

Docket No.: 888968004US10  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Manku et al.

Application No.: 13/768,906

Confirmation No.: 4793

Filed: February 15, 2013

Art Unit: 1615

For: STABLE PHARMACEUTICAL  
COMPOSITION AND METHODS OF USING  
SAME

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Examiner: A. Sasan

**AMENDMENT IN RESPONSE TO  
NON-FINAL OFFICE ACTION UNDER 37 C.F.R. 1.111**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Madam:

**INTRODUCTORY COMMENTS**

In response to the Office Action dated May 24, 2013, please amend the above-identified U.S. patent application as follows:

**Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.

**Remarks/Arguments** begin on page 5 of this paper.

LEGAL26918830.1

### **AMENDMENTS TO THE CLAIMS**

This listing of Claims will replace all prior versions, and listings, of Claims in the application:

1. (Currently amended) A method of reducing triglycerides in a subject with treating mixed dyslipidemia ~~in a subject~~ on statin therapy comprising, administering to the subject a pharmaceutical composition comprising about 2500 mg to 5000 mg per day of ethyl eicosapentaenoate and not more than about 5%, by weight of all fatty acids, docosahexaenoic acid or its esters, ~~by weight of all fatty acids,~~ to effect a reduction in ~~of at least 10%~~ fasting triglyceride levels in the subject and a reduction in LDL-C compared to placebo control.

2. (Original) The method of claim 1 wherein upon 12 weeks of said administration the subject exhibits a reduction in LDL-C of at least 5% compared to placebo control.

3. (Original) The method of claim 1 wherein the subject exhibits a reduction in fasting triglycerides of at least 15% compared to placebo control.

4. (Original) The method of claim 1 wherein upon 12 weeks of said administration the subject exhibits a reduction in fasting triglycerides of at least 20% compared to placebo control.

5. (Original) The method of claim 1 wherein upon 12 weeks of said administration the subject exhibits a reduction in fasting triglycerides of at least 25% compared to placebo control

6. (Original) The method of claim 1 wherein the subject exhibits a reduction in fasting VLDL-C compared to placebo control.

7. (Original) The method of claim 1 wherein the subject exhibits a reduction in fasting VLDL-C of at least 5% compared to placebo control.

8. (Original) The method of claim 1 wherein the subject exhibits a reduction in hs-CRP compared to placebo control.

9. (Original) The method of claim 1 wherein the subject exhibits a reduction in non-HDL-C compared to placebo control.

10. (Original) The method of claim 1 wherein the subject exhibits a reduction in total cholesterol compared to placebo control.

11. (Original) The method of claim 1 wherein the subject exhibits a reduction in non-HDL-C, total cholesterol and VLDL-C compared to placebo control.

12. (Original) The method of claim 1 wherein the subject exhibits a reduction in oxidized LDL-C compared to placebo control.

13. (Original) The method of claim 1 wherein the subject exhibits a reduction in lipoprotein associated phospholipase A2 compared to placebo control.

14. (Original) The method of claim 1 wherein the ethyl eicosapentaenoate is administered to the subject in dosage units each comprising about 500 mg to about 1.5 g of ethyl eicosapentaenoate.

15. (Original) The method of claim 14 wherein the dosage units are capsules.

16. (Original) The method of claim 1 wherein the ethyl eicosapentaenoate is administered to the subject in dosage units each comprising about 900 mg to about 1 g of ethyl eicosapentaenoate.

17. (Original) The method of claim 16 wherein the ethyl eicosapentaenoate is administered to the subject in dosage units each comprising about 1 g of ethyl eicosapentaenoate.

18. (Original) The method of claim 17 wherein the dosage units are capsules.

19. (Original) The method of claim 1 wherein the ethyl eicosapentaenoate comprises at least about 90%, by weight, of all fatty acids.

### **REMARKS**

Reconsideration of this application is respectfully requested. At the time the present Office Action was mailed (May 24, 2013), claims 1-19 were pending. Claims 1-19 are rejected. Claim 1 has been amended. No new matter has been added. Claims 1-19 are now pending in this application.

#### **Claim Rejections Under 35 U.S.C. § 103**

Claims 1-12 and 14-19 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Katayama et al. (Prog. Med. 2001; 21:457-467 - English Translation) ("Katayama") in view of Davidson et al. (Clinical Therapeutics Vol. 29, Number 7, 2007, pp. 1354-1367) ("Davidson") and Saito et al. (Atherosclerosis 200 (2008) 135-140) ("Saito").

Claim 13 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Katayama in view of Davidson, Saito and Anderson (The American Journal of Cardiology, 2008; 101:23F-33F) ("Anderson").

Claims 1-12 and 14-19 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent Publication No. 2007-0191467 to Rongen et al. ("Rongen") in view of Saito.

Claim 13 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Katayama in view Rongen in view of Saito and Anderson. Applicants respectfully traverse each of the foregoing rejections.

#### **I. Rejections over Katayama, Davidson, Saito and Anderson.**

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103, the Office must articulate a reason or rationale that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

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