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 SIDE EFFECTS	Attorney Docket No. AGP-002 Confirmation No. 5393

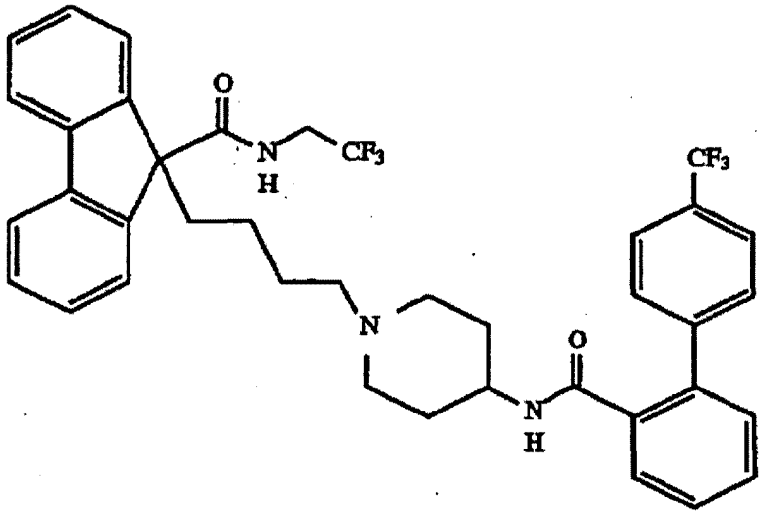
RESPONSE UNDER C.F.R. § 1.116

Dear Sir:

This Response is being filed in response to the outstanding Office Action, mailed July 26, 2010 in connection with the above-identified application. Applicant submits the following remarks:

In the claims:

1. (Previously Presented) A method of treating a subject suffering 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 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. (Previously Presented) The method of claim 1 wherein one or more of Total Cholesterol, LDL, fasting triglycerides (TG), VLDL, lipoprotein (a) (Lp(a)), and-lipoprotein B are reduced by at least 15%, compared to control levels.

4. (Previously Presented) The method of claim 1 wherein one or more of Total Cholesterol, LDL, fasting triglycerides (TG), VLDL, lipoprotein (a) (Lp(a)), and-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. (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.-15. (Canceled)

16. (Previously Presented) The method of claim 1 wherein said MTP inhibitor is administered to said subject in combination with a further 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)

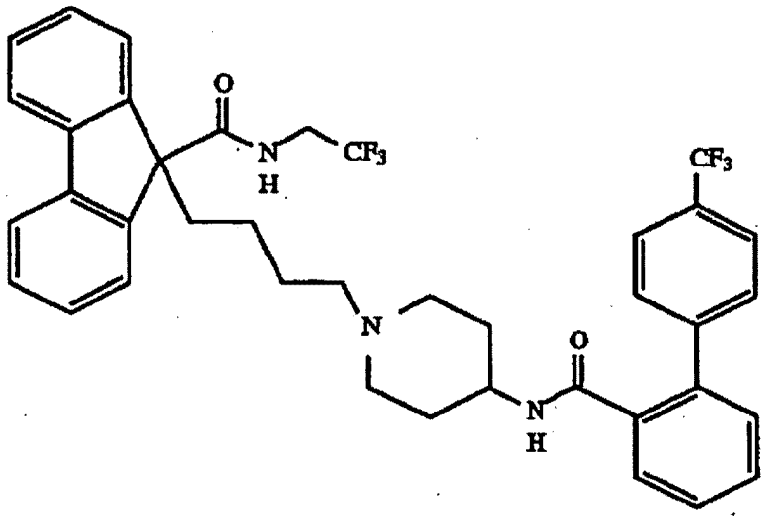
18. (Previously Presented) The method of claim 16 wherein the MTP inhibitor and the further compound are present in the same dosage unit.

19. -25. (Canceled).

26. (Previously Presented) 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. (Previously Presented) 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. (Previously Presented) The method of claim 16, wherein the further compound is ezetimibe.

REMARKS

Claims 1-4, 6, 8, 9, 16, 18, 26-28 are pending.

Applicants note that independent claim 27, which stands rejected as obvious under 35 U.S.C. 103, is directed to a specific method of treating hyperlipidemia or hypercholesterolemia including administering the recited dosages of the claimed MTP inhibitor, and such methods offer surprising and unexpected advantages, as was discussed in the previous response and the previously submitted Declaration of William Sasiela, Ph.D. Because there is no mention of the substantial effort and evidence of this previous submission in the instant Action, such evidence does not appear to be considered by the Office. Applicants therefore respectfully request reconsideration and withdrawal of the final rejection of these claims.

Further, as the Action notes, claim 1 was amended to include some limitations of original claim 13, reciting the specific dosing of three claimed dosage levels. As is clear from the pending claims, the claimed invention is directed in part to the recited dosage levels of claim 1 or claim 27, which does not necessarily include a fifth dose level.

Claim Rejections under 35 U.S.C. § 102

Claims 1-4, 6, 8, 16 and 18 stand rejected under 35 U.S.C. 102(b) as being anticipated by Gregg et al., US 5,883,109. Applicants respectfully disagree with the Office analysis of this rejection on both a legal and factual basis.

Independent claim 1 recites a specific method that includes three step-wise, increasing dose levels 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*. Nowhere in the Gregg et al. reference is there any teaching of such a method. Rather, Gregg et al., for example, teaches oral dose forms containing "5 to about 500 mg, preferably from about 10 to about 400 mg, and more preferably from about 20 to about 250 mg." Gregg et al. col. 23 ll. 17-19. As the Examiner knows, in order to anticipate claims, the claimed subject matter must be disclosed in the reference with "**sufficient specificity** to constitute an anticipation under the statute." M.P.E.P. 2131.03 (emphasis added). Applicant notes that the first dose level in recited in instant claim 1 includes a narrow range that in part falls out of the

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