IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Klaus DUGI, et al	Art Unit:	1629
U.S. Appln. No.	12/946,193	Examiner:	K. WEDDINGTON
U.S. Filing Date:	November 15, 2010	Confirm. No.:	9433
Title of Invention:	USES OF DDP-IV INHIBITORS		
Docket No.:	01-2051-1-C1		

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

RESPONSE UNDER 37 C.F.R. § 1.111

Sir:

This paper is responsive to a nonfinal office action having a notification date of October 29, 2012 in connection with the above-identified patent application. A response to the office action was initially due three (3) months from the notification date of the office action, that is, by January 29, 2013. Accordingly, filed concurrently herewith is a Petition for Extension of Time to extend the time for responding to the office action by three (3) months, such that it expires on April 29, 2013.

PETITION FOR EXTENSION OF TIME

Applicants' agent hereby petitions for a three (3) month extension of time under 37 C.F.R. § 1.136, to extend the time for responding to the October 29, 2012 office action such that expires on April 29, 2012. The fee required under 37 C.F.R. § 1.17(a) in connection with this petition will be paid during electronic filing via the Revenue Accounting and Management System.

Amendments to the Claims:

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

Listing of Claims:

Claims 1-55. (Cancelled).

56. (Previously presented) A method of treating type II diabetes mellitus comprising administering to a patient in need thereof a pharmaceutically effective 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, and a pharmaceutically effective amount of metformin, which is from 300 mg to 1000 mg once or twice a day, or 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.

57. (Previously presented) The method according to claim 56, wherein the pharmaceutically effective 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 is an oral daily dose of from 2.5 mg to 10 mg.

58. (New) The method according to claim 56, wherein the 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 an oral dosage of from 0.5 mg to 50 mg.

59. (New) The method according to claim 56, wherein the 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 an oral dosage of from 2.5 mg to 10 mg.

60. (New) The method according to claim 56, wherein the 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 an oral dosage of 0.5 mg, 1 mg, 2.5 mg, 5 mg or 10 mg.

61. (New) The method according to claim 56, wherein the 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 an oral dosage of 1 mg, 2.5 mg or 5 mg.

62. (New) The method according to claim 56, wherein the 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 an oral dosage of 2.5 mg or 5 mg.

63. (New) The method according to claim 56, wherein the 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 an oral dosage of from 2.5 mg to 50 mg.

64. (New) The method according to claim 56, wherein the 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 an oral daily dose of 5 mg.

65. (New) A method of treating type 2 diabetes or pre-diabetes comprising administering to a patient in need thereof a therapeutically effective oral dose of 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in combination with a therapeutically effective dose of metformin, which is 500 mg, 850 mg or 1000 mg metformin as a single dose with a total daily dose of metformin of 500-2850 mg, or which is 500 mg, 1000 mg, 1500 mg or 2000 mg metformin in delayed release form.

66. (New) The method according to claim 65, wherein the 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 an oral dosage of from 0.5 mg to 50 mg.

67. (New) The method according to claim 65, wherein the 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 an oral dosage of from 2.5 mg to 10 mg.

68. (New) The method according to claim 65, wherein the 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 an oral dosage of 0.5 mg, 1 mg, 2.5 mg, 5 mg or 10 mg.

69. (New) The method according to claim 65, wherein the 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 an oral dosage of 1 mg, 2.5 mg or 5 mg.

70. (New) The method according to claim 65, wherein the 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 an oral dosage of 2.5 mg or 5 mg.

71. (New) The method according to claim 65, wherein the 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 an oral dosage of from 2.5 mg to 50 mg.

72. (New) The method according to claim 65, wherein the 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 an oral daily dose of 5 mg.

73. (New) A method of treating type II diabetes mellitus comprising administering to a patient in need thereof a pharmaceutically effective 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 which is an oral daily dose of from 2.5 mg to 10 mg, and a pharmaceutically effective amount of metformin.

74. (New) A method of treating type II diabetes mellitus comprising administering to a patient in need thereof a pharmaceutically effective 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 which is an oral daily dose of 5 mg, and a pharmaceutically effective amount of metformin.

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