

Electronically filed

AMENDMENT UNDER 37 C.F.R. §1.116 Address to: Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Attorney Docket Confirmation No.	CHOR-029 6322
	First Named Inventor	Morris, Claudia R.
	Application Number	12/033,431
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	Group Art Unit	1653
	Examiner Name	Macauley, Sheridan R.
Title	<i>Fatty Acid Formulations and Methods of Use Thereof</i>	

Sir:

This amendment is responsive to the final Office Action dated December 6, 2011 for which a three-month period for response was given, making this response due on March 6, 2012. ***A fee for a one-month extension of time was filed in this application on April 4, 2012.*** Accordingly, this response is timely filed.

Applicants submit that the amendments set forth below raise no new issues. Rather, the amendments place the claims in form for allowance or in better form for appeal. Entry of these amendments is thus respectfully requested.

In view of the remarks put forth below, reconsideration and allowance are respectfully requested.

I. AMENDMENTS

IN THE CLAIMS

Cancel claims 5, 6, and 10 without prejudice to renewal.

Please enter the amendments to claim 1, as shown below.

Please enter new claims 33-38, as shown below.

1. (Currently amended) A dietary formulation suitable for treating an autism spectrum disorder and/or apraxia, the formulation comprising:

- a) eicosapentaenoic acid (EPA);
- b) docosohexaenoic acid (DHA);
- c) α -tocopherol;
- d) γ -tocopherol;
- e) β -tocopherol, δ -tocopherol, α -tocotrienol, β -tocotrienol, γ -tocotrienol, and δ -tocotrienol;

[[and]]

f) glutamine [[.]] ;

g) vitamin K; and

h) γ -linolenic acid (GLA),

wherein the ratio of EPA to DHA is in a range of from about 1.5:1 to about 5:1,

wherein the α -tocopherol is present in an amount of from about 500 mg to about 3000 mg per unit dose,

wherein the γ -tocopherol is present in an amount of from about 200 mg to about 1000 mg per unit dose,

wherein the EPA is present in an amount of from about 500 mg to about 3000 mg per unit dose,

wherein the DHA ~~is EPA~~ is present in an amount of from about 100 mg to about 400 mg per unit dose,

[[and]] wherein the glutamine is present in an amount of from about 500 mg to about 750 mg per unit dose,

wherein the vitamin K is present in an amount of from about 100 μ g to about 2 mg, and

wherein the GLA is present in an amount of from about 50 mg to about 75 mg.

2. (Cancelled)

3. (Original) The formulation of claim 1, further comprising α -lipoic acid in an amount of from about 50 mg to about 600 mg per unit dose.

4. (Original) The formulation of claim 1, further comprising carnitine in an amount of from about 200 mg to about 3000 mg per unit dose.
- 5.-6. (Cancelled)
7. (Original) The formulation of claim 1, further comprising an omega-9 fatty acid.
8. (Original) The formulation of claim 7, wherein the omega-9 fatty acid is oleic acid.
9. (Original) The formulation of claim 1, further comprising vitamin C in an amount of from about 200 mg to about 500 mg.
10. (Cancelled)
11. (Original) The formulation of claim 1, further comprising phosphocholine.
12. (Original) The formulation of claim 1, further comprising zinc.
13. (Original) The formulation of claim 1, further comprising one or more additional components selected from coenzyme Q, selenium, vitamin A, vitamin B₁, riboflavin, vitamin B₆, vitamin B₁₂, vitamin D, arginine, calcium, magnesium, vitamin B₇, vitamin B₉, vitamin B₅, tetrahydrobiopterin, and vitamin B₃.
14. (Original) The formulation of claim 1, further comprising a pancreatic enzyme.
15. (Original) The formulation of claim 1, further comprising a leukotriene inhibitor.
16. (Original) The formulation of claim 1, wherein the formulation is in a dosage form selected from a tablet, a capsule, a powder, a gel, and a liquid.
17. (Original) The formulation of claim 1, further comprising one or more food-grade components.
18. (Withdrawn) A method of treating apraxia and/or autism spectrum disorder, the method comprising orally administering to an individual in need thereof an effective amount of the formulation of claim 1.

19. (Withdrawn) The method of claim 18, wherein the formulation is administered three times daily.
20. (Withdrawn) The method of claim 18, wherein the formulation is administered twice daily.
21. (Withdrawn) The method of claim 18, wherein the formulation is administered once daily.
22. (Withdrawn) The method of claim 18, wherein said administration is effective to increase the percentile score of at least one of oral movement score, simple phonemic/syllabic score, complex phonemic/syllabic score, and spontaneous length and complexity score, by at least about 10 percentile points.
23. (Withdrawn) A method of treating an allergic disorder, the method comprising orally administering to an individual in need thereof an effective amount of the formulation of claim 1.
24. (Withdrawn) The method of claim 23, wherein the disorder is selected from celiac disease, sprue, gluten sensitivity, a malabsorption syndrome, asthma, food allergy, leaky gut syndrome, and/or eczema.
25. (Withdrawn) A method of treating an inflammatory condition, the method comprising orally administering to an individual in need thereof an effective amount of the formulation of claim 1, wherein the inflammatory condition is rheumatic arthritis, diabetes, or cardiovascular disease.
26. (Previously presented) The formulation of claim 1, further comprising an anti-oxidant.
27. (Previously presented) The formulation of claim 1, further comprising an anti-inflammatory agent.
28. (Previously presented) The formulation of claim 1, further comprising an amino acid.
29. (Previously presented) The formulation of claim 28, wherein the formulation further comprises arginine.
30. (Previously presented) The formulation of claim 1, further comprising an anti-fungal agent.

31. (Previously presented) The formulation of claim 1, wherein the β -tocopherol, δ -tocopherol, α -tocotrienol, β -tocotrienol, γ -tocotrienol, and δ -tocotrienol are each present in an amount of from about 5 mg to about 2000 mg per unit dose.

32. (Previously presented) The formulation of claim 1, wherein a unit dose of the formulation is effective to treat an autism spectrum disorder and/or apraxia.

33. (New) A dietary formulation suitable for treating an autism spectrum disorder and/or apraxia, the formulation comprising:

- a) eicosapentaenoic acid (EPA);
- b) docosohexaenoic acid (DHA);
- c) α -tocopherol;
- d) γ -tocopherol;
- e) vitamin K; and
- f) γ -linolenic acid (GLA),

wherein the ratio of EPA to DHA is in a range of from about 1.5:1 to about 5:1,

wherein the α -tocopherol is present in an amount of from about 500 mg to about 3000 mg per unit dose,

wherein the γ -tocopherol is present in an amount of from about 200 mg to about 1000 mg per unit dose,

wherein the EPA is present in an amount of from about 500 mg to about 3000 mg per unit dose,

wherein the DHA is present in an amount of from about 100 mg to about 400 mg per unit dose,

wherein the vitamin K is present in an amount of from about 100 μ g to about 2 mg, and

wherein the GLA is present in an amount of from about 50 mg to about 75 mg.

34. (New) The formulation of claim 33, wherein a unit dose of the formulation is effective to treat an autism spectrum disorder and/or apraxia.

35. (New) The formulation of claim 33, further comprising carnitine in an amount of from about 200 mg to about 3000 mg per unit dose.

36. (New) A dietary formulation suitable for treating an autism spectrum disorder and/or apraxia, the formulation comprising:

- a) eicosapentaenoic acid (EPA);
- b) docosohexaenoic acid (DHA);
- c) α -tocopherol;
- d) γ -tocopherol;

wherein the ratio of EPA to DHA is in a range of from about 1.5:1 to about 5:1,

wherein the α -tocopherol is present in an amount of from about 500 mg to about 3000 mg per unit dose,

wherein the γ -tocopherol is present in an amount of from about 200 mg to about 1000 mg per unit dose,

wherein the EPA is present in an amount of from about 500 mg to about 3000 mg per unit dose,

wherein the DHA is EPA is present in an amount of from about 100 mg to about 400 mg per unit dose.

37. (New) The formulation of claim 36, further comprising carnitine in an amount of from about 200 mg to about 3000 mg per unit dose.

38. (New) The formulation of claim 36, further comprising vitamin K in an amount of from about 100 μ g to about 2 mg.

II. REMARKS

Formal Matters

Claims 1, 3, 4, and 7-9, and 11-38 are pending after entry of the amendments set forth herein.

Claims 1, 3-17, and 26-31 were examined and were rejected. Claims 18-25 were withdrawn from consideration.

Claim 1 is amended. The amendments to claim 1 were made solely in the interest of expediting prosecution, and are not to be construed as acquiescence to any objection or rejection of any claim. Support for the amendments to claim 1 is found in the claims as originally filed, and throughout the specification, in particular at the following locations: paragraphs 0052-0054; and paragraphs 0006 and 0036. Accordingly, no new matter is added by the amendments to claim 1.

Claims 5, 6, and 10 are canceled without prejudice to renewal, without intent to acquiesce to any rejection, and without intent to surrender any subject matter encompassed by the canceled claims. Applicants expressly reserve the right to pursue any canceled subject matter in one or more continuation and/or divisional applications.

Claims 33-38 are added. Support for new claims 33-35 is found in the claims as originally filed, and throughout the specification, including the following exemplary locations: claim 33: paragraphs 0022, 0023, 0030-0032, 0034-0036, 0052-0054, 0006, and 0036; claim 34: paragraph 00140; claim 35: paragraphs 0027 and 0041. Accordingly, no new matter is added by new claims 33-35. No new matter is added by new claims 36-38.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Examiner Interview

The undersigned Applicants' representative thanks Examiner Sheridan McCauley and Examiner Ruth Davis for the courtesy of a telephonic interview which took place on January 25, 2012, and which was attended by Examiners McCauley and Davis, inventor Claudia Morris, Mark Nottoli, Kara Bolton, and Applicants' representative and Paula A. Borden.

During the interview, the rejection under 35 U.S.C. § 103(a) was discussed.

Rejection under 35 U.S.C. §112, second paragraph

Claims 1, 3-17, and 26-32 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite.

The Office Action stated that the claims are rendered indefinite by the recitation of "the DHA is EPA is present in an amount of..."

Claim 1 is amended to recite "wherein the DHA is present in an amount of..."

Conclusion as to the rejection under 35 U.S.C. §112, second paragraph

Applicants submit that the rejection of claims 1, 3-17, and 26-32 under 35 U.S.C. §112, second paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejections under 35 U.S.C. §103(a)

Claims 1, 3-13, 15-17, and 26-32 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Ernest (U.S. Patent Publication No. 2005/0070498; "Ernest") in view of Dreon et al. (U.S. Patent Publication No. 2004/0048919; "Dreon") and Chilton et al. (U.S. Patent Publication No. 2006/0052446; "Chilton"). Claims 1, 3-14, 17, 26-29, 31, and 32 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Ernest in view of Dreon and Girsh (U.S. Patent Publication No. 2005/0260181; "Girsh").

Claims 1, 3-13, 15-17, and 26-32 over Ernest in view of Dreon and Chilton

The Office Action stated:

- 1) Ernest teaches a dietary composition comprising EPA, DHA, alpha-tocopherol, and gamma-tocopherol;
- 2) Ernest does not teach that the compositions comprise the specific amounts of tocopherols and tocotrienols recited in the claims, or that the composition comprises a leukotriene inhibitor or an antifungal agent;
- 3) Dreon teaches compositions for the treatment of inflammatory symptoms, wherein the compositions comprises fatty acids, and that Dreon teaches the use of alpha-, beta-, gamma-, and delta-tocopherols and tocotrienols; and
- 4) Chilton teaches dietary compositions comprising fatty acids, and that Chilton teaches that GLA acts as a leukotriene inhibitor.

The Office Action stated that one would have been motivated to use the amounts of tocopherols taught by Dreon in the compositions of Ernest "because Dreon teaches that the elevated amounts of tocopherols are beneficial because they have CRP-lowering activity, which indicates a reduction in inflammation." Office Action, page 7. The Office Action stated that since Ernest is directed to the treatment of disorders, including inflammatory

The cited references do not teach each and every claim element.

In order to meet its burden in establishing a rejection under 35 U.S.C. §103, the Office must first demonstrate that a prior art reference, or references when combined, teach or suggest **all claim elements**. See, e.g., *Süd-Chemie, Inc. v. Multisorb Technologies, Inc.* 554 F.3d 1001 (Fed. Cir. 2009); *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007); *Pharmastem Therapeutics v. Viacell et al.*, 491 F.3d 1342, 1360 (Fed. Cir.

2007); MPEP § 2143(A)(1).

Ernest neither discloses nor suggests the unit dose amounts of particular components of a formulation of claim 1.

- 1) **Glutamine.** Ernest states that the formulation disclosed therein “includes from about 1.5 grams to about 7.5 grams of glutamine per 240 calories of the formulation.” Ernest, paragraph 0008. Elsewhere, Ernest indicates that L-Glutamine is present in an amount of 3 grams per 240 calories of the formulation. These amounts are **significantly higher** than the 500 mg to about 750 mg glutamine per unit dose recited in instant claim 1, and reflect the fact that the formulations of Ernest are designed to provide **general nutritional support**.
- 2) **Tocopherols.** Ernest discusses generally including vitamin E, but does not disclose or suggest providing vitamin E the various forms of vitamin E in the amounts recited in instant claim 1. For example, Ernest states that alpha tocopherol is present in the formulation in an amount of 10-160 IU, which corresponds to about 6.7 mg (10 IU) to about 107 mg (160 IU). In contrast, instant claim 1 recites that α -tocopherol is present in an amount of from about 500 mg to about 3000 mg per unit dose. Thus, the amount of α -tocopherol disclosed in Ernest is **significantly lower** than the range recited in claim 1.
- 3) **γ -tocopherol.** Ernest does not provide any specific amounts of γ -tocopherol that should be included. In contrast, instant claim 1 recites that γ -tocopherol is present in an amount of from about 200 mg to about 1000 mg per unit dose.
- 4) **EPA and DHA.** Ernest neither discloses nor suggests the amounts of EPA and DHA recited in instant claim 1. Ernest states that EPA and DHA can be included in an amount of 0.5 to about 7.0 grams each. Ernest, paragraph 0017. In contrast, the amount of DHA recited in claim 1 is 100 mg to 400 mg per unit dose. Thus, the amount of DHA disclosed in Ernest is **significantly lower** than the range recited in claim 1.

The Office Action has mis-characterized the disclosure of Ernest with respect to the amounts of EPA and DHA. The Office Action stated that Ernest “teaches that the compositions may comprise 0.5 to 7 g of the fatty acids (p.2, par. 17; note that 14.5% of 7 g is about 1000 mg EPA and 3.5% of 7 g is about 250 mg DHA).” Office Action, page 6. This is a mis-characterization of Ernest.

Ernest states:

- 1) “The structured lipid blend further contains, per 240 calories, an Omega 3 Fatty acid chosen from the group EPA, DHA, STA, DPA, and/or ETA, at a range of about 0.5 to about 7.0 gm...”; Ernest, paragraph 0017;

- 2) “It should be understood that the following are suitable sources for GLA, EPA, MCTs, and MUFAs in the lipid blend” (Ernest, paragraph 0025), where the “suitable sources” include “(f) Menhadin oil” (Ernest, paragraph 0031).

The Office Action extrapolated an amount of 250 mg DHA from the percent of DHA in menhaden oil, which is given as 3.6% in Ernest.

However, Ernest specifically states that an omega-3 fatty acid (which can be DHA) is present “at a range of about 0.5 to 7.0 gm.” Ernest, paragraph 0017. The extrapolation of 250 mg DHA in the Office Action appears to be at odds with the disclosure in Ernest. Nowhere in Ernest is there any disclosure of DHA in the formulation of Ernest, in an amount of 250 mg. The Office Action appears to have interpreted Ernest’s disclosure to mean adding up to 7 g of menhaden oil. That is not what Ernest discloses. Instead, Ernest discloses extracting particular fatty acids from the menhaden oil. Ernest, paragraph 0022. Ernest clearly states that fatty acids such as DHA are to be included in a range of from about 0.5 g to 7.0 g. Ernest does not disclose adding 7 g of menhaden oil to the formulation, as the Office Action appears to suggest.

The fact remains that Ernest’s disclosure of DHA “at a range of about 0.5 to 7.0 gm” is substantially higher than the claimed amount of “from about 100 mg to 400 mg.”

During the telephone interview, Examiner McCauley stated that although Ernest teaches that the amounts disclosed are per 240 calories, the calories can be increased or decreased. However, it would not be feasible to deliver the amount of α -tocopherol in Ernest’s formulation per 240 calories to the level recited in instant claim 1. For example, if one were to deliver 500 mg α -tocopherol, given Ernest’s disclosure of 6.7 mg to 107 mg per 240 calories, one would have to deliver at least 1,121 calories. Such would simply not be feasible.

During the telephone interview, Examiner McCauley stated that although Ernest teaches that the amounts disclosed are per 240 calories, the calories can be increased or decreased. Examiner McCauley appeared to suggest that such a disclosure indicates that the amounts of the components disclosed in Ernest could be increased or decreased. However, it would be an improper analysis under 35 U.S.C. §103(a) to suggest that an amount of a first component could be increased while the amount of a second component could be decreased. However, that is exactly the sort of modification one would have to make to Ernest in order to arrive at the instant claims. Such an analysis would be precisely the sort of impermissible hindsight analysis that is impermissible. Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. *ATD Corp. v. Lydall, Inc.*, 48 USPQ2d 1321 (Fed. Cir. 1998). The courts prohibit hindsight reconstruction of an invention by cherry-picking particular elements of the prior art reference, and making them work together in a manner **that is different from what the reference intends**.

Thus, Ernest fails to disclose or suggest a formulation that includes:

- 1) **glutamine** in an amount of from about 500 mg to about 750 mg per unit dose;
- 2) **α -tocopherol** in an amount of from about 500 mg to about 3000 mg per unit dose;
- 3) **γ -tocopherol** in an amount of from about 200 mg to about 1000 mg per unit dose; and
- 4) **DHA** in an amount of from about 100 mg to about 400 mg per unit dose.

None of the secondary references cures the deficiencies of Ernest.

The Office Action stated that Dreon teaches “compositions for the treatment of inflammatory symptoms”; and that Dreon “teaches the use of alpha-, beta-, gamma- and delta-tocopherols and tocotrienols at amounts of from about 50 mg to about 2000 mg per unit dose.” Office Action, page 6.

Chilton was cited as teaching dietary compositions comprising gamma-linolenic acid.

None of the cited art discloses or suggests a formulation that includes glutamine in an amount of from about 500 mg to about 750 mg per unit dose.

None of the cited art discloses or suggests a formulation that includes DHA in an amount of from about 100 mg to about 400 mg per unit dose

The Office Action has failed to demonstrate that the cited references teach or suggest **all claim elements**. As such, the Office Action has not established a prima facie case of obviousness under 35 U.S.C. §103. *Süd-Chemie, Inc. v. Multisorb Technologies, Inc.*

The Office Action has failed to provide adequate reasoning as to why one skilled in the art would combine the cited references.

A subject formulation is designed to treat specific disorders, which disorders include, e.g., autism spectrum disorder and apraxia. Specification, paragraphs 00140 and 00154. None of the cited art discloses or suggests a formulation that is designed to treat autism spectrum disorder and apraxia.

Ernest discusses enteral formulations that are designed for providing nutritional needs for “patients suffering from traumatic injury, burns, post-surgery, and some disease states” that “have a significant need for increased nutrients and energy.” Ernest, paragraph 0004. The enteral formulations of Ernest are said to provide general nutritional support to patients. Ernest, paragraphs 0007 and 0012. The enteral formulations of Ernest are not for the treatment of the specific disorders listed paragraph 0012 of Ernest; instead, the enteral formulations are said to provide **general nutritional support**.

One skilled in the art, when seeking to design a formulation suitable for treating autism spectrum disorder and apraxia, would not have looked to Ernest. First, Ernest does not disclose a formulation suitable for treating any disease, much less for treating autism spectrum disorder and apraxia. Indeed, during prosecution of Ernest, the U.S. Patent Office stated that Ernest's claims to "treating a disease" **were not enabled** under 35 U.S.C. §112, first paragraph; and that the specification was enabling only for "providing nutrition to a patient in need thereof." Office Action dated August 8, 2006 in U.S. Patent Application No. 10/992,985 (which published as US 2005/0070498; "Ernest"). In response, Ernest amended the claims to recite a "method of providing nutrition to a patient in need thereof."

Dreon relates to formulations for treating symptoms relating to premenstrual syndrome, premenstrual dysphoric syndrome, perimenopause, menopause, endometriosis, post-partum depression, or administration of oral contraceptives. None of the formulations in Dreon includes components in amounts effective to treat an autism spectrum disorder and/or apraxia. Thus, one skilled in the art, when seeking to design a formulation suitable for treating autism spectrum disorder and apraxia, would not have looked to Dreon.

Chilton relates to fatty acid-containing compositions and methods for the treatment of cytokine mediated disorders. For example, Chilton relates to treatment of asthma and arthritis. Chilton, paragraph 0012. Chilton was cited merely for disclosure of a formulation comprising GLA. However, none of the formulations in Chilton includes components in amounts effective to treat an autism spectrum disorder and/or apraxia. Thus, one skilled in the art, when seeking to design a formulation suitable for treating autism spectrum disorder and apraxia, would not have looked to Chilton.

None of the cited art discloses or suggests a formulation of claim 1 as amended.

Claim 1 is amended to recite that the formulation includes:

- vitamin K in an amount of from about 100 µg to about 2 mg; and
- γ-linolenic acid (GLA) in an amount of from about 50 mg to about 75 mg.

Ernest mentions vitamin K, in an amount of 5 µg to 70 µg (Ernest, paragraph 0064), which is **substantially lower** than the range recited in amended claim 1.

Ernest mentions GLA at a range of about 0.1 gm to about 4.0 gm (Ernest, paragraph 0016), which is substantially higher than the range recited in amended claim 1.

Chilton discusses a dietary supplement preparation "consisting essentially of GLA" "present in an amount

of from about 1 gram to about 15 grams” (Chilton, paragraph 0023) which is **substantially higher** than the range recited in claim 1.

Unexpected results

As discussed during the telephone interview, it would not have been obvious in view of the cited art that a formulation as recited in claim 1, or a formulation as recited in claim 33 or claim 36, would be effective to treat an autism spectrum disorder or apraxia.

Those skilled in the art would not have expected a formulation comprising EPA, DHA, α -tocopherol, and γ -tocopherol, in the amounts recited in the claims, to treat an autism spectrum disorder or apraxia.

The unexpected results that led to the instant formulations as claimed arose in part from the discovery that children with apraxia (many of whom also exhibit autism spectrum disorder) presented with neurological symptoms that overlap those of vitamin E deficiency, yet have normal plasma vitamin E levels (which does not rule out an intracellular deficiency). These children responded dramatically to a formulation that includes EPA, DHA, and vitamin E. Initial observations on 2 children led to further investigation and a larger case study involving 187 children. See, e.g., Morris and Agin (2009) *Alt. Ther.* 15:34 (“Morris 2009”). Prior to the Morris 2009 publication, this condition had not been previously described in the scientific literature as treatable with a formulation as claimed. Indeed, it is still not recognized by many in the field.

It is believed that at least some of the features of autism spectrum disorder (ASD) are due to malabsorption of nutrients. This could explain why many children respond dramatically to a formulation as claimed. Indeed, there are reports of impaired carbohydrate digestion and transport, and mucosal dysbiosis in the intestines of children with autism. Williams et al. (2011) *PLoS One* 6:e24585. However, as recently as 2010, treatment suggestions included treatments similar to those for celiac. See, e.g., Buie et al. (2010) *Pediatrics* 125:S19.

Long-felt, unmet need/commercial success

Until the formulations as claimed were developed and became available, viable treatment options for ASD and apraxia were limited, and generally not efficacious.

A formulation comprising EPA, DHA, α -tocopherol, and γ -tocopherol in the ranges recited in claims 1, 33, and 36 has been sold under the tradename SPEAK™. SPEAK™ includes EPA in a range of from about 500 mg to about 3000 mg per unit dose; DHA in a range of from about 100 mg to about 400 mg per unit dose, α -tocopherol in a range of from about 500 mg to about 3000 mg per unit dose; and γ -tocopherol in a range of from

III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number CHOR-029.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: April 6, 2012

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