REMARKS

This is in response to the Official Action of November 23 2005 for the above-captioned application. Claims 1-44 are pending in the application. Claim 1 has been amended as described below.

The Official Action alleges that Claims 1-15 and 19-44 are obvious over Cohen et al. (US 4708834) in view of Bacopoulos (US 5130338), based on the alleged disclosure of Cohen et al. of "a controlled release pharmaceutical unit dosage form comprising a gelatin capsule enclosing a fill, an active agent, a surfactant, a thickener, a co-solvent, and a buffer" in which the liquid fill "can comprise one or more active agents include antidepressant and fatty acids" - Official Action, page 2, last four lines. The Official Action further states that in Cohen et al., the fill "comprises solvent, co-solvent, bulking agent, and one or more dispersing agents" and concludes that "Cohen teaches the use of liquid fill capsule composition for ... [an] antidepressant that exhibits a number of advantageous including ability to uniformly deliver an accurate does of the active ingredient, and controlled release of one or more active compounds in vitro or in vivo" - Official Action, page 3, lines 14-18. While the Official Action acknowledges that Cohen does not teach sertraline as a suitable antidepressant, it alleges that Bacopoulos teaches "administering from about 50-200 mg per day of sertraline in oral dosage forms including capsule (column 2, lines 24-68)". According to the Official Action, it would have been obvious to one of ordinary skill in the art to modify the controlled release composition of Cohen using sertraline as an antidepressant in view of the teachings of Bacopoulos to obtain the claimed invention.

Applicants request that the rejection be withdrawn. The Official Action does not establish a prima facie case of obviousness, since no suggestion or motivation has been established to modify the controlled release composition of Cohen using sertraline as an antidepressant as taught by Bacopoulos. Without such motivation or hint to combine references, no obviousness may be found. See MPEP 2142.

In particular, independent claim 1 has been amended to recite that the vehicle has a sertraline aspartate, acetate or lactate solubility of greater than about 16.7 mgA/ml and a sertraline hydrochloride solubility of greater than about 0.1 mgA/ml. The claimed invention as recited in claim 1 as amended is not disclosed or suggested by Cohen et al., alone or in combination with Bacopoulos. The instant invention is directed to solving a problem that is peculiar to sertraline, i.e., the precipitation of low solubility sertraline salts at intestinal pH [0016]. Cohen et al., which does not teach sertraline as a suitable antidepressant as acknowledged by the Official Action, does not provide any disclosure or suggestion regarding solubility properties, let alone solubility properties with regard to specific salts of the specific drug sertraline, as required by the instant claims as amended. Instead, the purpose of the invention of Cohen et al. is to provide a controlled-release composition (col. 2, lines 1-2), and is therefore directed to an entirely unrelated problem to that solved by the instant invention.

Moreover, Cohen et al. achieves this by a process that includes the step of "gelling said liquid fill with an effective amount of a cationic gelling agent" (col. 2, lines 41-43). Gelling is therefore used to achieve the controlled-release profile of Cohen et al., as also demonstrated, for example, in Example E ("The data summarized in FIG. 2 establish that the gelled matrix of the capsule of Example II is effective for the controlled release of niacin, releasing 60% of the vitamin in about 1.75 hrs and 90% of the vitamin after about 4.5 hours"). In contrast, while not wishing to be bound by theory, it is believed that the formulations of the instant invention may interfere with the chloride-induced gelling of sertraline in vivo (see [0016]). Accordingly, not only does Cohen et al. fail to solve the problem of precipitation of low solubility sertraline salts at intestinal pH, which is solved by providing a vehicle as defined in claim 1 as amended, but the gelling feature that is required by Cohen et al. is undesirable in the instant invention. Cohen therefore teaches away from the invention of Claim 1, and for this additional reason does not render Claim 1 (and claims dependent thereon) obvious, alone or in combination with Bacopoulos, as discussed below.

Similarly, Claim 23 (and claims dependent thereon) is not obvious over Cohen et al. Claim 23 requires the solubility of sertraline in said water-immiscible vehicle to be at least 1.6 mg/ml per mg dose. The claimed invention as recited in claim 23 as amended is not disclosed or suggested by Cohen et al., alone or in combination with Bacopoulos, since Cohen et al. does not provide any disclosure or suggestion regarding solubility properties, let alone solubility properties with regard to the specific drug sertraline, as required by claim 23.

Therefore, one skilled in the art would not find any motivation in Cohen et al. to combine this reference with a reference that teaches sertraline as a suitable antidepressant to obtain the present invention. Bacopoulos does not cure the deficiency of Cohen et al., since Bacopoulos is utterly silent about any release profile of the administration of sertraline or about the problem of precipitation of low solubility sertraline salts at intestinal pH. Therefore, the invention is non-obvious over Cohen et al. in combination with Bacopoulos, and the rejection should therefore be withdrawn.

The Official Action also alleges that Claims 1-44 are obvious over Lacy et al. (US 6096338) in view of Bacopoulos (US 5130338). Lacy et al., like Cohen et al., fails to teach or suggest either the use of sertraline as the antidepressant. The Official Action, analogously to what it previously stated in the context of the rejection over Cohen et al. in combination with Bacoupoulos, alleges that the claimed invention is obvious over Lacy et al. in view of Bacopoulos.

Applicants request that the rejection be withdrawn. Once again, the Official Action does not establish a prima facie case of obviousness, since no suggestion or motivation has been established to modify the controlled release composition of Lacy et al. using sertraline as an antidepressant as taught by Bacopoulos.

As previously discussed, claim 1 has been amended to recite that the vehicle has a sertraline aspartate, acetate or lactate solubility of greater than about 16.7 mgA/ml and a

sertraline hydrochloride solubility of greater than about 0.1 mgA/ml. The claimed invention as recited in claim 1 as amended is not disclosed or suggested by Lacy et al., alone or in combination with Bacopoulos. In particular, as previously discussed, the instant invention is directed to solving a problem that is peculiar to sertraline, i.e., the precipitation of low solubility sertraline salts at intestinal pH [0016]. Lacy et al., which does not teach sertraline as a suitable antidepressant as acknowledged by the Official Action, is instead directed to an entirely unrelated problem, which is to provide a carrier for hydrophobic drugs that includes a digestible oil and a surfactant for dispersing the oil, where the surfactant does not substantially inhibit the in vivo lipolysis of the digestible oil. There is no disclosure or suggestion in Lacy et al. that the digestible oil must have certain solubility properties, let alone solubility properties with regard to specific salts of the specific drug sertraline, as required by the instant claims as amended.

Similarly, Claim 23 (and claims dependent thereon) is not obvious over Lacy et al. Claim 23, as previously discussed, requires the solubility of sertraline in said water-immiscible vehicle to be at least 1.6 mg/ml per mg dose. The claimed invention as recited in claim 23 as amended is not disclosed or suggested by Lacy et al., alone or in combination with Bacopoulos, since Lacy et al. does not provide any disclosure or suggestion regarding solubility properties, let alone solubility properties with regard to the specific drug sertraline, as required by claim 23.

Therefore, one skilled in the art would not find any motivation in Lacy et al. to combine this reference with a reference that teaches sertraline as a suitable antidepressant to obtain the present invention. Bacopoulos does not cure the deficiency of Lacy et al., since Bacopoulos is utterly silent about the problem of the solubility of sertraline. Therefore, the invention is non-obvious over Lacy et al. in combination with Bacopoulos, and the rejection should therefore be withdrawn.

The Official Action further tries to justify both rejections by stating that "where the claimed and prior art products are identical or substantially identical in composition, a prima facie case of either anticipation or obviousness has been made," citing *In re Best*, 562 F2d 1252, 1255. The problem with the Official Action's statements is that, as is easily apparent from a review of *In re Best*, that particular case only discusses 35 USC 102 and 103 rejections over a single reference (referred to as "Hansford" in *In re Best*). Accordingly, while in that particular case, the claimed invention may have been "identical or substantially identical in composition" to the disclosure or suggestion in the single cited reference, that scenario clearly does not apply here, where the claimed invention is allegedly suggested in two or more references (as acknowledged by the Official Action). But such references have to be properly combined before a prima facie case can even be made. For the reasons discussed above, one skilled in the art would not be motivated to combine the composition of Cohen et al. or of Lacy et al. using sertraline as an antidepressant with the teachings of Bacopoulos to obtain the claimed invention. The Official Action's rejections are therefore inappropriate, and their withdrawal is respectfully requested.

In view of the foregoing, allowance of all pending claims in the application is respectfully requested.

Please charge any appropriate fee to cover this submission to Pfizer Deposit Account No. 16-1445. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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