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 AND RESPONSE TO 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 October 2, 2012, in connection with the above-identified application, together with a terminal disclaimer and a copy of the Declaration of William Sasiela, Ph.D., under 37 C.F.R. § 1.132, which was filed in the parent application, U.S. Application No. 10/591,923. Applicant also submits herewith an Information Disclosure Statement, a form used in lieu of a PTO/SB/08, copies of the references cited thereon, and a petition for a Two Month Extension of Time.

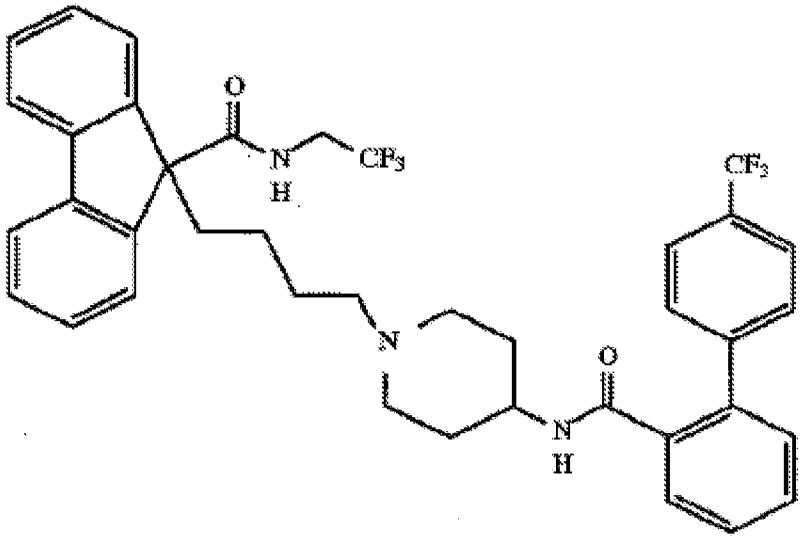
Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 5 of this paper.

AMENDMENTS TO THE CLAIMS

What is claimed is:

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

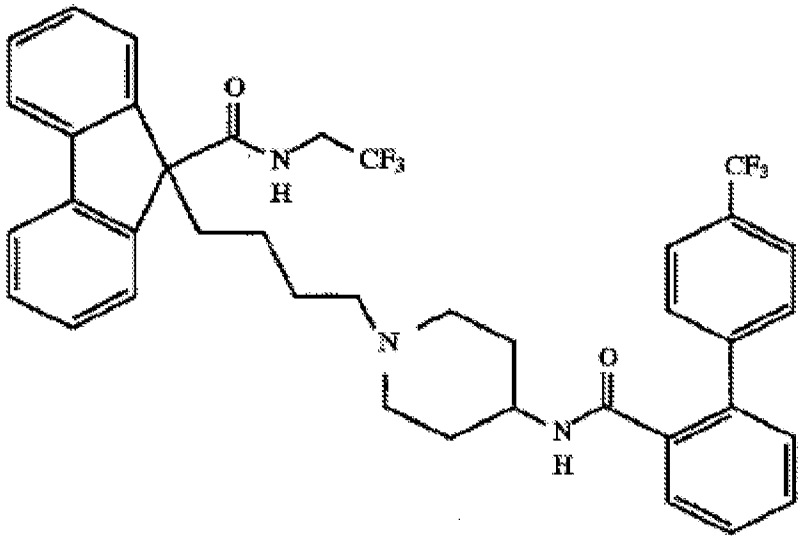
9. (Currently amended) The method of claim 1 [[7]] wherein said increasing dose levels ~~escalating doses~~ further comprise a fourth and a fifth dose level.

10-12. (Cancelled)

13. (Currently amended) The method of claim 9 wherein said ~~first dose level is from about 2 to about 13 mg/day, said second dose level is from about 5 to about 30mg/day, and said third dose level is from about 10 to about 50 mg/day, 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. (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 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.

REMARKS

Claim 1-4, 6, 8, 9, 13, and 26 are pending. Claims 5, 7, 10-12, and 14-25 have been cancelled. Claims 8, 9 and 13 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 5. Further support for the amendments to claim 1 are found throughout the application as filed, including, for example, at paragraphs 56 and 63. New claim 26 has been added. Support for new claim 26 is found throughout the application as filed, including, for example, in original claims 1, 5, 13, and 17 and in paragraphs 56 and 63. No new matter has been added.

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.

Double Patenting

Claims 2-9 and 11-13 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-8 of U.S. Patent No. 7,932,268. Applicant submits herewith a terminal disclaimer over U.S. Patent No. 7,932,268. Applicant respectfully requests the rejection be reconsidered and withdrawn.

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.

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