Docket No.: AGP-002C2
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Daniel J. Rader

Application No.: 13/046,118 | Confirmation No.: 4237

Filed: March 11, 2011 | Art Unit: 1629

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

AMENDMENT

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Commissioner for Patents
P.O. Box 1450
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This Response is being filed together with a Request for Continued Examination, and an Information Disclosure Statement.

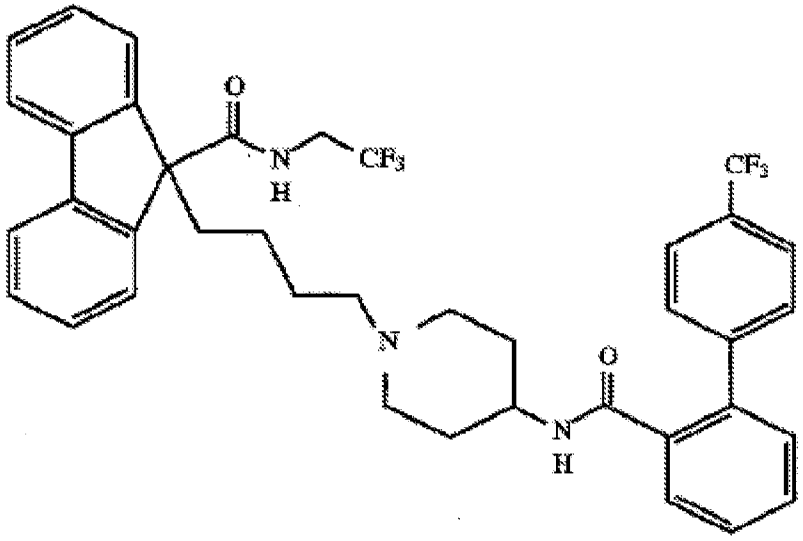
Amendments to the Claims begin on page 2 of this paper.

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 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 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. (Previously Presented) The method of claim 1 wherein said increasing dose levels further comprise a fourth and a fifth dose level.

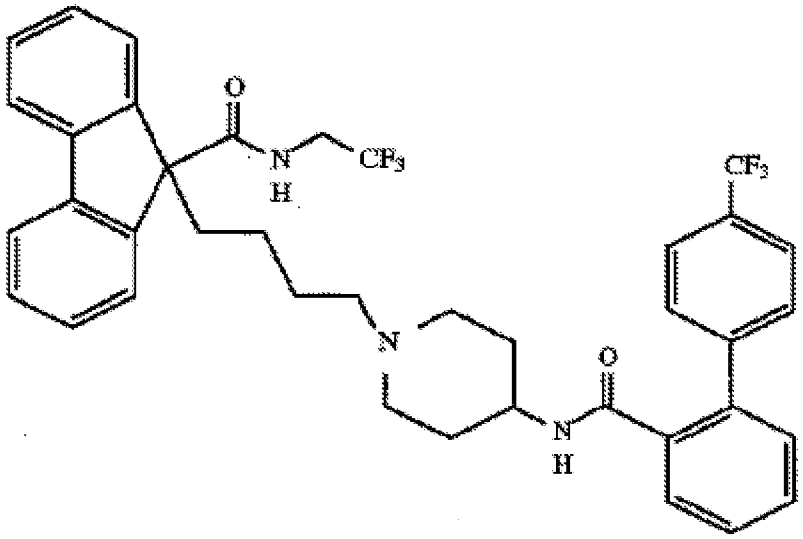
10-12. (Cancelled)

13. (Previously Presented) The method of claim 9 wherein said fourth dose level is from about 20 to about 60 mg/day, and said fifth dose level is from about 30 to about 75 mg/day.

14-25. (Cancelled)

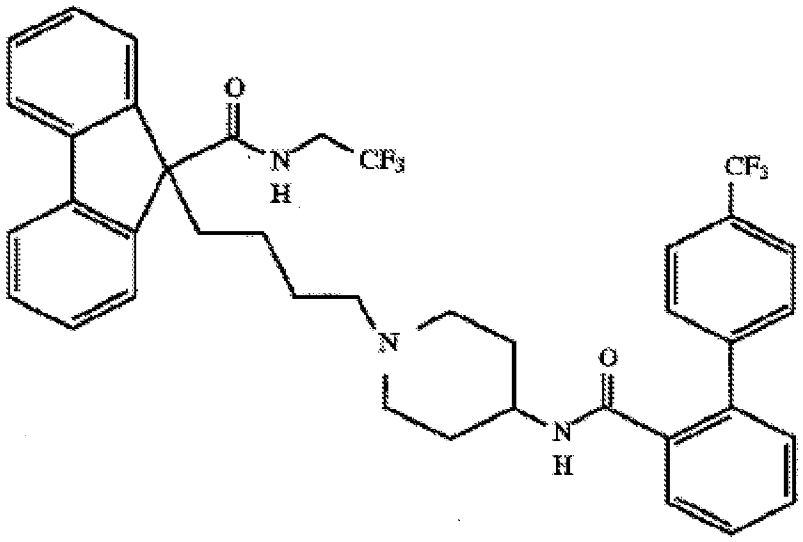
26. (Previously Presented) A method of treating a subject suffering from hyperlipidemia or hypercholesterolemia, the method comprising administering to the subject an effective amount of an

MTP inhibitor, wherein said administration comprises at least three step-wise, increasing dose levels of the MTP inhibitor wherein a first dose level is from about 2 to about 13 mg/day, administered to the subject for about 2 weeks; a second dose level is from about 5 to about 30 mg/day, administered to the subject for about 2 weeks to about 4 weeks; and a third dose level is from about 10 to about 50 mg/day, administered to the subject for about 2 weeks to about 4 weeks; and wherein the MTP inhibitor is represented by:



or a pharmaceutically acceptable salt thereof or the piperidine N-oxide thereof.

27. (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, administered to the subject for about 1 to about 12 weeks; a second dose level is from about 5 to about 30 mg/day, administered to the subject for about 4 weeks; and a third dose level is from about 10 to about 50 mg/day, administered to the subject for about 4 weeks; and wherein the MTP inhibitor is represented by:



or a pharmaceutically acceptable salt thereof or the piperidine N-oxide thereof

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