

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of: Klaus DUGI, et al      Art Unit: 1629  
U.S. Appln. No. 14/161,007      Examiner: K. WEDDINGTON  
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Title of Invention: USES OF DDP-IV INHIBITORS  
Docket No.: 01-2051-US-3

VIA EFS Web  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO FINAL OFFICE ACTION**

Sir:

This paper is responsive to a final office action having a notification date of April 16, 2015 in connection with the above-identified patent application and is being filed concurrently with a request for continued examination. A response to the final office action is initially due three (3) months from the notification date of the office action, that is, by July 16, 2015. Accordingly, this response is timely filed.

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

**Remarks** begin on page 6 of this paper.

**AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions and listings of claims in the application:

**Listing of Claims:**

Claims 1-14 (Cancelled).

15. (Previously presented) A method of treating type 2 diabetes comprising administering to a patient in need thereof 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, or a therapeutically active salt thereof, in an oral dosage of 2.5 mg or 5 mg wherein the dose of metformin is 100 mg to 500 mg or 200 mg to 850 mg (1-3 times a day), or 300 mg to 1000 mg once or twice a day, or as delayed-release metformin in a dose of 500 mg to 1000 mg once or twice a day, or 500 mg to 2000 mg once a day, or wherein the dose of metformin is 500 mg, 850 mg or 1000 mg as a single dose with a total daily dose of metformin of 500-2850 mg, or 500 mg, 1000 mg, 1500 mg or 2000 mg metformin in delayed release form, or wherein the dose of metformin is 500 mg to 1000 mg.

16. (Cancelled)

17. (Previously presented) The method according to claim 15, wherein 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine and metformin are administered orally in the form of a fixed combination.

18. (Previously presented) The method according to claim 17, wherein the fixed combination is a tablet or capsule.

19. (Previously presented) The method according to claim 17, wherein the fixed combination is a tablet.

Claims 20-23. (Cancelled)

24. (Previously presented) The method according to claim 17, wherein the dosage of 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine is 2.5 mg.

25. (Previously presented) The method according to claim 17, wherein the dosage of 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine is 5 mg.

26. (Cancelled)

27. (Previously presented) The method according to claim 17, wherein metformin is provided in a dose of 100 mg to 500 mg or 200 mg to 850 mg (1-3 times a day), or 300 mg to 1000 mg once or twice a day, or as delayed-release metformin in a dose of 500 mg to 1000 mg once or twice a day, or 500 mg to 2000 mg once a day.

28. (Previously presented) The method according to claim 17, wherein the dose of metformin is 500 mg, 850 mg or 1000 mg as a single dose with a total daily dose of metformin of 500-2850 mg, or 500 mg, 1000 mg, 1500 mg or 2000 mg metformin in delayed release form.

29. (Previously presented) The method according to claim 17, wherein the amount of metformin is 500 mg to 1000 mg.

30. (Previously presented) The method according to claim 17, wherein the amount of metformin is 500 mg.

31. (Previously presented) The method according to claim 17, wherein the amount of metformin is 850 mg.

32. (Previously presented) The method according to claim 17, wherein the amount of metformin is 1000 mg.

33. (Cancelled)

34. (Cancelled)

35. (Previously presented) A method of treating type 2 diabetes comprising administering twice daily to a patient in need thereof 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in an oral dosage of 2.5 mg in fixed combination with metformin in an amount of 500 mg to 1000 mg.

36. (Previously presented) An oral tablet formulation comprising 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in an amount of 2.5 mg or 5 mg optionally in combination with metformin, and an pharmaceutically acceptable carrier or diluent.

37. (Previously presented) The oral tablet according to claim 36, containing 500 mg to 1000 mg metformin.

38. (Previously presented) A method of treating type 2 diabetes comprising administering to a patient in need thereof 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in a daily oral amount of 5 mg the form of a fixed combination, wherein metformin is administered in a dose of 100 mg to 500 mg or 200 mg to 850 mg (1-3 times a day), or 300 mg to 1000 mg once or twice a day, or as delayed-release metformin in a dose of 500 mg to 1000 mg once or twice a day, or 500 mg to 2000 mg once a day.

39. (Previously presented) A method of treating type 2 diabetes comprising administering to a patient in need thereof 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in a daily oral amount of 5 mg and metformin, the form of a fixed combination, wherein the dose of metformin is 500 mg, 850 mg or 1000 mg as a single dose with a total daily dose of metformin of 500-2850 mg, or 500 mg, 1000 mg, 1500 mg or 2000 mg metformin in delayed release form.

40. (Previously presented) A method of treating type 2 diabetes comprising administering to a patient in need thereof 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in a daily oral amount of 5 mg and metformin, the form of a fixed combination, wherein the amount of metformin is 500 mg to 1000 mg.

41. (Previously presented) The method according to claim 15, wherein 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine is administered in a daily oral amount of 5 mg.

42. (Previously presented) A method of treating type 2 diabetes comprising administering to a patient in need thereof the oral tablet of claim 36, wherein the daily oral amount of 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine administered to said patient is 5 mg.

43. (New) The method according to claim 24, wherein 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in a dosage of 2.5 mg is administered twice daily.

44. (New) The method according to claim 25, wherein 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in a dosage of 5mg is administered once daily.

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