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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/768,906	02/15/2013	Mehar Manku	88896-8004.US10	4793

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
05/24/2013	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 13/768,906	Applicant(s) MANKU ET AL.	
	Examiner ARADHANA SASAN	Art Unit 1615	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2013*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-19* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-19* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *15 February 2013* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some * c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Interim copies:

a)☐ All b)☐ Some c)☐ None of the: Interim copies of the priority documents have been received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/07/13*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 1-19 are included in the prosecution.

Information Disclosure Statement

2. The information disclosure statement (IDS) filed on 03/07/2013 is acknowledged.

The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98.

Accordingly, the examiner is considering the information disclosure statement.

See attached copy of PTO-1449.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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

The claimed invention is a method of 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% docosahexaenoic acid or its esters, by weight of all fatty acids, to effect a reduction in fasting triglycerides of at least 10% and a reduction in LDL-C compared to placebo control.

Katayama et al. teach a method of lowering triglycerides in a subject comprising administering three capsules containing 300 mg each of ethyl eicosapentaenoate (EPADEL®). The administration is 3 times a day for a daily dose of 2700 mg. The subjects have a baseline triglyceride level of at least 150 mg/dl (Page 3, section “Method”, Page 8, last paragraph - "Triglyceride", Figure 3 “Transition in serum triglyceride”). The treatment period is 3 months (or 12 weeks), after which the subjects show 25.1 ± 3.0% reduction in triglyceride level (Figure 3). The baseline HDL-C level is 49.1 ± 1.2 mg/dL before treatment (Page 9, “HDL-Cholesterol and Figure 4).

Katayama et al. do not expressly teach that the subject is on statin therapy.

Davidson et al. teach that adding prescription omega-3-acid ethyl esters (P-OM3 – at 4g/d; Lovaza™, formerly Omacor®) to stable statin therapy in patients with persistent hypertriglyceridemia was associated with significant reductions in triglyceride (TG) levels (29.5% vs 6.3%) and very-low-density lipoprotein cholesterol (VLDL-C) (27.5% vs 7.2%), and a significant reduction in the total cholesterol:HDL-C ratio (9.6% vs 0.7%) (all, $P < 0.001$ vs placebo) (Page 1354). Davidson et al. teach that under hypertriglyceridemic conditions, VLDL-C becomes an important component of non-HDL-C, and that statin treatment alone may be insufficient to achieve non-HDL-C targets

(Page 1355). Each 1-g capsule of P-OM3 contains highly concentrated ethyl esters of omega-3 fatty acids, primarily eicosapentaenoic acid (EPA) 465 mg and docosahexaenoic acid (DHA) 375 mg (Page 1355). Table II (Page 1360) shows the lipid and lipoprotein results wherein TG reduction was 29.5% for patients receiving the combination vs. 6.35 reduction for patients on statin only, non-HDL-C reduction was 9.0% vs. 2.2%, VLDL-C reduction was 27.5% vs. 7.2% respectively, total cholesterol (TC) reduction was 4.8% vs. 1.7%), the TC/HDL-C ratio reduction was 9.6% vs. 0.7%, and reduction in Apolipprotein B (Apo-B) was 4.2% and 1.9% respectively.

Davidson et al. do not expressly teach a reduction in LDL-C compared to placebo control.

Saito et al. teach that administration of 1800 mg per day of EPA ethylester in combination with a statin (Page 136, Section 2.2 “Procedures”) in patients with high TG and high TC led to a significant reduction in TG (23%) which was even significant when compared to individuals on statin alone (18% decrease), and a significant decrease in LDL-C (20%) (Table 2, Page 138).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of lowering triglycerides in a subject having a baseline triglyceride level of at least 150 mg/dl comprising administering capsules containing 300 mg each of ethyl eicosapentaenoate for a 25.1 + 3.0% reduction in triglyceride level, as taught by Katayama et al., in view of the method of adding prescription omega-3-acid ethyl esters at 4g/d to stable statin therapy in patients with persistent hypertriglyceridemia in order to achieve significant reductions in TG levels (29.5% vs 6.3%), VLDL-C levels (27.5% vs 7.2%), and in the total cholesterol:HDL-C

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