Docket No.: AGP-002C3
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Daniel J. Rader

Application No.: 14/075,483 | Confirmation No.: 4350

Filed: November 8, 2013 | Art Unit: 1629

For: METHODS FOR TREATING DISORDERS OR DISEASES ASSOCIATED WITH HYPERLIPIDEMIA AND HYPERCHOLESTEROLEMIA WHILE MINIMIZING SIDE EFFECTS | Examiner: K. E. Weddington

AMENDMENT AND RESPONSE TO FINAL OFFICE ACTION

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

This Response is being filed in response to the outstanding Office Action, mailed May 28, 2015, in connection with the above-identified application, together with a Certification and Request for Prioritized Examination, a Request for Continued Examination, a Declaration under 37 C.F.R. §1.131, an Information Disclosure Statement, a form PTO/SB/08, copies of references cited thereon, and a petition for an extension of time.

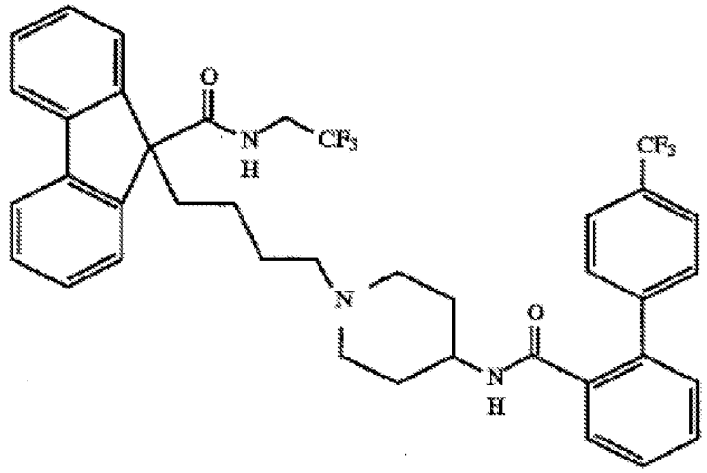
Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 6 of this paper.

AMENDMENTS TO THE CLAIMS

What is claimed is:

1. (Previously presented) A method of treating a subject suffering from hyperlipidemia or hypercholesterolemia, the method comprising administering to the subject an effective amount of an MTP inhibitor, wherein said administration comprises at least three step-wise, increasing dose levels of the MTP inhibitor wherein the dose levels are from about 2 to about 13 mg/day, from about 5 to about 30 mg/day, and from about 10 to about 50 mg/day; and wherein the MTP inhibitor is represented by:



or a pharmaceutically acceptable salt thereof or the piperidine N-oxide thereof, and wherein each dose level is administered to the subject for about 1 to about 5 weeks.

2. (Original) The method of claim 1 wherein the disorder is severe hypercholesterolemia.

3. (Original) The method of claim 1 wherein one or more of Total Cholesterol, LDL, fasting triglycerides (TG), VLDL, lipoprotein (a) (Lp(a)), and apolipoproteins A-I, A-II, B, and E are reduced by at least 15%, compared to control levels.

4. (Original) The method of claim 1 wherein one or more of Total Cholesterol, LDL, fasting triglycerides (TG), VLDL, lipoprotein (a) (Lp(a)), and apolipoproteins A-I, A-II, B, and E are reduced by at least 25%, compared to control levels.

5. (Cancelled)

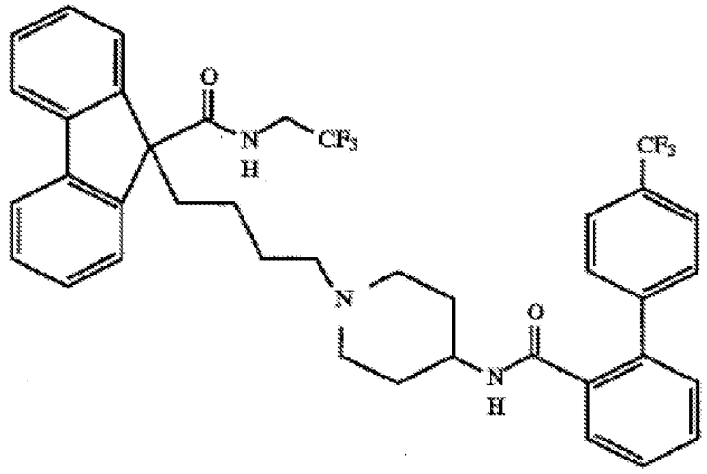
6. (Original) The method of claim 1 wherein the MTP inhibitor is administered orally.

7. (Cancelled)

8. (Previously presented) The method of claim 1 wherein said increasing dose levels further comprise a fourth dose level.

9. - 25. (Cancelled)

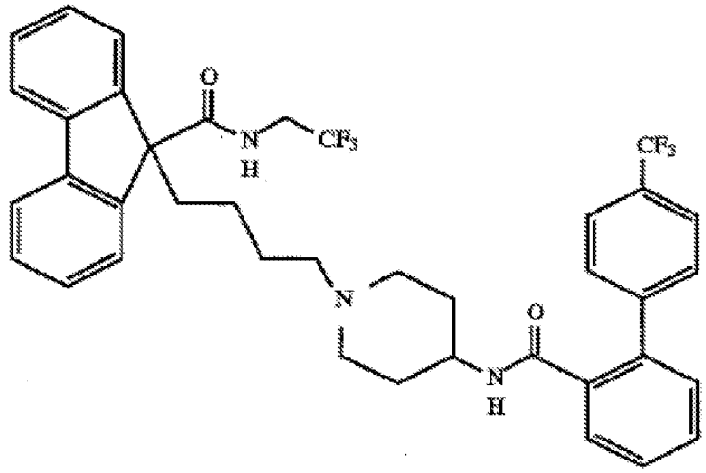
26. (New) A method of treating a subject suffering from hyperlipidemia or hypercholesterolemia, the method comprising administering to the subject an effective amount of an MTP inhibitor, wherein said administration comprises at least three step-wise, increasing dose levels of the MTP inhibitor up to a maximum dose level, wherein a first starting dose level is from about 2 to about 13 mg/day, a second dose level is from about 5 to about 30 mg/day, and a third dose level is from about 10 to about 50 mg/day; and wherein the MTP inhibitor is represented by:



or a pharmaceutically acceptable salt thereof or the piperidine N-oxide thereof, and wherein each dose level is administered to the subject for about 1 to 4 weeks, wherein upon administration the patient has reduced steatorrhea as compared to a patient administered a starting dose of 25 mg/day.

27. (New) The method of claim 26, wherein the administering increasing dose levels further comprises a fourth dose level of about 20 to about 60 mg/day and a maximum dose level of about 30 to about 75 mg/day.

28. (New) A method of treating a subject suffering from hyperlipidemia or hypercholesterolemia, the method comprising administering to the subject an effective amount of an MTP inhibitor, wherein said administration comprises at least three step-wise, increasing dose levels of the MTP inhibitor, wherein a first dose level is from about 2 to about 13 mg/day, a second dose level is from about 5 to about 30 mg/day, and a third dose level is from about 10 to about 50 mg/day; and wherein the MTP inhibitor is represented by:



or a pharmaceutically acceptable salt thereof or the piperidine N-oxide thereof, and wherein each dose level is administered to the subject for about 1 to 4 weeks, wherein the method reduces symptoms of steatorrhea and/or hepatic fat in the subject.

29. (New) The method of claim 28, wherein the administering increasing dose levels further comprises a fourth dose level of about 20 to about 60 mg/day and a maximum dose level of about 30 to about 75 mg/day.

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