

Applicants' Written Arguments in Response to Examiner's Opinion

The Examiner has cited seven documents against the novelty and inventive step of the claims. The most relevant citation would appear to be DE-3308385. The citation is concerned with the enrichment of milks and/or their derivatives with PUFAs, particularly essential fatty acids in order to rectify the imbalance between saturated/mono-unsaturated fats and polyunsaturated fats in natural milk. The PUFAs are added in amounts of 10-65% relative to the total lipid content and, according to one embodiment of the invention, using various oils such as evening primrose oil.

The citation does not specifically mention GLA or DGLA, referring by name only to LA and ALA. However, the references to "essential fatty acids" and to the GLA-containing EPO may make it difficult to convince the Examiner of the novelty and especially the inventive step of the present subject matter in light of this citation. With regard to the amounts used, the Examiner has stated that the quantities of PUFAs used in the citation fall within the range of claim 1.

Nevertheless, there are distinguishing features of the present invention and we should argue initially that there is no specific mention in the citation of GLA or higher acids such as DGLA. The fact that LA is exemplified in the emulsion given on page 4, and more importantly the fact that it is present in such large amounts, indicates that the subject matter of the citation is very different from that of the present invention. It is stated in our description that LA and ALA are not of sufficient therapeutic value in many disease states owing to the rate-limiting step of 6-desaturation which converts LA to GLA and which is slow or sometimes completely blocked in a range of disorders. Accordingly, the citation can be considered as teaching away from the present invention. It can also be pointed out that the oils exemplified in the citation have very low GLA and DGLA contents, EPO having the highest at (8% GLA), and would not be capable of supplying the requisite amounts of these acids recited in the claims.

The remaining citations which disclose fatty acid enrichment would seem to be concerned with the provision of infant formula. The specification of the present application specifically discloses the prior art related to infant formula and the majority of the Examiner's citations relate to infant formula. They also all relate to concentrations of GLA less than 100mg/100ml. The text of the present application specifically states that the present invention is not about fortifying infant formula to make it more like breast milk but it is to use milk as a vehicle for fatty acid therapy in people other than infants. The aim is not just to treat deficiency but to use it as a vehicle for treatment, hence the much higher concentrations of GLA and DGLA which are specified. The only prior art citation which does not refer to infant formula is US-5223285 which instead discloses a product which is not a milk. The Examiner seems to have completely missed the point that the milk mixture known in Japan is specifically for infants and this is why it is disclosed in the applicant's US patent 5328691 and implicitly in the present application where we refer to infant formula.