34. (currently amended): A method of treating a bipolar disorder ~~selected from the group consisting of bipolar disorder I, bipolar disorder II, bipolar disorder with or without psychotic features, mania, acute mania, bipolar depression and mixed episodes thereof~~ in a patient partially nonresponsive to lithium or valproic acid, divalproex sodium or a salt thereof monotherapy comprising separate administration of a first amount of ~~at least one compound selected from the group consisting of aripiprazole, or a metabolite of aripiprazole selected from the group consisting of dehydroaripiprazole, 2,3 dichloro 4 {4 [4 (2 oxo 1,2,3,4 tetrahydroquinolin 7 yloxy) butyl] piperazin 1 yl} phenyl sulfate (DM 1458), 7 {4 [4 (2,3 dichloro 4 hydroxyphenyl) 1 piperazinyl]butoxy} 3,4 dihydro 2 (1H) quinolinone (DM 1451), 7 {4 [4 (2,3 dichlorophenyl) 1 piperazinyl]butoxy} 3,4 dihydro 4 hydroxy 2 (1H) quinolinone (DM 1452), 1β (2,3 dichloro 4 {4 [4 (2 oxo 1,2,3,4 tetrahydroquinolin 7 yloxy) butyl] piperazin 1 yl} phenoxy) D glucopyaranuronic acid (DM 1454) and 1 (2,3 dichlorophenyl)piperazine (DCPP)~~ and a second amount of ~~at least one mood stabilizer selected from the group consisting of~~ lithium ~~and~~or a salt thereof, wherein the amount of lithium is about 0.01 to about 500 parts by weight and the amount of aripiprazole is about 1 part by weight ~~administration is effective to treat the mood disorder in the patient~~.

35. - 36. (cancelled)

37. (previously presented): The method of claim 35, wherein aripiprazole is anhydrous aripiprazole crystals B.

38. - 40. (cancelled)

41. (currently amended): The method of claim 33, wherein the bipolar disorder is bipolar disorder I.

42. (currently amended): The method of claim 33, wherein the bipolar disorder is mania with bipolar disorder I.

43. (currently amended): The method of claim 34, wherein the bipolar disorder is bipolar disorder II.

44. (currently amended) The method of claim 34, wherein the bipolar disorder is mania with bipolar disorder II.

45. (new): The method of claim 33, wherein the bipolar disorder is mixed episode associated with bipolar disorder I.

46. (new): The method of claim 34, wherein the bipolar disorder is mixed episode associated with bipolar disorder I.

REMARKS

Claims 32, 34 and 41-44 are amended herein. New claims 45-46 are added. Support is found, for example, at page 34, line 26 to the last line and the original claims. No new matter is presented.

Response to Claim Rejections - 35 USC § 112

(1). Claims 33-37 and 41-44 are rejected under 35 U.S.C. §112(b) or 35 U.S.C. §112 second paragraph, as being indefinite.

According to the Examiner, there is no antecedent basis for the recitation of "the mood disorder" in line 15 of claims 33 and 34.

Claims 33 and 34 are amended herein, thereby obviating the rejection. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

(2). Claims 41, and 43 rejected under 35 U.S.C. §112(b) or 35 U.S.C. §112 (pre-AIA), second paragraph, as being indefinite.

According to the Examiner, claims 41 and 43 recite "wherein the bipolar disorder is bipolar disorder" which renders the claims vague and indefinite.

Claims 41 and 43 are amended to recite wherein the bipolar disorder is bipolar disorder I and bipolar disorder II, respectively, thereby obviating the rejection. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Response to Claim Rejections - 35 USC § 103

(1). Claims 33-35, 41-44 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kowatch et al. (CNS Spectrum, April 2003, Vol. 8, No. 4, pp 273-280, PTO-1449), in view of Clinical Trial Report, CN138-00ST (2002) (April 2003 published, PTO-892).

(2). Claim 37 is rejected under 35 U.S.C. §103(a) as being unpatentable over Kowatch et al. (CNS Spectrum, April 2003, Vol. 8, No. 4, pp. 273-280, PTO-1449), in view of Clinical Trial Report, CN138-00ST (2002) (April 2003 published, PTO-892) as applied to claims 33-35, 41-44 above, and further in view of Takuji et al. (WO 03/026659, PTO 1449).

(3). Claim 36 is rejected under 35 U.S.C. §103(a) as being unpatentable over Kowatch et al. (CNS Spectrum, April 2003, Vol. 8, No. 4, pp. 273-280, PTO-1449), in view of Clinical Trial report, CN138-00ST (2002) (April 2003 published, PTO-892) as applied to claims 33-35, 41-44 above, in view of Jordan et al. (US 2002/0173513, PTO-1449).

Kowatch et al. is relied on essentially for the reasons of record. The Examiner recognizes that Kowatch et al. do not explicitly teach a method of treating bipolar disorder, mania employing aripiprazole, and Lithium. The Examiner points out that Kowatch teaches that atypical antipsychotics are efficient in treatment of manic phase of bipolar disorder at page 277, right column, lines 9-12.

To remedy the deficiency of Kowatch et al., the Examiner relies on the Clinical Trial Report, CN138-00ST as teaching that aripiprazole is useful in treating acute mania episode. See April, 2003, Clinical Trial Report, CN138-00ST (2002).

It is the Examiner's position that it would have been obvious to a person of ordinary skill in the art at the time of invention to treat a bipolar disorder, acute mania in a patient partially nonresponsive to lithium therapy by employing a combination of atypical antipsychotic agent, aripiprazole with lithium because Kowatch teaches that addition of an atypical antipsychotic to lithium gives better overall response in the method of treating bipolar disorder i.e., one can treat patients more effectively than monotherapy. The Examiner asserts that it is generally considered *prima facie* obvious to combine compounds each of which is taught by the prior art to be useful

for the same purpose, in order to form a composition which is used for the very same purpose i.e., for treating bipolar disorder, mania. The idea for combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Kowatch et al. and Clinical Trial Report, the instant claims contain two compounds aripiprazole, and lithium used for treating bipolar disorder, mania, manic phase of bipolar disorder. Thus, the Examiner considers that it would have been obvious to administer aripiprazole and lithium with a reasonable expectation of success of treating bipolar disorder in a patient who is partially nonresponsive to monotherapy to treat bipolar disorder, mania, manic phase of bipolar disorder.

The Examiner did not find the arguments presented in the Amendment and evidence filed July 1, 2011 to be persuasive. With respect to the Declaration of Dr. Tsuyoshi Hirose, the Examiner provides the following comments.

1) First, in Table 1, the Locomotor Counts for (Vehicle 1 + lithium chloride + methamphetamine) are (12666.3±1175.9), (See row 5, in Table), whereas the Locomotor Counts for the same combination is (Vehicle 1 + lithium chloride + methamphetamine) are (15142.0±11400.6), (See row 9, in Table). The Examiner asserts that it is not clear how can the same amount of lithium chloride give different Locomotor Counts. Further, the Examiner questions if the Locomotor Counts for (Vehicle 1 + lithium chloride + methamphetamine) (15142.0±11400.6) (See row 9, in Table) is supposed to be (15142.0±1140.6) i.e., ±1140.6 or ±11400.6?

2) Second, in Table 1, for the Olanzapine, lithium chloride group, Locomotor Counts for (Vehicle 1 + lithium chloride + methamphetamine) are (15142.0±11400.6), (See row 9, in Table) which is even higher than the Locomotor Counts for (Vehicle 1 + Vehicle 2 + methamphetamine) which (14368.0±2278.4) i.e., lithium chloride has negative effect, which

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