Docket No.: 888968004US10
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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 | 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.

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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