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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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- 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
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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:

Name: Asha Nutrition Sciences, Inc.
Address: PO Box 1000, Palo Alto, CA 94302
Email: admin@asha-nutrition.com
Phone Number: 650-322-7861
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).

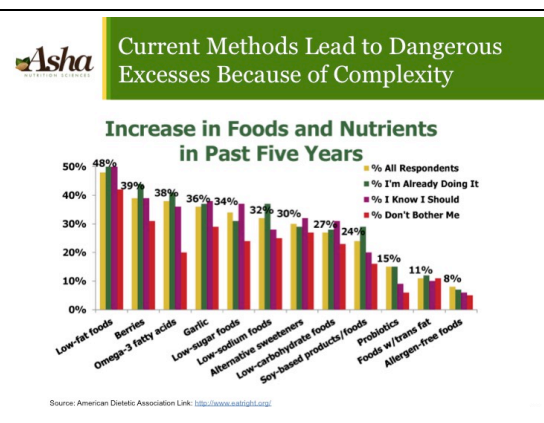
Natural lipid sources, oils, nuts and seeds etc, are variable and unreliable in lipid content and composition, and they contain many components that materially affect lipid metabolism. Important lipids such as polyphenols and several phytochemicals are poorly understood and absent from available dietary 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	36	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.

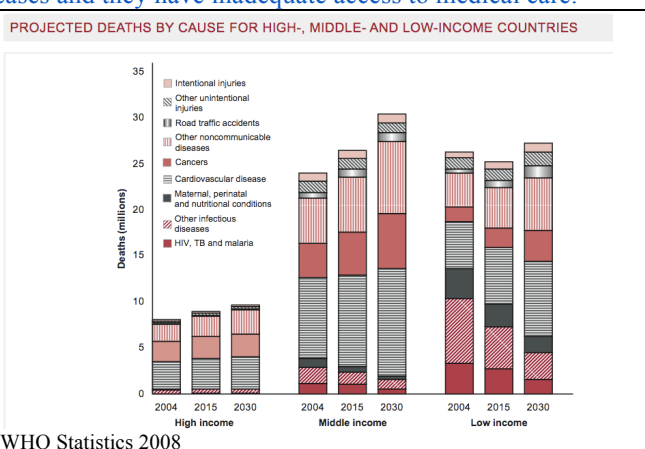
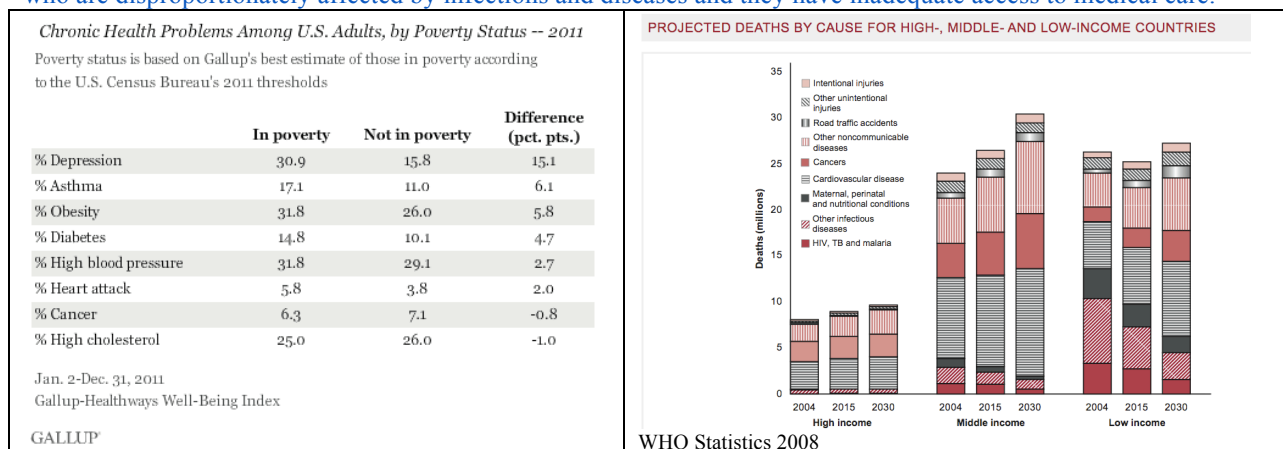
Technologies covered; product name: **LIPILIFE** (subject to change):

- 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.






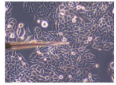



Thus, the disclosed solutions can especially reduce the burden of disease for impoverished populations. Applicant is targeting to provide the disclosed solutions in all economies with large share of impoverished populations.

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><small>Burns et al. "Fatty Acids in cardiovascular health and disease: A comprehensive update." <i>Journal of Clinical Lipidology</i> (2012) 6, 216–234</small></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><small>Lu et al. "Linoleic acid suppressed colorectal cancer cell growth by inducing oxidant stress and mitochondrial dysfunction." <i>Lipids in Health and Disease</i> 2010, 9:156</small></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>  <p><small>N.L. Morse. "A meta-analysis of blood fatty acids in people with learning disorders with particular interest in arachidonic acid." <i>Prostaglandins, Leukotrienes and Essential Fatty Acids</i> 91 (2009) 375–389</small></p>



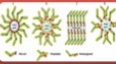




Most tissue contains ~10 times omega-6 as compared omega-3 and utilization of omega-6 is higher than omega-3. Omega-6 and other lipids are critical for optimal functioning of the cells and organisms (see *Bhagat et al, 2015* and *Morse 2009*). Further, immunity is materially enhanced by controlled lipid 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>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>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.

<p>Consumer Feedback to LipiLife*</p>  <ul style="list-style-type: none"> 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 <p><small>* Preliminary Market Research</small></p>	 <h3>LipiLife Solves 100-Year Old Problem Toxicity of Lipids and Correct Dosage</h3> <ul style="list-style-type: none">  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
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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>

PRIVILEGED AND CONFIDENTIAL

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
ASHA NUTRITION SCIENCES, INC.
Ph. (650) 322-7861
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Palo Alto, CA 94302
<http://www.asha-nutrition.com>
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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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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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Palo Alto, CA 94302

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

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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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Palo Alto, CA 94302

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

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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.

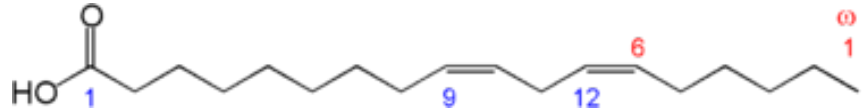
[0023] I further declare that all statements made herein of my own knowledge are true and that statements made of information and belief are believed to be true. I further acknowledge that any willful false statements and the like so made are punishable by fine or imprisonment, or both, and may jeopardize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

Contents

Biochemistry

Pharmacology

Suggested negative health effects

Omega-6 consumption

List of omega-6 fatty acids

Dietary linoleic acid requirement

Dietary sources

See also

Notes and references

Additional sources

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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