IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Utility Application of:
Andreas Bathe et al.

Application No.: Not Yet Assigned   Confirmation No.: N/A

Filed: Concurrently Herewith   Art Unit: N/A

For: POLYMORPHIC FORMS OF 1-[4-(5-   Examiner: Not Yet Assigned
       CYANOINDOL-3-YL)BUTYL-4-(2-
       CARBAMOYLBENZOFURAN-5-YL)
       PIPERAZINE HYDROCHLORIDE

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT UNDER 37 C.F.R. 1.115

Dear Madam:

Prior to examination on the merits, please amend the above-identified U.S. patent application as follows:

Amendments to the Specification begin at page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins at page 3 of this paper.

Remarks/Arguments begin at page 6 of this paper.

AMENDMENTS TO THE SPECIFICATION

Please insert the following new paragraph after the Title of the invention on page 1, line 3:

RELATED APPLICATIONS

This application is a continuation application of U.S. Patent Application No. 13/658,088, filed on October 23, 2012, which is a continuation of U.S. Patent Application No. 13/085,117, filed April 12, 2011, now U.S. Patent No. 8,318,744, issued November 27, 2012, which is a continuation application of U.S. Patent Application No. 12/566,835, filed September 25, 2009, now U.S. Patent No. 7,981,894, issued July 19, 2011, which is a divisional application of U.S. Patent Application No. 12/110,704, filed April 28, 2008, now U.S. Patent No. 7,834,020, issued November 16, 2010, which is a divisional application of U.S. Patent Application No. 10/481,270, filed December 19, 2003, now U.S. Patent No. 7,381,726, issued June 3, 2008, which is a national phase application of International Application No. PCT/EP2002/006153, filed June 5, 2002, which claims priority to European Patent Application No. 01113647.0, filed June 19, 2001. The entire contents of each of the foregoing applications and patents are hereby incorporated by reference.

AMENDMENTS TO THE CLAIMS

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

Listing of Claims:

1.- 55. **(Cancelled)**

56. **(New)** A compound which is 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride in its crystalline modification, wherein the compound is an anhydrate, hydrate, solvate or dihydrochloride.

57. **(New)** The compound of claim 56, wherein the compound is an anhydrate in crystalline modification III.

58. **(New)** The compound of claim 56, wherein the compound is an anhydrate in crystalline modification VII.

59. **(New)** The compound of claim 56, wherein the compound is a solvate in crystalline modification XI.

60. **(New)** A pharmaceutical composition comprising 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride anhydrate in its crystalline modification IV and one or more hydrated forms of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride.

61. **(New)** A pharmaceutical composition according to claim 60, wherein the composition comprises 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride monohydrate in its crystalline modification Form V.

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62. (**New**) A pharmaceutical composition according to claim 61, wherein Form IV and Form V are in a molar ratio of about 100 to 1 to 10 to 1.

63. (**New**) A pharmaceutical composition according to claim 61 comprising an active ingredient consisting essentially of a mixture of Form IV and Form V.

64. (**New**) A pharmaceutical composition according to claim 63, wherein Form IV and Form V are in a molar ratio of about 100 to 1 to 10 to 1.

65. (**New**) A method of treating a patient suffering from a depressive disorder, an anxiety disorder, a bipolar disorder, mania, dementia, a substance-related disorder, a sexual dysfunction, an eating disorder, obesity, fibromyalgia, a sleeping disorder, a psychiatric disorder, cerebral infarct, tension, side-effects in the treatment of hypertension, a cerebral disorder, chronic pain, acromegaly, hypogonadism, secondary amenorrhea, premenstrual syndrome and undesired puerperal lactation, or combinations thereof, comprising administering to the patient in need thereof the pharmaceutical composition of claim 61.

66. (**New**) A pharmaceutical composition comprising a compound which is 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride anhydrate in its crystalline modification IV, and one or more conventional auxiliary substances and /or carriers.

67. (**New**) A method of treating a patient suffering from a depressive disorder, an anxiety disorder, a bipolar disorder, mania, dementia, a substance-related disorder, a sexual dysfunction, an eating disorder, obesity, fibromyalgia, a sleeping disorder, a psychiatric disorder, cerebral infarct, tension, side-effects in the treatment of hypertension, a cerebral disorder, chronic pain, acromegaly, hypogonadism, secondary amenorrhea, premenstrual syndrome and undesired puerperal lactation, or combinations thereof, comprising administering to the patient in need thereof the pharmaceutical composition of claim 66.

68. **(New)** A method of treating a patient suffering from a depressive disorder, an anxiety disorder, a bipolar disorder, mania, dementia, a substance-related disorder, a sexual dysfunction, an eating disorder, obesity, fibromyalgia, a sleeping disorder, a psychiatric disorder, cerebral infarct, tension, side-effects in the treatment of hypertension, a cerebral disorder, chronic pain, acromegaly, hypogonadism, secondary amenorrhea, premenstrual syndrome and undesired puerperal lactation, or combinations thereof, comprising administering to the patient in need thereof an effective amount of a compound, wherein the compound is 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride monohydrate in its crystalline modification (V).

69. **(New)** A method of treating a patient suffering from a depressive disorder, an anxiety disorder, a bipolar disorder, mania, dementia, a substance-related disorder, a sexual dysfunction, an eating disorder, obesity, fibromyalgia, a sleeping disorder, a psychiatric disorder, cerebral infarct, tension, side-effects in the treatment of hypertension, a cerebral disorder, chronic pain, acromegaly, hypogonadism, secondary amenorrhea, premenstrual syndrome and undesired puerperal lactation, or combinations thereof, comprising administering to the patient in need thereof an effective amount of a compound of claim 56.

70. **(New)** A pharmaceutical composition comprising a compound according to claim 56, and one or more conventional auxiliary substances and/or carriers.

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