is described in the Detailed Description of Invention of the specification, as follows.

That is, firstly, [0042] in the specification describes as follows: "a sudden stop of a habitual large amount of supply of a long chain omega-3 fatty acid or an immunosuppressive phytochemicals/nutrient, or a sudden increase of an omega-6 fatty acid to a host sometimes cause a cytokine storm response accompanied with a severe consequences, including systemic inflammatory responses (capillary leak, fever, tachycardia, tachypnea), multi-organ failures (digestive organ, lung, liver, kidney, heart), and damages to connective tissue of arthron". In the description, it is stated that various diseases can occur, even only in cases which do not employ the administration method in which "an increase in omega-6 is gentle and/or a discontinuation of omega-3 is gentle". As such, the specification describes in [0042] the technical matter concerning the administration method in which "an increase in omega-6 is gentle and/or a discontinuation of omega-3 is gentle".

The specification also sets forth that dose of omega-6 fatty acid of the lipid composition to be administered to vegetarian or specific non-vegetarian 19 to 30-year old and 31 to 50-year old males is made 40 g or less (Example 3 Table 9); dose of omega-6 fatty acid of the lipid composition to be administered to high-seafood male consumers of the same age is made 40 g or less (Example 3

Table 11); dose of omega-6 fatty acid of the lipid composition to be administered to subjects with obesity as a medical indication is made 40 g or less (Example 6 Table 13). As such, technical matters relating to administration method in which "dose of omega-6 is 40 or less" are described as applied to a part of the subjects of Table 9, Table 11 of Example 3, and Table 13 of Example 6 of the specification.

Furthermore, as set forth above, the specification describes in [0042] that various diseases can occur, even only in cases which do not employ the administration method in which "an increase in omega-6 is gentle and/or a discontinuation of omega-3 is gentle", from which it should be said that the description discloses that the administration method in which "an increase in omega-6 is gentle and/or a discontinuation of omega-3 is gentle" is preferred generally, not only to specific subjects. Accordingly, it can be said that the specification describes a technical matter relating to an administration method which is a combination of such an administration method as above, and the administration method in which "a dosage of omega-6 is 40 g or less" as described in parts of each of Table 9 and Table 11 of Example 3, and Table 13 of Example 6, namely, for example, a method of administering a lipid-containing composition, in which omega-6 fatty acid

of 40 g or less dosage is administered to vegetarian or specific non-vegetarian 19 to 30-year old and 31 to 50-year old males, and at the time of administration, omega-6 fatty acid is gently increased and/or omega-3 fatty acid is gently discontinued.

(4) Therefore, the trial decision has not only an incorrectness in the part of judgment formally made on the support requirement, but also a problem in framework of the judgment, for not having made substantial discussion and judgment on the requirement, after all. Thus, Cancellation Reason 3 is reasonable in claiming the point.

5 Conclusion

As above, Cancellation Reasons 2 and 3 argued by the plaintiff are reasonable, and therefore, the plaintiff's demand is approved and the judgment is rendered as described in the main text.

Intellectual Property High Court, First Division

Presiding judge: TAKABE Makiko

Judge: SUGIURA Masaki

Judge: KATASE Ryo

[DOCUMENT]	Amendment
[SERIAL NUMBER]	B174618
[DATE OF SUBMISSION]	November 9, 2017
[ADDRESSED TO]	Chief Trial Examiner
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[A PERSON WHO FILES AN AMENDMENT]	
[Identification Number]	513088537
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[Telephone Number]	03-5470-1900
[DISPATCH NUMBER]	032804
[CONTENT OF AMENDMENT]	
[Document] CLAIMS	
1.	<p>Use of one or more factors of a subject selected from: age of the subject, sex of the subject, diet of the subject, the body weight of the subject, physical activity level of the subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and ambient temperature range of the subject's living area as an indicator for selecting a lipid-containing formulation for administration to the subject,</p> <p style="padding-left: 40px;">wherein the formulation comprises one or more mutually complementing daily dosages of fatty acids comprising omega-6 and omega-3 fatty acids, wherein the ratio of omega-6 to omega-3 fatty acids and their amounts are based on the one or more factors; wherein the omega-6 to omega-3 ratio is:</p> <p style="padding-left: 80px;">4:1 or greater, wherein the dosage of omega-6 is not more than 40 grams;</p> <p>or</p> <p style="padding-left: 80px;">1:1 to 50:1 based on amount of antioxidants, phytochemicals, and seafood in the subject's diet and/or the formulation; or</p>

wherein increase of omega-6 is gradual and/or withdrawal of omega-3 is gradual and the dosage of omega-6 is not more than 40 grams; or wherein the fatty acid content is matched to Table 6.

[Table. 1]

Table 6. Unsaturated Fatty Acid Contents According to Climate

% by Weight Ranges by Temperature (in °F)	HOT 90°- 135°		WARM 70°- 99°		COOL 50°- 75°		COLD 33°- 55°		BELOW FREEZING 0°- 37°		ARCTIC -50°- 5°		POLAR -100°- -45°	
	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High
Omega-9 Fats	20	90	20	90	20	90	10	80	10	80	10	80	10	80
Omega-6 Fats	4	60	4	60	6	60	10	60	12	70	13	70	15	73
Omega-3 Fats	0.3	5	0.5	6	0.8	7	1	8	1.5	9	1.8	12	2	13

- A method of preparing a lipid-containing formulation for a subject, comprising: one or more mutually complementing daily dosages of fatty acids for the subject based on one or more factors selected from: age of the subject, sex of the subject, diet of the subject, the body weight of the subject, physical activity level of the subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and ambient temperature range of the subject's living area,

wherein the formulation comprises omega-6 and omega-3 fatty acids and wherein the ratio of omega-6 to omega-3 fatty acids and their amounts are based on the one or more factors; wherein the omega-6 to omega-3 ratio is:

4:1 or greater, wherein the dosage of omega-6 is not more than 40 grams;

or

1:1 to 50:1 based on amount of antioxidants, phytochemicals, and seafood in the subject's diet and/or the formulation; or

wherein increase of omega-6 is gradual and/or withdrawal of omega-3 is gradual and the dosage of omega-6 is not more than 40 grams; or

wherein the fatty acid content is matched to Table 6.

[Table. 2]

Table 6. Unsaturated Fatty Acid Contents According to Climate

% by Weight Ranges by Temperature (in °F)	HOT 90°- 135°		WARM 70°- 99°		COOL 50°- 75°		COLD 33°- 55°		BELOW FREEZING 0°- 37°		ARCTIC -50°- 5°		POLAR -100°- -45°	
	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High
Omega-9 Fats	20	90	20	90	20	90	10	80	10	80	10	80	10	80
Omega-6 Fats	4	60	4	60	6	60	10	60	12	70	13	70	15	73
Omega-3 Fats	0.3	5	0.5	6	0.8	7	1	8	1.5	9	1.8	12	2	13

3. The use or method of claim 1 or 2, wherein one or more fatty acids are selected from butyric acid (C4:0), lauric acid (C12:0), myristic acid (C14:0), palmitic acid (C16:0), stearic acid (C18:0), arachidic acid (C20:0), myristoleic acid (C14:1), palmitoleic acid (C16:1), oleic acid (C18:1), gadoleic acid (C20:1), ercucic acid (C22:1), nervonic acid (C24:1), linoleic acid (C18:2), conjugated-linoleic acid (C18:2), gamma-linolenic acid (C18:3), eicosadienoic acid (C20:2), di-homo-gamma-linolenic acid (C20:3), arachidonic acid (C20:4), alpha-linolenic acid (C18:3), stearidonic acid (C18:4), eicosapentaenoic acid (C20:5), docosapentaenoic acid (C22:5), and docosahexaenoic acid (C22:6).

4. The use or method of any one of claims 1 to 3, wherein one or more of the following apply:
 - (i) omega-6 fatty acids are present at 4% to 75% by weight of total lipids;
 - (ii) omega-3 fatty acids are present at 0.1 to 30% by weight of total lipids; or
 - (iii) omega-9 fatty acids are present at 10% to 90% by weight of total lipids.

5. The use or method of any one of claims 1 to 4, wherein one or more of the following apply:
 - (i) comprising one or more of seeds, nuts, oils, legumes, dairy, cocoa, lentils, grains, and culinary nuts and/or seeds in their whole form or their oils;
 - (ii) comprising oils, butters, nuts, seeds, herbs, sweeteners, and other foods, as a source of fatty acids, antioxidants, minerals, and/or phytochemicals;

(iii) comprising one or more of peanut oil, corn oil, avocado oil, olive oil, sunflower oil, safflower oil, coconut oil, mustard oil, palm oil, soybean lecithin, and anhydrous butter;

(iv) comprising one or more of peanuts, almonds, olives, soybeans, cashews, flaxseeds, pistachios, pumpkin seeds, sunflower seeds, sesame seeds, walnuts, anhydrous butter, and coconut meat, or their oils;

(v) comprising omega-6 fatty acids at 4% to 75% by weight and omega-3 fatty acids at 0.1% to 30% by weight of total lipids, and wherein the nuts or their oils comprise almonds, peanuts, and/or coconut meat, and the formulation optionally comprises anhydrous butter.

6. The use or method of any one of claims 1 to 5, wherein the omega-6 to omega-3 ratio is 4:1 to 45:1.
7. The use or method of any one of claims 1 to 6, wherein the omega-6 to omega-3 ratio is at least 9:1.
8. The use or method of any one of claims 1 to 7, wherein one or more of the following apply:
 - (i) the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 0.25:1 to 6:1; or
 - (ii) the ratio of total fatty acids to monounsaturated fatty acids is in the range of 1:1 to 15:1; and/or the ratio of total fatty acids to saturated fatty acids is 1:1 to 15:1.
9. The use or method of any one of claims 1 to 8, wherein one or more of the following apply:
 - (i) the dosage of total lipids in grams is from 10-100 grams;
 - (ii) the daily dosage of omega-6 fatty acids is less than 40 grams;
 - (iii) the dosage of omega-6 fatty acids is from 1 to 40 grams;

- (iv) the dosage of omega-3 fatty acids is from 0.1 to 6.0 grams, wherein eicosapentaenoic acid (C20:5) is not more than 0.5 grams, and/or docosahexaenoic acid (C22:6) is not more than 0.2 grams.
- (v) total dosage of total lipids is 10-100 grams, the dosage of omega-6 fatty acids is from 1 to 40 grams, the dosage of omega-3 fatty acids is from 0.1 to 5 grams, the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 1:1 to 3:1, the ratio of monounsaturated fatty acids to saturated fatty acids is 1:1 to 5:1, the ratio of omega-9 to omega-6 fatty acids is in the range of 1:1 to 3:1, and the ratio of omega-6 to omega-3 fatty acids is in the range of 4:1 to 45:1;
- (vi) the formulation supplies 50-90% of a diet's fat calories; or
- (vii) the formulation is designed for use in combination with or provided with a lipid-free or low-lipid food product.

10. The use or method according to any one of claims 1 to 9, wherein one or more of the following apply:
- (i) comprising one or more phytochemicals selected from: polyphenols, flavonoids, flavanones, flavones, isoflavones, anthocyanidins, anthocyanins, phytoestrogens, catechins, resveratrol, lignins, phenolic acids, gallic acid, ellagic acid, hydroxycinnamic acid, curcumin, flavonols, quercetin, and kaempferol; or
 - (ii) comprising one or more phytochemicals selected from: phytosterols, campesterol, sitosterol, stigmasterol, organosulfides, melatonin, saponins, carotenoids, coumarins, beta-carotene, lycopene, lutein, zeaxanthin, and monophenols;
 - (iii) comprising one or more phytochemicals, antioxidants, vitamins, minerals, and trace elements;
 - (iv) comprising vitamin E in the range of 0.001 % to 0.5% by weight of total lipids;
 - (v) comprising a source of fiber;
 - (vi) comprising one or more nutrients effective to reduce omega-3 requirement and/or allow for higher omega-6 to omega-3 ratio than in the absence of the nutrient and/or increase effective levels of omega-3 in a subject;

(vii) comprising one or more polyphenols effective to increase omega-3 levels in the subject; or

(viii) comprising one or more of vitamin A, folic acid or folate, vitamin, C, vitamin D, vitamin E, Cu, Zn, Mn, Fe, Se, and/or Mg.

11. The use or method of any one of claims 1 to 10, wherein lipid-free or low-lipid foods are designed for use with the lipid formulation; optionally wherein foods are selected from one or more of grains, legumes, fruits, vegetables, yogurt, herbs, spices, sweeteners, beverages, eggs, cheese, milk, poultry, seafood, and meat.
12. The use or method according to any one of claims 1 to 11, wherein one or more of the following apply:
 - (i) a source of nutrients selected from one or more of grains, legumes, fruits, vegetables, yogurt, herbs, spices, sweeteners, eggs, cheese, milk, poultry, seafood, and meat;
 - (ii) 20-45% of diet's calories are from fat, 45-65% of diet's calories are from carbohydrates, and 10%-25% of diet's calories are from protein;
 - (iii) carbohydrates calories are 50-70% from grains, 15-30% from vegetables, and 10-30 % from fruits, wherein optionally grains are selected from wheat, rice, corn, barley, spelt, oats, rye, buckwheat, millet, and quinoa; or
 - (iv) protein calories are less than 75% from legumes, less than 25% from eggs, less than 25% from cheese, less than 25% from milk, less than 25% from yogurt, less than 30% from poultry, less than 30% from seafood, less than 30% from meat, and less than 15% from other sources.
13. The use or method according to any one of claims 1 to 12 wherein one or more of the following apply:
 - (i) the formulation is in the form of full meal or a dietary component selected from an oil, gel, sauce, dressing, spread, butter, drops, nutritional bar, snack, bread, bakery product, dairy product, side dish, salad, dessert, chocolate, fudge, pastry, truffle, pudding, cake, yogurt, drink, or a combination thereof; or

(ii) the formulation is in the form of enteral, parenteral, a liquid, a semi-solid, a solid, capsule, tablet, granule, powder, lozenge, pill, or a combination thereof; or
(iii) the formulation is one-part or comprises multi-part mutually complementing components, for one or more days, one or more weeks, or one or more months.

14. The use or method of any one of claims 1 to 13, wherein the fatty acids, phytochemical, antioxidant, vitamins and minerals content of the formulation is effective for the subject to maintain nutrient balance, and/or avoid unfavorable dietary interactions.
15. The use or method of any one of claims 1 to 14, wherein the subject is an infant, a child, or an adult.
16. The use or method of any one of claims 1 to 15, wherein the formulation is administered to the subject by steady delivery without large fluctuations, wherein any omega-3 and/or phytochemical withdrawal is gradual, and/or any omega-6 and/ or other fatty acid increase is gradual.
17. The use or method of any one of claims 1 to 16, wherein the formulation is for prophylaxis and/or treatment of a medical condition in a subject.
18. The use of claim 17, wherein said medical condition is selected from: menopause, aging, musculoskeletal disorders, mood swing, reduced cognitive function, neural disorders, mental disorders, thyroid disturbances, weight gain, obesity, diabetes, endocrine disorders, digestive system disorders, reproductive disorders, pulmonary disorders, renal diseases, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, cancer, autoimmune diseases, infectious diseases, inflammatory diseases, hypercholesterolemia, dyslipidemia, or cardiovascular disease.

19. A lipid-containing formulation comprising a mixture of lipids from different sources, wherein the formulation comprises a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater, wherein:
 - (i) omega-3 fatty acids are 0.1-20% by weight of total lipids; or
 - (ii) the dosage of omega-6 fatty acids is not more than 40 grams.

20. A lipid-containing formulation comprising a mixture of lipids from different sources, wherein the formulation comprises a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 9:1 or greater, wherein:
 - (i) omega-3 fatty acids are 0.1-10% by weight of total lipids; or
 - (ii) the dosage of omega-6 fatty acids is not more than 40 grams.

21. A formulation according to claim 19 or 20, wherein the omega-6 fatty acids are 4-75% by weight of total lipids.

22. A formulation according to claim 19 or 20, wherein omega-6 fatty acids are greater than 20% by weight of the total lipids.

23. A formulation according to claim 19 or 20, which comprises one or more nutrients.

24. A formulation according to claim 23, wherein the one or more nutrients comprises one or more polyphenols, or one or more phytochemicals selected from the group consisting of phytosterols, organosulfides, melatonin, saponins, coumarins, lycopene, lutein, zeaxanthin and monophenols.

25. The formulation of any one or more of claims 19 to 24, comprising at least three of (A):
 - (A-1) a peanut oil present at 8 to 56 percent by weight in the formulation; and
 - (A-2) at least two of: (A-2-1) a vegetable oil present at 8 to 46 percent by weight in the formulation, wherein the vegetable oil is selected from one or more of acai oil, amaranth oil, apple seed oil, apricot kernel oil, argan oil, artichoke oil,

babassu oil, ben oil, blackcurrant seed oil, borage seed oil, borneo tallow nut oil, bottle gourd oil, buffalo gourd oil, canola oil (rapeseed), cape chestnut oil, carob pod oil, cocklebur oil, cocoa butter oil, cohune oil, coriander seed oil, corn oil, cottonseed oil, dika oil, evening primrose oil, false flax oil (*Camelina sativa*), grapeseed oil, kapok seed oil, lallemantia oil, marula oil, meadowfoam seed oil, mustard oil, nutmeg butter, okra seed oil, palm oil, papaya seed oil, pequi oil, perilla oil, prune kernel oil, quinoa oil, ramtil oil, rice bran oil, royle oil, sacha inchi oil, sheanut oil, soybean lecithin oil, tea oil, thistle oil, tomato seed oil, ucuhuba butter oil, wheat germ oil, acorn oil, almond oil, beech nut oil, brazilnut oil, breadnut oil, candlenut oil, chestnut oil, chilacayote nut oil, chilean hazelnut oil, coconut oil, cashew oil, colocynth nut oil, filbert oil, hazelnut oil, hickory oil, kola nut oil, macadamia oil, mamoncillo oil, mongongo oil, obongo nut oil, pecan oil, pili nut oil, pine nut oil, pistachio oil, soya oil, poppy seed oil, pumpkin seed oil, hemp seed oil, flax seed oil, sesame seed oil, walnut oil, and watermelon seed oil;

(A-2-2) an avocado oil present at 3 to 16 percent by weight in the formulation;

(A-2-3) an olive oil present at 5 to 32 percent by weight in the formulation;

(A-2-4) a sunflower oil present at 6 to 34 percent by weight in the formulation;

and

(A-2-5) a safflower oil present at 2 to 30 percent by weight in the formulation;

or comprising at least three of (B):

(B-1) an almond oil present at 2 to 23 percent by weight in the formulation;

(B-2) an avocado oil present at 1 to 7 percent by weight in the formulation;

(B-3) a soybean oil present at 1 to 7 percent by weight in the formulation;

(B-4) a cashew oil present at 2 to 15 percent by weight in the formulation;

(B-5) a pistachio oil present at 1 to 7 percent by weight in the formulation;

(B-6) a pumpkin seed oil present at 1 to 8 percent by weight in the formulation;

(B-7) a walnut oil present at 3 to 25 percent by weight in the formulation;

(B-8) a peanut oil present at 5 to 30 percent by weight in the formulation;

(B-9) a corn oil present at 3 to 19 percent by weight in the formulation;

(B-10) an olive oil present at 3 to 17 percent by weight in the formulation;

(B-11) a safflower oil present at 1 to 14 percent by weight in the formulation; and

(B-12) an anhydrous butter present at 5 to 29 percent by weight in the formulation;

or comprising at least three of (C):

(C-1) an almond oil present at 1 to 36 percent by weight in the formulation;

(C-2) a pumpkin seed oil present at 1 to 24 percent by weight in the formulation;

(C-3) an oil from walnuts present at 2 to 36 percent by weight in the formulation;

(C-4) a peanut oil present at 4 to 72 percent by weight in the formulation;

(C-5) a corn oil present at 1 to 24 percent by weight in the formulation;

(C-6) an olive oil present at 2 to 36 percent by weight in the formulation;

(C-7) a sunflower oil present at 4 to 72 percent by weight in the formulation;

(C-8) a safflower oil present at 2 to 60 percent by weight in the formulation; and

(C-9) an anhydrous butter present at 2 to 36 percent by weight in the formulation;

further comprising one or more of:

(C-10) a mustard oil present at 8 percent or less by weight in said formulation,

(C-11) a palm oil present at 2 percent or less by weight in said formulation,

(C-12) a flaxseed oil at 8 percent or less by weight in said formulation,

(C-13) a coconut oil present at 8 percent or less by weight in said formulation,

and

(C-14) a soybean lecithin present at 4 percent or less by weight in said formulation;

or comprising at least three of (D):

(D-1) peanuts present at 2 to 11 percent by weight in the formulation;

(D-2) almonds present at 5 to 32 percent by weight in the formulation;

(D-3) olives present at 6 to 36 percent by weight in the formulation;

(D-4) soybeans present at 4 to 25 percent by weight in the formulation;

(D-5) cashews present at 4 to 21 percent by weight in the formulation;

(D-6) pistachios present at 2 to 9 percent by weight in the formulation;

(D-7) pumpkin seeds present at 2 to 15 percent by weight in the formulation;

(D-8) sunflower seeds present at 1 to 4 percent by weight in the formulation;

(D-9) walnuts present at 3 to 25 percent by weight in the formulation;

(D-10) anhydrous butter present at 4 to 24 percent by weight in the formulation;

and

(D-11) coconut meat present at 1 to 6 percent by weight in the formulation;

or comprising at least three of (E):

safflower oil, sunflower oil, peanut oil, almond or almond oil, corn oil, and anhydrous butter;

or comprising at least three of (F):

or peanuts, almonds, olives, soybeans, cashews, flaxseeds, pistachios, pumpkin seeds, sunflower seeds, sesame seeds, walnuts, anhydrous butter and coconut meat, or their oils;

26. The formulation of any one or more of claims 19 to 25, comprising one or more fatty acids selected from butyric acid (C4:0), lauric acid (C12:0), myristic acid (C14:0), palmitic acid (C16:0), stearic acid (C18:0), arachidic acid (C20:0), myristoleic acid (C14:1), palmitoleic acid (C16:1), oleic acid (C18:1), gadoleic acid (C20:1), ercucic acid (C22:1), nervonic acid (C24:1), linoleic acid (C18:2), conjugated-linoleic acid (C18:2), gamma-linolenic acid (C18:3), eicosadienoic acid (C20:2), di-homo-gamma-linolenic acid (C20:3), arachidonic acid (C20:4), alpha-linolenic acid (C18:3), stearidonic acid (C18:4), eicosapentaenoic acid (C20:5), docosapentaenoic acid (C22:5), and docosahexaenoic acid (C22:6).

27. The formulation of any one or more of claims 19 to 26, comprising fatty acids wherein one or more of the following apply:

(i) omega-3 fatty acids are present at 0.1 to 10% by weight of total lipids; or

(ii) omega-9 fatty acids are present at 10% to 90% by weight of total lipids.

28. The formulation of any one or more of claims 19 to 27, wherein one or more of the following apply:

- (i) comprising one or more of seeds, nuts, oils, legumes, dairy, cocoa, lentils, grains, and culinary nuts and/or seeds in their whole form or their oils;
- (ii) comprising oils, butters, nuts, seeds, herbs, sweeteners, and other foods, as source of fatty acids, antioxidants, minerals, and/or phytochemicals;
- (iii) comprising one or more of peanut oil, corn oil, avocado oil, olive oil, sunflower oil, safflower oil, coconut oil, mustard oil, palm oil, soybean lecithin, and anhydrous butter;
- (iv) comprising one or more of peanuts, almonds, olives, soybeans, cashews, flaxseeds, pistachios, pumpkin seeds, sunflower seeds, sesame seeds, walnuts, anhydrous butter, and coconut meat, or their oils; or
- (v) comprising omega-3 fatty acids at 0.1% to 10% by weight of total lipids, and wherein the nuts or their oils comprise almonds, peanuts, and/or coconut meat, and the formulation optionally comprises anhydrous butter.

29. The formulation of any one or more of claims 19 to 28, comprising omega-6 and omega-3 fatty acids wherein the omega-6 to omega-3 ratio is 9:1 to 45:1.

30. The formulation of any one or more of claims 19 to 29, comprising monounsaturated and polyunsaturated fatty acids wherein one or more of the following apply:

- (i) the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 0.25:1 to 6:1; or
- (ii) the ratio of total fatty acids to monounsaturated fatty acids is in the range of 1:1 to 15:1; and/or the ratio of total fatty acids to saturated fatty acids is 1:1 to 15:1.

31. The formulation of any one or more of claims 19 to 30, wherein one or more of the following apply:

- (i) the dosage of total lipids in grams is from 10-100 grams;
- (ii) the daily dosage of omega-6 fatty-acids is less than 40 grams;
- (iii) the dosage of omega-6 fatty acids is from 1 to 40 grams;

- (iv) the dosage of omega-3 fatty acids are from 0.1 to 6.0 grams, wherein if present eicosapentaenoic acid (C20:5) is not more than 0.5 grams, and/or docosahexaenoic acid (C22:6) is not more than 0.2 grams.
- (v) the dosage of total lipids is 10-100 grams, the dosage of omega-6 fatty acids is from 1 to 40 grams, the dosage of omega-3 fatty acids is from 0.1 to 5 grams, the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 1:1 to 3:1, the ratio of monounsaturated fatty acids to saturated fatty acids is 1:1 to 5:1, the ratio of omega-9 to omega-6 fatty acids is in the range of 1:1 to 3:1, and the ratio of omega-6 to omega-3 fatty acids is in the range of 9:1 to 45:1;
- (vi) the formulation supplies 50-90% of a diet's fat calories; or
- (vii) the formulation is designed for use in combination with or provided with a lipid-free or low-lipid food product.

32. The formulation of any one or more of claims 19 to 31, wherein one or more of the following apply:

- (i) comprising one or more polyphenols selected from: flavonoids, flavanones, flavones, isoflavones, anthocyanidins, anthocyanins, phytoestrogens, catechins, resveratrol, lignins, phenolic acids, gallic acid, ellagic acid, hydroxycinnamic acid, curcumin, flavonols, quercetin, and kaempferol; or
- (ii) comprising one or more phytochemicals selected from: campesterol, sitosterol, stigmasterol, carotenoids, beta-caroten;
- (iii) comprising one or more phytochemicals, antioxidants, vitamins, minerals, and trace elements;
- (iv) comprising vitamin E in the range of 0.001 % to 0.5% by weight of total lipids;
- (v) comprising a source of fiber;
- (vi) comprising one or more nutrients effective to reduce omega-3 requirement and/or allow for higher omega-6 to omega-3 ratio than in the absence of the nutrient and/or increase effective levels of omega-3 in a subject;
- (vii) comprising one or more polyphenols effective to increase omega-3 levels in a subject; or

(viii) comprising one or more of vitamin A, folic acid or folate, vitamin, C, vitamin D, vitamin E, Cu, Zn, Mn, Fe, Se, and/or Mg.

33. The formulation of any one or more of claims 19 to 32, wherein one or more of the following apply:
- (i) comprising a source of nutrients selected from one or more of grains, legumes, fruits, vegetables, yogurt, herbs, spices, sweeteners, eggs, cheese, milk, poultry, seafood, and meat;
 - (ii) comprising 20-45% of diet's calories from fat, 45-65% of diet's calories from carbohydrates, and 10%-25% of diet's calories from protein;
 - (iii) comprising carbohydrates calories of which 50-70% are from grains, 15-30% are from vegetables, and 10-30 % are from fruits, wherein optionally grains are selected from wheat, rice, corn, barley, spelt, oats, rye, buckwheat, millet, and quinoa;
 - (iv) comprising protein calories of which less than 75% are from legumes, less than 25% are from eggs, less than 25% are from cheese, less than 25% are from milk, less than 25% are from yogurt, less than 30% are from poultry, less than 30% are from seafood, less than 30% are from meat, and less than 15% are from other sources; or
 - (v) lipid-free or low-lipid foods are designed for use in combination with said lipid composition to achieve a balanced diet plan.
34. The formulation of any one or more of claims 19 to 33, wherein the formulation comprises daily amounts of fatty acids for a subject based on one or more factors selected from: age of the subject, sex of the subject, diet of the subject, the body weight of the subject, physical activity level of the subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and climate of the subject's living area.
35. The formulation of any one or more of claims 19 to 34, wherein one or more of the following apply:

- (i) the formulation is in the form of full meal or a dietary component selected from an oil, gel, sauce, dressing, spread, butter, drops, nutritional bar, snack, bread, bakery product, dairy product, side dish, salad, dessert, chocolate, fudge, pastry, truffle, pudding, cake, yogurt, drink, or a combination thereof; or
 - (ii) the formulation is in the form of enteral, parenteral, a liquid, a semi-solid, a solid, capsule, tablet, granule, powder, lozenge, pill, or a combination thereof; or
 - (iii) the formulation further comprises one or more carriers selected from starches, sugars, granulating agents, binders and disintegrating agents; or
 - (iv) the formulation is one-part or comprises multi-part mutually complementing components, for one or more days, one or more weeks, or one or more months.
36. The formulation of any one or more of claims 19 to 35, wherein the formulation is configured for administration to a subject by gradual and/or steady delivery.
37. The formulation of any one or more of claims 19 to 36 for use in maintaining a moderate level of oxidation, avoiding unfavorable dietary interactions, or restricting calorie intake, in a subject characterized in that an effective amount of the formulation is administered to the subject, thereby maintaining a moderate level of oxidation, avoiding unfavorable dietary interactions, or restricting calorie intake in the subject.
38. The formulation of any one or more of claims 19 to 37 for use in prophylaxis and/or treatment of a medical condition in a subject.
39. The formulation of claim 38, wherein the subject has a diet of low-antioxidants and/or low phytochemicals; or the subject has a diet of high seafood.
40. The formulation of claim 38 or 39, wherein the dosage of total fat is 10-100 grams, the dosage of omega-6 fatty acids is from 1 to 35 grams, the dosage of omega-3 fatty acids is from 0.1 to 6 grams, the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 1:1 to 3:1, the ratio of monounsaturated fatty acids to saturated fatty acids is 1:1 to 5:1, the ratio of

omega-9 to omega-6 fatty acids is in the range of 1:1-3:1, and the ratio of omega-6 to omega-3 fatty acids is in the range of 9:1-45:1.

41. The formulation of claim 38, wherein the formulation is administered to the subject by steady delivery without large fluctuations, wherein any omega-3 and/or phytochemical withdrawal is gradual, and/or any omega-6 and/ or other fatty acid increase is gradual.
42. The formulation of any one or more of claims 38 to 41, wherein said medical condition is linked with a lipid imbalance in said subject.
43. The formulation of any one or more of claims 38 to 42, wherein said medical condition is selected from: menopause, aging, musculoskeletal disorders, mood swing, reduced cognitive function, neural disorders, mental disorders, thyroid disturbances, weight gain, obesity, diabetes, digestive system disorders, reproductive disorders, pulmonary disorders, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, autoimmune diseases, infectious diseases, inflammatory diseases, hypercholesterolemia, dyslipidemia, or cardiovascular disease.
44. A formulation according to any one or more of claims 19 to 43, wherein the fatty acids are in free form, and/or in ester form.
45. A formulation according to any one or more of claims 19 to 44, wherein one or more dosages are therapeutically effective.
46. A lipid containing formulation, wherein the dosage of omega-6 fatty acids is from 1 to 35 grams, the dosage of omega-3 fatty acids is from 0.1 to 6 grams, the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 1:1-3:1, and the ratio of omega-6 to omega-3 fatty acids is in the range of 1:1-45:1.

47. The formulation of claim 46, for use in prevention or treatment of a medical condition selected from: menopause, cardiovascular disease, mental disorders, musculoskeletal disorders, aging, endocrine disorders, viral infections, bacterial infections, obesity, renal diseases, pulmonary disorders, ophthalmologic disorders, dental disorders, or cancer.

Attachment L:

Translation of the Decision of the Intellectual Property Trial and Appeal Board of South Korea and the allowed claims in corresponding application

Korean Intellectual Property Tribunal

The Seventh Department

Decision

Trial No. 2017 won 5015

Case No. Appeal to Decision of Rejection concerning 2010 Patent Application
No. 7026029 [LIPID-CONTAINING COMPOSITIONS AND
METHODS OF USE THEREOF]

Applicant ASHA NUTRITION SCIENCES, INC.
PO Box 1000. Palo Alto, California 94302, U.S.A.
Agent KIM, Jin-Hoe and KIM, Taehong
14F, POONGSAN BLDG., 23 CHUNGJEONG-RO SEODAEMUN-
GU, Seoul (Lee International IP&Law)

Original Decision Rejection on July 18, 2017

Date of Decision June 27, 2019

Formal Adjudication

The original decision shall be cancelled and this case shall be remanded to the Examiner for examination.

Purport of Appeal

The original decision should be cancelled. A decision to grant a patent for Korean Patent Application No. 7026029 of 2010 should be made.

Grounds

1. Basic facts

Examining the procedural history of the subject objection against the refusal decision for Korean Patent Application No. 7026029 of 2010 (hereinafter referred to as “the subject patent invention”), the following facts are acknowledged.

A. Procedural history

- ① Translation submission date/international filing date/priority date: 2010. 11. 19./2009. 4. 20./2018. 4. 21., 2008. 6. 25., 2008. 11. 5. and 2009. 4. 17.
- ② Amendment(specification): 2010. 11. 24. and 2014. 4. 10.
- ③ Office action: 2015. 10. 1.
- ④ Amendment(specification): 2016. 4. 1.
- ⑤ Office action: 2016. 8. 18.
- ⑥ Amendment(specification): 2017. 3. 10.
- ⑦ Decision of rejection: 2017. 7. 18.
- ⑧ Request for trial: 2017. 10. 17.
- ⑨ Amendment(specification): 2017. 11. 16.
- ⑩ Maintenance of original decision: 2017. 12. 7.

B. Claims of subject patent invention

1. A lipid-containing formulation, comprising a mixture of lipids from different sources, wherein the formulation comprises a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of at least 4:1 w/w, w/v, or v/v, wherein omega-3 fatty acids are 0.1-20% by weight of total lipid. (hereinafter, referred to as “the subject invention of claim 1,” and the rest of the claims are referred to in the same way).

2. A lipid-containing formulation, comprising a mixture of lipids from different sources, wherein the formulation comprises a dosage of omega-6 and omega-3 fatty acids at an omega-6

to omega-3 ratio of at least 4:1 w/w, w/v, or v/v, wherein the dosage of omega-6 fatty acids is from 0.00000001mg to 40 grams.

3. A lipid-containing formulation, comprising a mixture of lipids from different sources, wherein the formulation comprises: polyunsaturated fatty acids, monounsaturated fatty acids, and saturated fatty acids, wherein the lower limit of omega-6 fatty acids is 20% by weight of the total lipids, and nutrients comprising one or more polyphenols, or one or more phytochemicals selected from phytosterols, organosulfides, melatonin, saponins, coumarins, lycopene, lutein, zeaxanthin, and monophenols, and wherein the formulation comprises a dosage of omega-6 fatty acids.

7. The formulation of claim 1, 2, or 3, wherein one or more of the following apply:

(i) comprising one or more of seeds, nuts, legumes, dairy, cocoa, lentils, grains, or their oils;

(ii) comprising oils, butters, nuts, seeds, herbs, sweeteners, or a combination thereof, as source of fatty acids, antioxidants, minerals, or phytochemicals, or a combination thereof;

(iii) comprising one or more of peanut oil, corn oil, avocado oil, olive oil, sunflower oil, safflower oil, coconut oil, mustard oil, palm oil, soybean lecithin, and anhydrous butter;

(iv) comprising one or more of peanuts, almonds, olives, soybeans, cashews, flaxseeds, pistachios, pumpkin seeds, sunflower seeds, sesame seeds, walnuts, anhydrous butter, and coconut meat, or their oils; or

(v) comprising omega-3 fatty acids at 0.1% to 10% by weight of total lipids, and wherein the nuts or their oils comprise almonds, peanuts, coconut meat, or anhydrous butter.

10. The formulation of claim 1, 2, or 3, comprising monounsaturated fatty acids and

polyunsaturated fatty acids wherein the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 0.25:1 to 6:1 w/w, w/v, or v/v.

15. The formulation of claim 1, 2, or 3, wherein the formulation comprises daily amounts of fatty acids for the subject based on one or more factors selected from: age of the subject, sex of the subject, diet of the subject, the body weight of the subject, physical activity level of the subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and climate of the subject's living area.

26. A method of selecting a lipid-containing formulation for administering to a subject, comprising:

a) evaluating the subject on the basis of one or more factors selected from: age of the subject, sex of the subject, diet of the subject, the body weight of the subject, physical activity level of the subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and ambient temperature range of the subject's living area, and

b) combining daily amounts of fatty acids comprising omega-6 and omega-3 fatty acids, wherein the ratio of omega-6 to omega-3 fatty acids and their amounts are based on the one or more factors; wherein the formulation provides a dosage of omega-6 and omega-3 at an omega-6 to omega-3 ratio of:

(i) at least 4:1 w/w, w/v, or v/v, wherein dosage of omega-6 fatty acids is from 0.00000001 mg to 40 grams; or

(ii) 1:1 to 10:1 if the subject has a diet of low antioxidants or low phytochemicals; or

(iii) 4:1 to 45:1 if the subject has a diet of high antioxidants or high

phytochemicals; or

(iv) 2:1 to 30:1 if the subject has a high-seafood diet; or

(v) 1:1 to 45:1 based on lipid tolerance of the subject; or

(vi) 1:1 to 50:1 if the subject has a condition wherein increase of omega-6 or withdrawal of omega-3 is necessary; or

(vii) wherein the fatty acid content is matched to the table below.

% by Weight Ranges by Temperature	HOT 32°C (90°F) to 57°C (135°F)		WARM 21°C (70 °F) to 37°C (99 °F)		COOL 10°C (50°F) to 24°C (75°F)		COLD 0.56°C (33°F) to 13°C (55°F)		BELOW FREEZING -18°C (0°F) to 2.8°C (37°F)		ARCTIC -46°C (- 50°F) to - 15°C (5°F)		POLAR -73°C (- 100°F) to - 43°C (-45°F)	
	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High
Omega-9	20	90	20	90	20	90	10	80	10	80	10	80	10	80
Omega-6	4	60	4	60	6	60	10	60	12	70	13	70	15	73
Omega-3	0.3	5	0.5	6	0.8	7	1	8	1.5	12	1.8	15	2	20

27. A method of preparing a lipid-containing formulation for a subject, comprising: combining daily amounts of fatty acids for the subject based on one or more factors selected from: age of the subject, sex of the subject, diet of the subject, the body weight of the subject, physical activity level of the subject, lipid tolerance of the subject, medical conditions of the subject, family medical history of the subject, and ambient temperature range of the subject's living area,

wherein the formulation comprises a dosage of omega-6 and omega-3 fatty acids, wherein the ratio of omega-6 to omega-3 fatty acids and their amounts are based on the one or more factors; wherein, the omega-6 to omega-3 ratio is:

(i) at least 4:1 w/w, w/v, or v/v, wherein the dosage omega-6 fatty acids is from 0.00000001 mg to 40 grams; or

- (ii) 1:1 to 10 if the subject has a diet of low antioxidants or low phytochemicals; or
- (iii) 4:1 to 45:1 if the subject has a diet of high antioxidants or high phytochemicals;
- or
- (iv) 2:1 to 30:1 if the subject has a high-seafood diet; or
- (v) 1:1 to 45:1 based on lipid tolerance of the subject; or
- (vi) 1:1 to 50:1 if the subject has a condition wherein increase of omega-6 or withdrawal of omega-3 is necessary; or
- (vii) wherein the fatty acid content is matched to the table below.

% by Weight Ranges by Temperature	HOT		WARM		COOL		COLD		BELOW FREEZING		ARCTIC		POLAR	
	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High
	32°C (90°F)	to 57°C (135°F)	21°C (70°F)	to 37°C (99°F)	10°C (50°F)	to 24°C (75°F)	0.56°C (33°F)	to 13°C (55°F)	-18°C (0°F)	to 2.8°C (37°F)	-46°C (-50°F)	to 15°C (5°F)	-73°C (-100°F)	to 43°C (-45°F)
Omega-9	20	90	20	90	20	90	10	80	10	80	10	80	10	80
Omega-6	4	60	4	60	6	60	10	60	12	70	13	70	15	73
Omega-3	0.3	5	0.5	6	0.8	7	1	8	1.5	12	1.8	15	2	20

30. The method of claim 26 or claim 27, wherein one or more of the following apply:
- (i) comprising one or more of seeds, nuts, legumes, dairy, cocoa, lentils, grains, or their oils;
 - (ii) comprising oils, butters, nuts, seeds, herbs, sweeteners, or a combination thereof, as a source of fatty acids, antioxidants, minerals, or phytochemicals, or a combination thereof;

(iii) comprising one or more of peanut oil, corn oil, avocado oil, olive oil, sunflower oil, safflower oil, coconut oil, mustard oil, palm oil, soybean lecithin, and anhydrous butter;

(iv) comprising one or more of peanuts, almonds, olives, soybeans, cashews, flaxseeds, pistachios, pumpkin seeds, sunflower seeds, sesame seeds, walnuts, anhydrous butter, and coconut meat, or their oils;

(v) comprising omega-3 fatty acids at 0.1% to 30% by weight of total lipids, and wherein the nuts or their oils comprise almonds, peanuts, coconut meat, or anhydrous butter, or a combination thereof.

36. The method of claim 26 or claim 27, wherein one or more of the following apply:

(i) comprising one or more phytochemicals selected from: polyphenols, flavonoids, flavanones, flavones, isoflavones, anthocyanidins, anthocyanins, phytoestrogens, catechins, resveratrol, lignins, phenolic acids, gallic acid, ellagic acid, hydroxycinnamic acid, curcumin, flavonols, quercetin, and kaempferol; or

(ii) comprising one or more phytochemicals selected from: phytosterols, campesterol, sitosterol, stigmasterol, organosulfides, melatonin, saponins, carotenoids, coumarins, beta-carotene, lycopene, lutein, zeaxanthin, and monophenols;

(iii) comprising one or more phytochemicals, antioxidants, vitamins, minerals, and trace elements, selected from vitamin A, folic acid or folate, vitamin C, vitamin D, vitamin E, Cu, Zn, Mn, Fe, Se, and Mg;

(iv) comprising vitamin E in the range of 0.001 % to 0.5% by weight of total lipids;

(v) comprising one or more nutrients effective to reduce omega-3 requirement or increase effective levels of omega-3 in a subject, than in the absence of the nutrient; or

(vi) comprising one or more polyphenols effective to increase omega-3 levels in a subject.

37. The method of claim 26 or claim 27, wherein lipid-free or low-lipid foods are designed for use with the lipid formulation.
42. A formulation produced by the method of claim 27, wherein the formulation is administered to the subject by steady delivery without large fluctuations.
43. The formulation produced by the method of claim 27 for prophylaxis or treatment of a medical condition in a subject, comprising administering an effective amount of the formulation, wherein said medical condition is selected from: menopause, aging, musculoskeletal disorders, mood swing, reduced cognitive function, neural disorders, mental disorders, thyroid disturbances, weight gain, obesity, diabetes, endocrine disorders, digestive system disorders, reproductive disorders, pulmonary disorders, renal diseases, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, cancer, autoimmune diseases, infectious diseases, inflammatory diseases, hypercholesterolemia, dyslipidemia, or cardiovascular disease (please refer to [Attachment] for the rest of the claims).

C. Main content of specification of the subject patent invention

The traditional emphasis on increasing omega-3 and reducing omega-6 consumption often does not result in satisfactory relieves. The American Heart Association issued an advisory to correct the perception that omega-6 are unhealthy (paragraph [0009]).

The subject patent invention relates to compositions and methods for prophylaxis and/or treatment of medical conditions linked with an imbalance in one or more lipids within context of other factors. More particularly, the present disclosure relates to the use of compositions and methods that use more advantageous sources of omega-6 fatty acids, in the presence of

nutritionally adequate omega-3 fatty acids. The disclosure also relates to methods and compositions that deliver omega-6 and omega-3 fatty acids along with other nutrients that optimize the daily delivery and bioavailability of omega-6 and omega-3 for prophylaxis and/or treatment of medical conditions linked with an imbalance in one or more lipids (paragraph [0011]).

A lipid-containing composition comprises optimal amounts of fatty acids, antioxidants, and minerals for a subject based on factors including the subject's age, sex, diet, body weight, medical conditions, and the climate of the subject's living area. In a lipid-containing composition, ratios and amounts of polyunsaturated, monounsaturated, and saturated fatty acids are controlled based on the above factors (paragraphs [0012] and [0013]).

In Example 12. (A Case Study on Hypercholesterolemia, Cardiovascular Disease): The subject was administered a daily lipid composition supplement containing 11 grams of omega-6 and 1.2 grams of omega-3. Administration of the lipid composition resulted in a reduction of LDL from 160mg to 120mg. Very low levels of blood pressure were observed, 90/55 mmHg, when omega-3 was increased to 1.8 grams; blood pressure levels normalized at 105/70 mmHg at 11 grams of omega-6 and 1.2 grams of omega-3. When omega-3 was reduced from 1.8 grams to 1.2 grams per day, the subject experienced an irregular heartbeat, which subsided over a period of 2-3 weeks. However, when omega-3 was further reduced to 0.5 grams per day, it resulted in an ongoing arrhythmia. This case study demonstrated that supplementation with vegetable oils, nuts, and seeds, wherein the omega-6 to omega-3 ratio was about 9: 1 results in a significant decrease in LDL cholesterol blood levels. This case study also demonstrated that the lipid compositions and ratios described herein may be useful in moderating blood pressure and arrhythmia.

Example 15.1 (Case Studies on Musculoskeletal Disorders): In a subject host, the inventor observed many musculoskeletal issues appear and disappear in the course omega-6

and omega-3 therapy by administration of lipid compositions. Increases in omega-3 beyond 0.5g, in a vegetarian host with omega-6 at 10-11 grams, yielded better muscular performance, lesser joint pain, lesser joint crackling sounds, and better spatial task performance. But a point of diminishing marginal returns was reached at about 1.2 grams of omega-3. Increases of omega-3 beyond 1.2 grams resulted in weaker muscle tone, posture, and exercise endurance. When the omega-3 was gradually brought back to 1.2 grams, the subject experienced leg cramps, lower back pain, burning sensation in the scalp, buckling of knee joints, and joint pains in knees and shoulders. Over a period of 3-6 weeks these symptoms subsided.

Example 17. (A Case Study on Weight Gain, Obesity): In a vegetarian host subject it was discovered that there was a band of optimal quantity and ratio of omega-6 and omega-3, beyond which the subject gained weight. At omega-6 of 11 grams and omega-3 of 2 grams, the subject was at 134 lbs. When the inventor gradually reduced omega-3 to 1.2 grams, the subject initially gained 6 lbs., and then after 6 weeks, lost 12 lbs. for an ending weight of 128 lbs.

Example 19. (A Case Study on Digestive System Disorders): In the host subject, incidences of acid reflux disease, irritable bowels, indigestion, and dyspepsia were observed. Each time omega-6 was increased or omega-3 was decreased the following symptoms appeared: stomach pain, bloating, heartburn, nausea (upset stomach), and burping; but they all disappeared as the body adjusted to increased omega-6. In the optimal omega-6 and omega-3 balance, bile production was optimal as determined by the yellowish brown color of the stools. It was also observed that mucus production in the alimentary canal was optimal with the proper omega-6 and omega-3 quantities and ratio, using mucus production in the oral cavity as an indicator.

Example 26. (A Case Study on Dental Diseases): In a vegetarian host subject, less dental sensitivity, reversal of gum receding, brightening of tooth enamel, and lessening of dental

spots and plaque were observed when omega-3 was reduced from 2 grams to 1.2 grams while holding omega-6 constant at 11 grams. Bioactivity of lipids may explain the linkage between periodontitis/tooth loss and coronary heart disease.

Example 27. (Case Studies on Immunity, Autoimmune and Infectious and Inflammatory Diseases): In a vegetarian host subject, a 48-year old menopausal woman, on 1 Ig of linoleic acid (LA) and 1.8g of alpha-linolenic acid (ALA), from oils and nuts, spinal burning sensation, heat in the body, skin and feet, and delayed wound healing were observed. Symptoms disappeared upon reducing to 1.2g after an initial adjustment period. It is hypothesized that omega-6 and omega-3 imbalance leads to inflammation, compromised immunity, and infection. It is further suspected that both omega-6 and omega-3 are anti-inflammatory in small doses and inflammatory in large doses; particularly in light of possible interactions with phytochemicals.

D. The Gist of the Original Decision

(1) ① The expressions “polyunsaturated fatty acids, monounsaturated fatty acids, and saturated fatty acids, ..., one or more polyphenols, or one or more phytochemicals selected from phytosterols, organosulfides, melatonin, saponins, coumarins, lycopene, lutein, zeaxanthin, and monophenols” as recited in the subject invention of claim 3 and the expressions “monounsaturated fatty acids and polyunsaturated fatty acids” as recited in the subject invention of claim 10, ② the expressions “(i) comprising one or more of seeds, nuts, legumes, dairy, cocoa, lentils, grains, or their oils; (ii) comprising oils, butters, nuts, seeds, herbs, sweeteners, or a combination thereof, as a source of fatty acids, antioxidants, minerals, or phytochemicals, or a combination thereof” as recited in the subject inventions of claims 7 and 30, ③ the expression “fatty acids for the subject” as recited in the subject invention of claim 15, ④ the expression “nutrients” as recited in the subject invention of claim 36, and ⑤ the expression “lipid-free or low-lipid foods” as recited in the subject invention of claim

37 are unclear since they cannot specify structures or components thereof. ⑥ The expression “one or more” as recited in the subject invention of claim 3 is unclear since it fails to clearly define an upper limit. Therefore, the above-mentioned claims and all claims of the subject patent invention which depend from these claims cannot be allowed pursuant to Article 42(4)(ii) of the Patent Act.

(2) The subject inventions of claims 1 to 17 and 19 to 23 relate to a lipid-containing formulation comprising a predetermined composition for prophylaxis and/or treatment of medical conditions. However, any specific or quantitative experimental data linked with the prophylaxis and/or treatment of the medical conditions are not described in the detailed description of the invention. The subject inventions of claims 26 to 41 relate to a method of selecting a lipid-containing formulation for administering to a predetermined subject or a method of preparing a lipid-containing formulation for a predetermined subject. However, any specific experimental data associated with the selection or preparation of a predetermined lipid-containing formulation are not mentioned in the detailed description of the invention. The subject inventions of claims 42 and 43 relate to the lipid-containing formulation produced by the method of the subject invention of claim 26 or 27. The lipid-containing composition is configured for administration to the subject by steady delivery or for prophylaxis and/or treatment of predetermined medical conditions. However, any specific or quantitative experimental data associated with the prophylaxis and/or treatment of the medical conditions are not described in the detailed description of the invention. Therefore, the detailed description of the subject patent invention does not describe the subject inventions of the above-mentioned claims in a manner sufficient to enable a person of ordinary skill in the art to which the subject patent invention pertains (hereinafter, referred to as a “skilled person”) to readily carry them out. Accordingly, pursuant to Article 42(3) of the Patent Act, the subject patent invention cannot be allowed. In addition, the subject patent invention cannot be

allowed pursuant to Article 42(4)(i) since it is not supported by the detailed description of the invention as set forth above.

2. Summary of plaintiff's argument

A. Pursuant to Article 42(4)(ii) of the Patent Act, claims shall define a claimed invention clearly and concisely. Thus, a patented invention in compliance with this provision serves to decide the scope for which protection is sought in one or more claims, and enables to determine patent requirements. However, this provision does not require that claims be defined in a narrow sense using specific structures or components. All the expressions in the claims of the subject patent invention which were pointed out as failing to specify structures or components thereof are widely known terms in the corresponding field. Thus, the use of these expressions will not preclude a clear understanding of the claims and determination of the scope of protection conferred by the subject patent invention.

B. A numerical-limitation invention is required to define an upper limit. On the other hand, since the subject invention of claim 3 is not a numerical-limitation invention, the expression "one or more" does not make this claim unclear.

C. Specific and quantitative data associated with the lipid-containing formulation as defined in the subject inventions of claims 1 to 3 are included in the detailed description of the subject patent invention (please refer to Tables 15 to 20).

D. Results of administration of a specific lipid formulation in association with prophylaxis or treatment of a medical condition are disclosed in the detailed description of the subject patent invention. According to Example 12, administration of the lipid composition resulted in the quantitative effect of a reduction of LDL from 160mg to 120mg. In terms of the qualitative effects, in Example 15.1, better muscular performance, lesser joint pain, lesser joint crackling sounds, and better spatial task performance were yielded; in Example 17,

weight was lost; in Example 19, the symptoms of stomach pain, bloating, heartburn and the like disappeared; in Example 26, less dental sensitivity and lessening of plaque were observed; and in Example 27, menopausal symptoms disappeared. Even if all diseases mentioned in the claims are not mentioned as Examples in the detailed description of the invention, it can be understood on the basis of the description of the above Examples that the lipid-containing formulation as disclosed in the subject patent invention is used to achieve the object of the subject patent invention. Therefore, the detailed description of the subject patent invention describes the subject inventions of the above-mentioned claims in a manner sufficient to enable a skilled person to carry them out, and the subject patent invention is supported by the detailed description of the invention.

3. Judgement

A. Whether the subject patent invention complies with the requirements of Article 42(4)(ii)

(1) Whether the expressions “polyunsaturated fatty acids, monounsaturated fatty acids, and saturated fatty acids, ..., or one or more phytochemicals selected from phytosterols, organosulfides, melatonin, saponins, coumarins, lycopene¹, lutein, zeaxanthin, and monophenols” are unclear

(a) the expressions “polyunsaturated fatty acids, monounsaturated fatty acids, and saturated fatty acids”

The subject invention of claim 3 includes the expressions “polyunsaturated fatty acids, monounsaturated fatty acids, and saturated fatty acids.” The subject inventions of claims 10, 12, 22, 33, and 35 depend from the subject invention of claim 3 and substantially include these expressions.

¹ The term “lypocene” appears to be a typo graphical error of “lycopene” with reference to the English specification of the PCT application of the subject patent invention. Hereinafter, this term will be referred to as “lycopene.”

The expressions “polyunsaturated fatty acids, monounsaturated fatty acids, and saturated fatty acids” used in the above claims refer to a group of fatty acids in the median concept which are differentiated based on the number of unsaturated bonds included in the fatty acids. It is acknowledged that a skilled person can clearly understand a range of fatty acids corresponding to the above expressions.

However, as indicated in the original decision, since the above expressions do not specify structures of fatty acids, they render these claims unclear, which will be discussed below.

Referring to the scope of the claims defined by the subject inventions of claims 3, 10, 12, 22, 33, and 35, with regard to polyunsaturated fatty acids, monounsaturated fatty acids, and saturated fatty acids included in a lipid-containing formulation, only ratios of omega-6 to omega-3 fatty acids are specified, whereas types of these fatty acids are not specified.

However, the technical feature of the subject invention of claim 3 is not directed to using an appropriate combination of specific types of fatty acids, such as linoleic acids or oleic acids, but is directed to controlling optimal ratios and amounts of polyunsaturated, monounsaturated, and saturated fatty acids based on one or more factors selected from the group including the subject's age, sex, diet, body weight, medical conditions, and the like, and more specifically, ratios and amounts of omega-6 and omega-3 fatty acids for prophylaxis and/or treatment of medical conditions linked with an imbalance in one or more lipids (please refer to paragraphs [0011] to [0013]). Therefore, it cannot be considered that the matters for which protection is sought in the subject inventions of claims 3, 10, 12, 22, 33, and 35 are clarified only by specifying types of omega-6 fatty acids or omega-3 fatty acids.

Accordingly, the above judgement in the original decision is unacceptable.

(b) the expressions “polyphenols,” “phytosterols,” “organosulfides,” “melatonin,” “saponins,” “coumarins,” “lycopene,” “lutein,” “zeaxanthin,” and “monophenols”

The subject inventions of claims 3, 13 and 36 use the expressions “polyphenols,” “phytosterols,” “organosulfides,” “melatonin,” “saponins,” “coumarins,” “lycopene,” “lutein,” “zeaxanthin,” and “monophenols.”

Each of the expressions used in the subject inventions of these claims refers to a compound composed of a predetermined chemical skeleton, or is used to collectively refer to a group of compounds having the corresponding chemical skeletons. Thus, it is recognized that a skilled person can clearly understand a range of compounds corresponding to the above expressions.

However, the original decision states that the claims are unclear since the above expressions do not specify structures of the compounds, which will be discussed below.

As mentioned earlier in connection with 3.A.(1)(a), the technical feature of the subject inventions of claims 3, 13 and 36 is directed to controlling optimal ratios and amounts of polyunsaturated, monounsaturated, and saturated fatty acids based on one or more factors selected from the group including the subject's age, sex, diet, body weight, medical conditions, and the like, and more specifically, ratios and amounts of omega-6 and omega-3 fatty acids for prophylaxis and/or treatment of medical conditions linked with an imbalance in one or more lipids (paragraphs [0011] to [0013]). In addition, “polyphenols,” “phytosterols,” “organosulfides,” “melatonin,” “saponins,” “coumarins,” “lycopene,” “lutein,” “zeaxanthin,” and “monophenols” are merely bioactive components which are supplemented in addition to fatty acids. Therefore, it is not regarded that the matters for which protection is sought in the subject inventions of claims 3, 13 and 36 can be clarified only by specifying kinds of the supplements as above.

Therefore, the above judgement in the original decision is also unacceptable.

(2) Whether the expressions “(i) comprising one or more of seeds, nuts, legumes, dairy, cocoa, lentils, grains, or their oils; (ii) comprising oils, butters, nuts, seeds, herbs, sweeteners,

or a combination thereof, as a source of fatty acids, antioxidants, minerals, or phytochemicals, or a combination thereof” are unclear

The subject inventions of claims 5 to 7, 14, 16, 26 to 28, 30, 38, 39, and 40 include the expressions “(i) seeds, nuts, legumes, dairy, grains, fatty acids, antioxidants, minerals nuts, seeds, herbs, sweeteners.” According to the original decision, these expressions do not specifically define components thereof and thus render these claims unclear.

However, as mentioned earlier in 3.A.(1)(a), the technical feature of the subject inventions of claims 5 to 7, 14, 16, 26 to 28, 30, 38, 39, and 40 is directed to controlling optimal ratios and amounts of polyunsaturated, monounsaturated, and saturated fatty acids based on one or more factors selected from the group including the subject's age, sex, diet, body weight, medical conditions, and the like, and more specifically, ratios and amounts of omega-6 and omega-3 fatty acids for prophylaxis and/or treatment of medical conditions linked with an imbalance in one or more lipids (paragraphs [0011] to [0013]). In addition, “seeds, nuts, legumes, dairy, grains, fatty acids, antioxidants, minerals nuts, seeds, herbs, sweeteners” merely correspond to a source of omega-3 and omega-6 fatty acids, or bioactive components which are supplemented thereto. Therefore, it cannot be considered that the matters for which protection is sought in the subject inventions of claims 5 to 7, 14, 16, 26 to 28, 30, 38, 39, and 40 can be clarified only by specifying components of the source of omega-3 and omega-6 fatty acids and the supplements.

Therefore, the above judgement in the original decision is also unacceptable.

(3) Whether the expression “fatty acids for the subject” is unclear

The subject inventions of claims 15 to 27 include the expression “fatty acids for the subject.” As stated in the original decision, the above expression does not specify components thereof and thus renders the subject inventions of these claims unclear, which will be discussed below.

First, the subject invention of claim 27 relates to a method of preparing a lipid-containing formulation for a subject in a predetermined group. As recited in the subject invention of claim 27, in terms of daily amounts of fatty acids for the subject, a specific numeral range of the omega-6 to omega-3 ratio is defined depending on if the subject has a diet of low antioxidants or low phytochemicals, if the subject has a diet of high antioxidants or high phytochemicals, or if the subject has a high-seafood diet. Therefore, it is recognized that the composition of the fatty acids for the subject is clearly described.

Next, the subject invention of claim 15 which depends from the subject inventions of claims 1 to 3 describes that the formulation comprises daily amounts of fatty acids for the subject based age of the subject, sex of the subject, diet of the subject, physical activity level of the subject, and the like. As long as the subject inventions of claims 1 to 3 from which the subject invention of claim 15 depends specify the composition of omega-6 fatty acids and omega-3 fatty acids, the subject invention of claim 15 is considered to clearly define types of fatty acids for the subject.

Accordingly, the above judgement in the original decision is also unacceptable.

(As to the subject invention of claim 15 which was not rejected for failing to describe the matter for which protection is sought in the claim as pointed out by the examiner in the office action on the subject patent invention, although the plaintiff argues that the omega-6 to omega-3 ratio varies depending on age of the subject, obesity of the subject, diet of the subject, and other bioactive substances administered usually as disclosed in the specification of the subject patent invention, the subject invention of claim 15 is silent on who the subject is and how and at what omega-6 to omega-3 ratios the formulation is prepared for the subject. In this regard, therefore, it seems that there is a need for further review on whether the subject invention of claim 15 is clearly described.

(4) Whether the expression “nutrients” is unclear

The subject inventions of claims 3, 13, 14, 36, and 38 include the expression “nutrients.” In the original decision, since the above expression does not specify components thereof, it renders the subject inventions of these claims unclear. This will be discussed below.

The subject invention of claim 3 specifies that the nutrients “comprise ① polyunsaturated fatty acids, monounsaturated fatty acids, and saturated fatty acids, ② one or more polyphenols, or ③ one or more phytochemicals selected from phytosterols, organosulfides, melatonin, saponins, coumarins, lycopene, lutein, zeaxanthin, and monophenols.” Therefore, it is deemed that a skilled person can clearly understand what components correspond to the nutrients of the subject invention of claim 3 even if names of the nutrients are not specifically identified.

The subject inventions of claims 13 and 36 describe “one or more nutrients effective to reduce omega-3 requirement or increase effective levels of omega-3 in a subject, than in the absence of the nutrient.” In addition, chemical structures of fatty acids and nutrients are well known. Therefore, it is recognized that a skilled person can easily understand what components correspond to nutrients that contain omega-3 fatty acids or are metabolized to omega-3 fatty acids in the body to satisfy the above condition.

The subject inventions of claims 14 and 38 mention “a source of nutrients selected from one or more of grains, legumes, fruits, vegetables, yogurt, herbs, spices, sweeteners, eggs, cheese, milk, poultry, seafood, and meat” as components additionally included in the lipid-containing formulation. However, since a range of the nutrients provided by these foods as the source of nutrients, other than lipids, is well known, it is considered that a skilled person can clearly understand the range of the above nutrients although types of the nutrients are not listed.

Therefore, the above judgement in the original decision is not acceptable.

(5) Whether the expression “lipid-free or low-lipid foods” is unclear

The subject inventions of claims 12, 14, 35, and 37 specify that “lipid-free or low-lipid foods” are designed for use in combination with or provided with the lipid-containing formulation. However, according to the original decision, since this expression does not specify components thereof, it renders the subject inventions of these claims unclear, which will be discussed below.

The technical feature of the subject inventions of claims 12, 14, 35, and 37 is directed to optimizing ratios of the omega-6 and omega-3 fatty acids included in the lipid-containing formulation. If foods for use in combination with or provided with a lipid-containing formulation contain large amounts of omega-3 fatty acids or omega-6 fatty acids, omega-6 to omega-3 ratios intended at the time of designing a lipid-containing formulation will be changed in the body of the subject. For these reasons, the formulation is specified as being designed for use in combination or provided with lipid-free or low-lipid foods. Thus, it is acknowledged that a skilled person can readily understand a range of lipid-free or low-lipid foods which do not affect ratios of omega-6 and omega-3 fatty acids of a lipid-containing formulation.

Accordingly, the above judgement in the original decision is unacceptable.

(6) Whether the expression “one or more” is unclear

The subject inventions of claims 3, 13, and 36 include the expression “one or more.” As stated in the original decision, since the above expression does not clearly define an upper limit thereof, it renders the subject inventions of these claims unclear, which will be discussed below.

Although the subject invention of claim 3 describes that a lipid-containing formulation comprises “one or more polyphenols,” the polyphenols are mentioned as one of types of various nutrients contained in the lipid-containing formulation. In addition, polyphenols are a

general term for nutrients having phenol mother nuclei in which one molecule has a plurality of hydroxyl groups, and exhibiting antioxidant effects. The technical feature of the subject invention of claim 3 lies in a ratio of omega-3 and omega-6 fatty acids in a lipid-containing formulation, but not in the number of polyphenols. Therefore, even if the upper limit of the number of polyphenols is not specified, it is recognized that a skilled person can include an appropriate number of polyphenols as antioxidant nutrients in a lipid-containing formulation. In addition, it cannot be seen that such description makes it difficult to understand the technical configuration of the subject invention of claim 3.

The subject inventions of claims 13 and 36 describe “(v) comprising one or more nutrients effective to reduce omega-3 requirement or increase effective levels of omega-3 in a subject, than in the absence of the nutrient; or (vi) comprising one or more polyphenols effective to increase omega-3 levels in a subject.” However, the technical meaning of nutrients or polyphenols which affect effective levels of omega-3 fatty acids does not lie in how many nutrients or polyphenols are included, but in how much they affect the effective levels of omega-3. Therefore, it is acknowledged that a skilled person can appropriately select the total number of nutrients or polyphenols depending on how much the selected number of nutrients or polyphenols can affect the effective levels of omega-3.

Therefore, the above judgement in the original decision is unacceptable.

B. Whether the subject patent invention complies with the requirements under Article 42(3) and Article 42(4)(i) of the Patent Act

(1) Whether the subject inventions of claims 1 to 17, 19 to 23, 42, and 43 comply with the requirements under Article 42(3) and Article 42(4)(i) of the Patent Act

In the original decision, although the subject inventions of claims 1 to 17, 19 to 23, 42, and 43 are directed to a lipid-containing formulation for prophylaxis or treatment of a medical condition, any specific or quantitative experimental data linked with the prophylaxis

and/or treatment of the medical condition are not described in the detailed description of the invention. Therefore, the specification of the subject patent invention does not describe the subject inventions of these claims in a manner sufficient to enable a skilled person to readily carry them out. This will be discussed below.

The subject inventions of claims 1 to 17, 19 to 23, 42, and 43 relate to a lipid-containing formulation comprising omega-3 fatty acids and omega-6 fatty acids at a predetermined ratio. Among these claims, the subject inventions of claims 19 to 23 and 43 further disclose that the formulation is for prophylaxis or treatment of the medical condition selected from menopause, aging, musculoskeletal disorders, mood swing, reduced cognitive function, neural disorders, mental disorders, thyroid disturbances, weight gain, obesity, diabetes, endocrine disorders, digestive system disorders, reproductive disorders, pulmonary disorders, renal diseases, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, cancer, autoimmune diseases, infectious diseases, inflammatory diseases, hypercholesterolemia, dyslipidemia, or cardiovascular disease.

However, it is known to a skilled person that fatty acids directly affect the functions of many proteins through covalent modifications of such proteins, hormones and biological messengers affect a broad range of physiological functions such as cardiovascular system, inflammation, and cell growth and that omega-3 fatty acids and omega-6 fatty acids, among fatty acids, show activity (please refer to paragraphs [0003] to [0009] in Background of the specification of the subject patent invention). In addition, as described in the specification of the subject patent invention, in Example 12, administration of the lipid composition resulted in the quantitative effect of a reduction of LDL from 160mg to 120mg. Results of case Studies on musculoskeletal disorders in Example 15.1, results of a case Study on weight gain, obesity in Example 17, results of a case study on digestive system disorders in Example 19, results of a case Study on dental diseases in Example 26, and case studies on immunity, and results of

autoimmune and infectious and inflammatory diseases in Example 27 are disclosed in the specification. Therefore, based on the above-mentioned case study results, a skilled person would understand the influence of the lipid-containing formulation as recited in the subject inventions of claims 1 to 17, 19 to 23, 42, and 43 on health and would readily carry them out without any particular difficulty.

Therefore, it is difficult to accept the above judgement in the original decision.

(2) Whether the subject inventions of claims 26 to 41 comply with the requirements under Article 42(3) and 42(4)(i) of the Patent Act

The original decision stated that claims 26 to 41 relate to a method of selecting a lipid-containing formulation for administering to a predetermined subject or a method of preparing a lipid-containing formulation for a predetermined subject. However, any specific experimental data relevant to the selection or preparation of a predetermined lipid-containing formulation are not mentioned in the detailed description of the invention. Thus, the specification of the subject patent invention fails to describe the subject inventions of the above-mentioned claims in a manner sufficient to enable a skilled person to carry them out. Accordingly, the subject inventions of claims 26 to 41 do not comply with the requirements under Article 42(3) and Article 42(4)(i) of the Patent Act. This will be discussed below.

The subject inventions of claims 26 to 41 are directed to controlling ratios of omega-6 and omega-3 fatty acids based on age and sex of a subject and whether the subject has a diet of low antioxidants, a diet of high antioxidants, or a high-seafood diet. In terms of controlling the ratios of omega-6 to omega-3 fatty acids as recited in the subject inventions of claims 26 to 41, it is regarded that a skilled person can prepare a lipid-containing formulation for a subject by appropriately selecting the omega-6 to omega-3 ratio in light of the nutritional technology generally known in the art, such as reducing a omega-3 fatty acid content for a subject having a high-seafood diet which is known to have a high omega-3 fatty acid content.

Therefore, even if embodiments for preparing lipid-containing formulations with various compositions intended for a subject are not described in the specification, a skilled person can readily carry the subject inventions of the above claims out without any difficulties. In addition, as described above in connection with 3.B.(1), a skilled person would understand the influence of the lipid-containing formulation as recited in the subject inventions of claims 26 to 41 on health and would readily carry them out without any particular difficulty.

Therefore, the above judgement in the original decision cannot be accepted.

C. Sub-conclusion

As set forth above, since the claims of the subject patent invention are clearly described, and the detailed description of the invention describes the subject patent invention in a manner sufficient to enable a skilled person to readily carry it out, the claims are considered to be supported by the detailed description of the invention. Therefore, the original decision holding that the subject patent invention cannot be allowed pursuant to Article 42(3), Article 42(4)(i) and Article 42(4)(ii) of the Patent Act is flawed, and the plaintiff's argument challenging the original decision is reasonable.

4. Conclusion

Therefore, the original decision is cancelled, and this case shall be remanded to the Examination Bureau of KIPO.

Presiding Judge	Ju, Yeong-sik
Chief Judge	LEE, Mi-jeong
Judge	CHO, Kyeong-ju

Claims of subject patent invention

1 to 3. (omitted)

4. The formulation of claim 1, 2, or 3, comprising at least three of (A):

(A-1) a peanut oil present at 8 to 56 percent by weight in the formulation;

(A-2) a vegetable oil present at 8 to 46 percent by weight in the formulation, wherein the vegetable oil is selected from one or more of acai oil, amaranth oil, apple seed oil, apricot kernel oil, argan oil, artichoke oil, babassu oil, ben oil, blackcurrant seed oil, borage seed oil, borneo tallow nut oil, bottle gourd oil, buffalo gourd oil, canola oil (rapeseed), cape chestnut oil, carob pod oil, cocklebur oil, cocoa butter oil, cohune oil, coriander seed oil, corn oil, cottonseed oil, dika oil, evening primrose oil, false flax oil (*Camelina sativa*), grapeseed oil, kapok seed oil, lallemantia oil, marula oil, meadowfoam seed oil, mustard oil, nutmeg butter, okra seed oil, palm oil, papaya seed oil, pequi oil, perilla oil, prune kernel oil, quinoa oil, ramtil oil, rice bran oil, royle oil, sacha inchi oil, sheanut oil, soybean lecithin oil, tea oil, thistle oil, tomato seed oil, ucuhuba butter oil, wheat germ oil, acorn oil, almond oil, beech nut oil, brazilnut oil, breadnut oil, candlenut oil, chestnut oil, chilacayote nut oil, chilean hazelnut oil, coconut oil, cashew oil, colocynth nut oil, filbert oil, hazelnut oil, hickory oil, kola nut oil, macadamia oil, mamoncillo oil, mongongo oil, obongo nut oil, pecan oil, pili nut oil, pine nut oil, pistachio oil, soya oil, poppy seed oil, pumpkin seed oil, hemp seed oil, flax seed oil, sesame seed oil, walnut oil, and watermelon seed oil;

(A-3) an avocado oil present at 3 to 16 percent by weight in the formulation;

(A-4) an olive oil present at 5 to 32 percent by weight in the formulation;

(A-5) a sunflower oil present at 6 to 34 percent by weight in the formulation; and

(A-6) a safflower oil present at 2 to 30 percent by weight in the formulation;

or comprising at least three of (B):

(B-1) an almond oil present at 2 to 23 percent by weight in the formulation;

(B-2) an avocado oil present at 1 to 7 percent by weight in the formulation;

(B-3) a soybean oil present at 1 to 7 percent by weight in the formulation;

(B-4) a cashew oil present at 2 to 15 percent by weight in the formulation;

(B-5) a pistachio oil present at 1 to 7 percent by weight in the formulation;

(B-6) a pumpkin seed oil present at 1 to 8 percent by weight in the formulation;

(B-7) a walnut oil present at 3 to 25 percent by weight in the formulation;

(B-8) a peanut oil present at 5 to 30 percent by weight in the formulation;

(B-9) a corn oil present at 3 to 19 percent by weight in the formulation;

(B-10) an olive oil present at 3 to 17 percent by weight in the formulation;

(B-11) a safflower oil present at 1 to 14 percent by weight in the formulation; and

(B-12) an anhydrous butter present at 5 to 29 percent by weight in the formulation;

or comprising at least three of (C):

(C-1) an almond oil present at 1 to 36 percent by weight in the formulation;

(C-2) a pumpkin seed oil present at 1 to 24 percent by weight in the formulation;

(C-3) an oil from walnuts present at 2 to 36 percent by weight in the formulation;

(C-4) a peanut oil present at 4 to 72 percent by weight in the formulation;

(C-5) a corn oil present at 1 to 24 percent by weight in the formulation;

(C-6) an olive oil present at 2 to 36 percent by weight in the formulation;

(C-7) a sunflower oil present at 4 to 72 percent by weight in the formulation;

(C-8) a safflower oil present at 2 to 60 percent by weight in the formulation; and

(C-9) an anhydrous butter present at 2 to 36 percent by weight in the formulation;

further comprising one or more of:

(C-10) a mustard oil present at 0 to 8 percent by weight in said formulation,

(C-11) a palm oil present at 0 to 2 percent by weight in said formulation,

(C-12) a flaxseed oil at 0 to 8 percent by weight in said formulation,

(C-13) a coconut oil present at 0 to 8 percent by weight in said formulation, and

(C-14) a soybean lecithin present at 0 to 4 percent by weight in said formulation;

or comprising at least three of (D):

(D-1) peanuts present at 2 to 11 percent by weight in the formulation;

(D-2) almonds present at 5 to 32 percent by weight in the formulation;

(D-3) olives present at 6 to 36 percent by weight in the formulation;

(D-4) soybeans present at 4 to 25 percent by weight in the formulation;

(D-5) cashews present at 4 to 21 percent by weight in the formulation;

(D-6) pistachios present at 2 to 9 percent by weight in the formulation;

(D-7) pumpkin seeds present at 2 to 15 percent by weight in the formulation;

(D-8) sunflower seeds present at 1 to 4 percent by weight in the formulation;

(D-9) walnuts present at 3 to 25 percent by weight in the formulation;

(D-10) anhydrous butter present at 4 to 24 percent by weight in the formulation; and

(D-11) coconut meat present at 1 to 6 percent by weight in the formulation;

or comprising at least three of (E):

safflower oil, sunflower oil, peanut oil, almond or almond oil, corn oil, and anhydrous butter;

or comprising at least three of (F):

or peanuts, almonds, olives, soybeans, cashews, flaxseeds, pistachios, pumpkin seeds, sunflower seeds, sesame seeds, walnuts, anhydrous butter and coconut meat, or their oils.

5. The formulation of claim 1, 2, or 3, comprising one or more fatty acids selected from butyric acid (C4:0), lauric acid (C12:0), myristic acid (C14:0), palmitic acid (C16:0), stearic acid (C18:0), arachidic acid (C20:0), myristoleic acid (C14:1), palmitoleic acid (C16:1), oleic acid (C18:1), gadoleic acid (C20:1), ercucic acid (C22:1), nervonic acid (C24:1), linoleic acid (C18:2), conjugated-linoleic acid (C18:2), gamma-linolenic acid (C18:3), eicosadienoic acid (C20:2), di-homo-gamma-linolenic acid (C20:3), arachidonic acid (C20:4), alpha-linolenic acid (C18:3), stearidonic acid (C18:4), eicosapentaenoic acid (C20:5), docosapentaenoic acid (C22:5), and docosahexaenoic acid (C22:6).

6. The formulation of claim 1, 2, or 3, comprising fatty acids wherein one or more of the following apply:
 - (i) omega-6 fatty acids are present at 4% to 75% by weight of total lipids;
 - (ii) omega-3 fatty acids are present at 0.1 to 30% by weight of total lipids; or
 - (iii) omega-9 fatty acids are present at 10% to 90% by weight of total lipids.

7. (omitted)

8. The formulation of claim 1, 2, or 3, comprising omega-6 and omega-3 fatty acids wherein the omega-6 to omega-3 ratio is 4:1 to 45:1 w/w, w/v, or v/v.

9. The formulation of claim 1, 2, or 3, comprising omega-6 and omega-3 fatty acids wherein the omega-6 to omega-3 ratio is at least 9:1 w/w, w/v, or v/v.

10. (omitted)

11. The formulation of claim 1, 2, or 3, wherein one or more of the following apply:
 - (i) the dosage of total lipids is from 10-100 grams;
 - (ii) the dosage of omega-6 fatty acids is from 1 to 40 grams;
 - (iii) the dosage of omega-3 fatty acids is from 0.1 to 6.0 grams;
 - (iv) the dosage of eicosapentaenoic acid (C20:5) is from 0.00000001 mg to 0.5 grams; or
 - (v) the dosage of docosahexaenoic acid (C22:6) is from 0.00000001 mg to 0.2 grams.

12. The formulation of claim 1, 2, or 3, wherein one or more of the following apply:
 - (i) the dosage of total lipids is 10-100 grams, the dosage of omega-6 fatty acids is from 1 to 40 grams, the dosage of omega-3 fatty acids is from 0.1 to 5 grams, the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 1:1 to 3:1 w/w, w/v, or v/v, the ratio of monounsaturated fatty acids to saturated fatty acids is 1:1 to 5:1 w/w, w/v, or v/v, the ratio of omega-9 to omega-6 fatty acids is in the range of 1:1 to 3:1 w/w, w/v, or v/v, and the ratio of omega-6 to omega-3 fatty acids is in the range of 4:1 to 45:1 w/w, w/v, or v/v;
 - (ii) the formulation supplies 50-90% of a diet's fat calories; or
 - (iii) the formulation is designed for use in combination with or provided with a lipid-free or low-lipid food product.

13. The formulation of claim 1, 2, or 3, wherein one or more of the following apply:
 - (i) comprising one or more polyphenols selected from: flavonoids, flavanones, flavones, isoflavones, anthocyanidins, anthocyanins, phytoestrogens, catechins, resveratrol, lignins, phenolic acids, gallic acid, ellagic acid, hydroxycinnamic acid, curcumin, flavonols, quercetin, and kaempferol; or
 - (ii) comprising one or more phytochemicals selected from: phytosterols, campesterol,

sitosterol, stigmasterol, organosulfides, melatonin, saponins, carotenoids, coumarins, beta-carotene, lycopene, lutein, zeaxanthin, and monophenols; or

(iii) comprising one or more of vitamin A, folic acid or folate, vitamin, C, vitamin D, vitamin E, Cu, Zn, Mn, Fe, Se, and Mg;

(iv) comprising vitamin E in the range of 0.001 % to 0.5% by weight of total lipids;

(v) comprising one or more nutrients effective to reduce omega-3 requirement or increase effective levels of omega-3 in a subject, than in the absence of the nutrient; or

(vi) comprising one or more polyphenols effective to increase omega-3 levels in a subject,

wherein the dosage of phytosterols is from 0.00000001 mg to 150 mg, the dosage of campesterol is from 0.00000001 mg to 1.5 mg, the dosage of sitosterol is from 0.00000001 mg to 30 mg, or the dosage of stigmasterol is from 0.00000001 mg to 1.5 mg, or a combination thereof;

wherein the dosage of vitamin A is from 0.00000001 mg to 30000 IU, the dosage of folic acid or folate is from 0.00000001 mg to 800 mcg, the dosage of vitamin C is from 0.00000001 mg to 400 mg, the dosage of vitamin D is from 0.00000001 mg to 400IU, if vitamin E is vitamin E tocopherol beta the dosage of vitamin E tocopherol beta is from 0.00000001 mg to 0.5 mg, if vitamin E is vitamin E tocopherol delta the dosage of vitamin E tocopherol delta is from 0.00000001 mg to 0.5 mg, if vitamin E is vitamin E tocopherol gamma the dosage of vitamin E tocopherol gamma is from 0.00000001 mg to 4 mg, if vitamin E is vitamin E tocopherol alpha the dosage of vitamin E tocopherol alpha is from 0.00000001 mg to 15 mg, the dosage of copper is from 0.00000001 mg to 3 mg, the dosage of zinc is from 0.00000001 mg to 14 mg, the dosage of manganese is from 0.00000001 mg to 8 mg, the dosage of iron is from 0.00000001 mg to 18 mg, the dosage of selenium is from 0.00000001 mg to 80 mcg, or the dosage of magnesium is

from 0.00000001 mg to 700 mg, or a combination thereof; or

wherein the dosage of alpha-carotene is from 0.00000001 mg to 4000 mcg, the dosage of beta-carotene is from 0.00000001 mg to 14000 mcg, the dosage of lycopene is from 0.00000001 mg to 1900 mcg, or the dosage of lutein or zeaxanthin is from 0.00000001 mg to 14000 mcg, or a combination thereof.

14. The formulation of claim 1, 2, or 3, wherein one or more of the following apply:
 - (i) comprising a source of nutrients selected from one or more of grains, legumes, fruits, vegetables, yogurt, herbs, spices, sweeteners, eggs, cheese, milk, poultry, seafood, and meat;
 - (ii) comprising 20-45% of diet's calories from fat, 45-65% of diet's calories from carbohydrates, and 10%-25% of diet's calories from protein;
 - (iii) comprising carbohydrates calories of which 50-70% are from grains, 15-30% are from vegetables, and 10-30 % are from fruits;
 - (iv) comprising 10%-25% calories from protein of which 0-75% are from legumes, 0-25% are from eggs, 0-25% are from cheese, 0-25% are from milk, 0-5% are from yogurt, 0-30% are from poultry, 0-30% are from seafood, 0-30% are from meat, and 0-15% are from other sources; or
 - (v) lipid-free or low-lipid foods are designed for use in combination with said lipid composition to achieve a balanced diet plan.

15. (omitted)

16. The formulation of claim 1, 2, or 3, wherein one or more of the following apply:
 - (i) the formulation is in the form of full meal or a dietary component selected from an oil,

- gel, sauce, dressing, spread, butter, drops, nutritional bar, snack, bread, bakery product, dairy product, side dish, salad, dessert, chocolate, fudge, pastry, truffle, pudding, cake, yogurt, drink, or a combination thereof; or
- (ii) the formulation is in the form of enteral, parenteral, a liquid, a semi-solid, a solid, capsule, tablet, granule, powder, lozenge, pill, or a combination thereof; or
- (iii) the formulation further comprises one or more carriers selected from starches, sugars, granulating agents, binders and disintegrating agents; or
- (iv) the formulation is one-part or comprises multi-part mutually complementing components, for one or more days, one or more weeks, or one or more months.
17. The formulation of claim 1, 2, or 3, wherein the formulation is configured for administration to the subject by steady delivery.
18. (Cancelled)
19. The formulation of claim 1, 2, or 3 for prophylaxis or treatment of a medical condition in a subject, comprising administering an effective amount of the formulation, wherein said medical condition is selected from: menopause, aging, musculoskeletal disorders, mood swing, reduced cognitive function, neural disorders, mental disorders, thyroid disturbances, weight gain, obesity, diabetes, endocrine disorders, digestive system disorders, reproductive disorders, pulmonary disorders, renal diseases, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, cancer, autoimmune diseases, infectious diseases, inflammatory diseases, hypercholesterolemia, dyslipidemia, or cardiovascular disease.

20. The formulation of claim 19, wherein the ratio of omega-6 to omega-3 is in the range of 1:1 to 10:1 w/w, w/v, or v/v and the subject has a diet of low antioxidants or low phytochemicals.
21. The formulation of claim 19, wherein the ratio of omega-6 to omega-3 is in the range of 2:1 to 30:1 w/w, w/v, or v/v, and the subject has a high-seafood diet.
22. The formulation of claim 19, wherein the dosage of total fat is 10-100 grams, the dosage of omega-6 fatty acids is from 1 to 35 grams, the dosage of omega-3 fatty acids is from 0.1 to 6 grams, the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 1:1 to 3:1 w/w, w/v, or v/v, the ratio of monounsaturated fatty acids to saturated fatty acids is in the range of 1:1 to 5:1 w/w, w/v, or v/v, the ratio of omega-9 to omega-6 fatty acids is in the range of 1:1-3:1 w/w, w/v, or v/v, and the ratio of omega-6 to omega-3 fatty acids is in the range of 1:1-45:1 w/w, w/v, or v/v.
23. The formulation of claim 19, wherein the formulation is administered to the subject by steady delivery without large fluctuations.
24. (Cancelled)
25. (Cancelled)
- 26 and 27. (omitted)
28. The method of claim 26 or of claim 27, wherein one or more fatty acids are selected from

butyric acid (C4:0), lauric acid (C12:0), myristic acid (C14:0), palmitic acid (C16:0), stearic acid (C18:0), arachidic acid (C20:0), myristoleic acid (C14:1), palmitoleic acid (C16:1), oleic acid (C18:1), gadoleic acid (C20:1), ercucic acid (C22:1), nervonic acid (C24:1), linoleic acid (C18:2), conjugated-linoleic acid (C18:2), gamma-linolenic acid (C18:3), eicosadienoic acid (C20:2), di-homo-gamma-linolenic acid (C20:3), arachidonic acid (C20:4), alpha-linolenic acid (C18:3), stearidonic acid (C18:4), eicosapentaenoic acid (C20:5), docosapentaenoic acid (C22:5), and docosahexaenoic acid (C22:6).

29. The method of claim 26 or claim 27, wherein one or more of the following apply:

- (i) omega-6 fatty acids are present at 4% to 75% by weight of total lipids;
- (ii) omega-3 fatty acids are present at 0.1 to 30% by weight of total lipids; or
- (iii) omega-9 fatty acids are present at 10% to 90% by weight of total lipids.

30. (omitted)

31. The method of claim 26 or claim 27, wherein the omega-6 to omega-3 ratio is 4:1 to 45:1 w/w, w/v, or v/v.

32. The method of claim 26 or claim 27, comprising omega-6 and omega-3 fatty acids wherein the omega-6 to omega-3 ratio is at least 9:1 w/w, w/v, or v/v.

33. The method of claim 26 or claim 27, wherein the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 0.25:1 to 6:1 w/w, w/v, or v/v.

34. The method of claim 26 or claim 27, wherein one or more of the following apply:

- (i) the dosage of total lipids is from 10-100 grams;
- (ii) the dosage of omega-6 fatty acids is from 1 to 40 grams;
- (iii) the dosage of omega-3 fatty acids is from 0.1 to 6.0 grams; or
- (iv) the dosage of eicosapentaenoic acid (C20:5) is from 0.00000001 mg to 0.5 grams; or
- (v) the dosage of docosahexaenoic acid (C22:6) is from 0.00000001 mg to 0.2 grams.

35. The method of claim 26 or claim 27, wherein one or more of the following apply:

- (i) the dosage of total lipids is 10-100 grams, the dosage of omega-6 fatty acids is from 1 to 40 grams, the dosage of omega-3 fatty acids is from 0.1 to 5 grams, the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 1:1 to 3:1 w/w, w/v, or v/v, the ratio of monounsaturated fatty acids to saturated fatty acids is in the range of 1:1 to 5:1 w/w, w/v, or v/v, the ratio of omega-9 to omega-6 fatty acids is in the range of 1:1 to 3:1 w/w, w/v, or v/v, and the ratio of omega-6 to omega-3 fatty acids is in the range of 4:1 to 45:1 w/w, w/v, or v/v;
- (ii) the formulation supplies 50-90% of a diet's fat calories; or
- (iii) the formulation is designed for use in combination with or provided with a lipid-free or low-lipid food product.

36 and 37. (omitted)

38. The method of claim 26 or claim 27, wherein one or more of the following apply:

- (i) a source of nutrients selected from one or more of grains, legumes, fruits, vegetables, yogurt, herbs, spices, sweeteners, eggs, cheese, milk, poultry, seafood, and meat;
- (ii) 20-45% of diet's calories are from fat, 45-65% of diet's calories are from carbohydrates, and 10%-25% of diet's calories are from protein;

(iii) carbohydrates calories are 50-70% from grains, 15-30% from vegetables, and 10-30 % from fruits; or

(iv) protein calories are 10%-25% of which 0-75% are from legumes, 0-25% are from eggs, 0-25% are from cheese, 0-25% are from milk, 0-25% are from yogurt, 0-30% are from poultry, 0-30% are from seafood, 0-30% are from meat, and 0-15% are from other sources.

39. The method of claim 26 or claim 27, wherein one or more of the following apply:
- (i) the formulation is in the form of full meal or a dietary component selected from an oil, gel, sauce, dressing, spread, butter, drops, nutritional bar, snack, bread, bakery product, dairy product, side dish, salad, dessert, chocolate, fudge, pastry, truffle, pudding, cake, yogurt, drink, or a combination thereof; or
 - (ii) the formulation is in the form of enteral, parenteral, a liquid, a semi-solid, a solid, capsule, tablet, granule, powder, lozenge, pill, or a combination thereof; or
 - (iii) the formulation comprises one or more carriers selected from starches, sugars, diluents, granulating agents, lubricants, binders and disintegrating agents; or
 - (iv) the formulation is one-part or comprises multi-part mutually complementing components, for one or more days, one or more weeks, or one or more months.
40. The method of claim 26 or claim 27, wherein the fatty acids, phytochemical, antioxidant, vitamins and minerals content of the formulation is effective for the subject to maintain oxidant balance, antioxidant balance, inflammation balance, or avoid unfavorable dietary interactions, or a combination thereof.
41. The method of claim 26 or claim 27, wherein the subject is an infant, a child, or an adult.

42 and 43. (omitted)