IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Rader	
Serial No: 10/591,923	Examiner: Weddington, Kevin E
Filed: June 21, 2007	Art Unit: 1614
For: METHODS FOR TREATING DISORDERS OR DISEASES ASSOCIATED WITH HYPERLIPIDEMIA AND HYPERCHOLESTEROLIMIA WHILE MINIMIZING SIZE EFFECTS	Attorney Docket No. AGP-002 Confirmation No. 5393

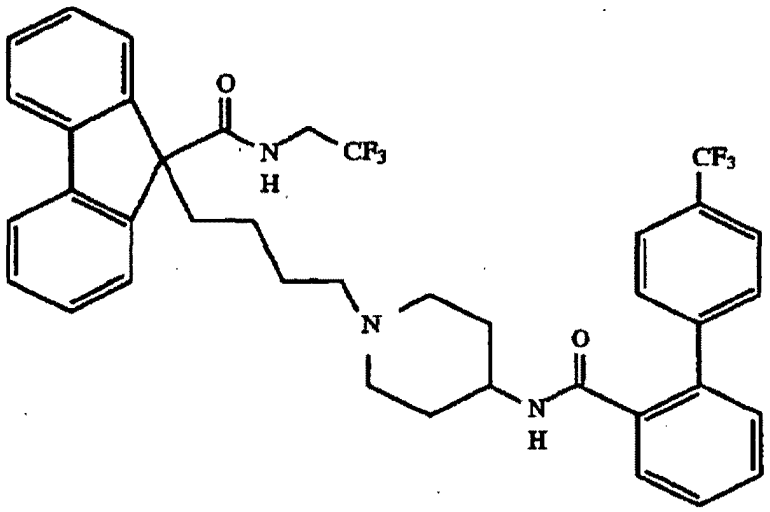
RESPONSE

Dear Sir:

This Response is being filed in response to the outstanding Office Action, mailed October 21, 2009 in connection with the above-identified application, together with a Declaration of William Sasiela, Ph.D., under 37 C.F.R § 1.132. A petition for a Three Month Extension of Time and a Supplemental Information Disclosure Statement accompanies this response. Applicant submits the following remarks:

In the claims:

1. (Currently Amended) A method of treating a subject suffering from ~~a disorder associated with~~ hyperlipidemia ~~and/~~or hypercholesterolemia, the method comprising administering to the subject an effective amount of an MTP inhibitor ~~effective to ameliorate the disorder~~, wherein said administration comprises at least three step-wise, increasing dose levels ~~dosages~~ of the MTP inhibitors wherein a first dose level is from about 2 to about 13 mg/day, a second dose level is from about 5 to about 30mg/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.

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

3. (Currently Amended) 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~~ lipoprotein B are reduced by at least 15%, compared to control levels.

4. (Currently Amended)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~~ lipoprotein B are reduced by at least 25%, compared to control levels.

5. (Canceled)

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

7. (Canceled)

8. (Currently Amended) The method of claim 1 ~~7~~ wherein said increasing dose levels ~~escalating doses~~ further comprise a fourth dose level.

9. (Currently Amended) The method of claim 1 ~~7~~ wherein said increasing dose levels ~~escalating doses~~ further comprise a fourth and a fifth dose level.

10.-15. (Canceled)

16. (Currently Amended) The method of claim 1 wherein said MTP inhibitor is administered to said subject in combination with a further ~~lipid-modifying~~ compound selected from the group consisting of: HMG CoA reductase inhibitors, cholesterol absorption inhibitors, ezetimibe, squalene synthetase inhibitors, fibrates, bile acid sequestrants, statins, probucol, niacin, thiazolidinediones, and cholesterol ester transfer protein (CETP) inhibitors.

17. (Canceled)

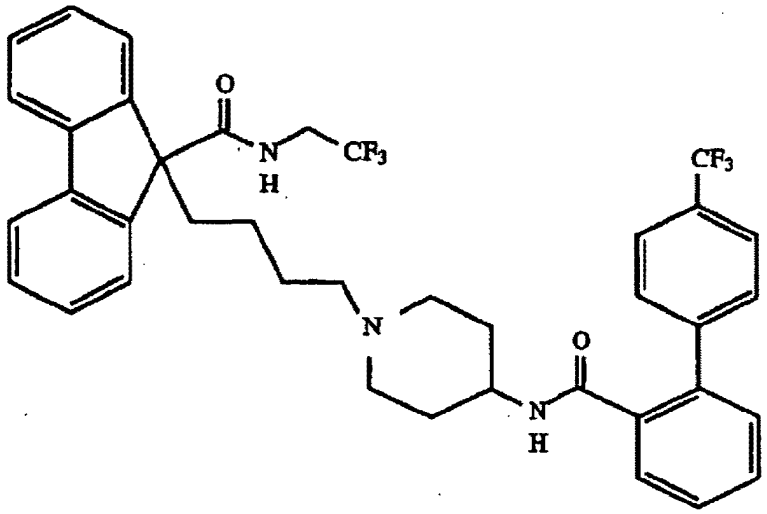
18. (Currently Amended) The method of claim 16 wherein the MTP inhibitor and the further compound ~~lipid-modifying compounds~~ are present in the same dosage unit.

19. -25. (Canceled).

26. (New) The method of claim 1, wherein the increasing dose levels comprise a fourth dose level from about 20 to about 60 mg/day and a fifth dose level from about 30 to about 75mg/day.

27. (New) A method of treating hyperlipidemia or hypercholesterolemia in a subject in need thereof, comprising:

initially administering to the subject a first dose level of about 2 to about 13 mg/day of a compound represented by:



or a pharmaceutically acceptable salt thereof or the piperidine N-oxide thereof, for about 1 week to about 4 weeks,

administering an increasing second and third dose level of the compound for about 1 week to about 4 weeks each, wherein said second and third dose level are no more than 50% of the immediately following dose level.

28. (New) The method of claim 16, wherein the further compound is ezetimibe.

REMARKS

Claims 1-25 are pending. Claims 5, 7, 10-15, 17, and 19-25 have been canceled. Claims 3, 4, 8, 9 and 18 have been amended for clarity. Claim 1 has been amended to recite limitations of original claims 13 and 17, and the MTP inhibitor of original claim 21. Claim 16 has been amended to particularly point out further compounds, as previously recited in original claim 23. No new matter has been added.

Claims 26-28 are new. Support for claim 26 may be found for example, on page 17, paragraph 58 of the instant specification. Support for claim 27 may be found throughout the specification and claims as originally filed, for example, on page 17, paragraph 58; page 18, paragraph 63; page 16, paragraph 53, and page 26, Example 8. Support for claim 28 may be found throughout the specification and claims as originally filed, for example, original claim 16.

Amendment of the originally filed claims, or cancellation of any claims should in no way be construed as an acquiescence, narrowing, or surrender of any subject matter. The amendments are being made not only to point out with particularity and to claim the present invention, but also to expedite prosecution of the present application. Applicant reserves the option to prosecute the originally filed claims further, or similar ones, in the instant or subsequently filed patent applications.

Claim Rejections under 35 U.S.C. § 112, first paragraph

Claim 1, 3-18, 20, 24 and 25 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because "the specification as original filed fails to provide sufficient written bases of any the agents demonstrating wherein possession of the use of the broad terms: a disorder associated with hyperlipidemia and/or hypercholesterolemia and a further lipid modifying agent." Applicant respectfully traverses this rejection.

However, solely to expedite prosecution of this application, claim 1 has been amended to recited a method of treating hyperlipidemia or hypercholestermia, diseases that are well known to those of skill in the art. Further, claim 16 has been amended to recite particular further

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