Docket No.: 085199-0034 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Amir SHOJAEI
Application No.: 11/383,066

Filed: May 12, 2006

Customer No.: 20277
Confirmation No.: 7083

Group Art Unit: 1618

Examiner: Micah Paul YOUNG

Title: CONTROLLED DOSE DRUG DELIVERY SYSTEM

AMENDMENT UNDER 37 CFR 1.116

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the final Office Action mailed April 30, 2010. A Request for Continued Examination (RCE) accompanies this response.

Remarks/arguments begin on page 2 of this paper.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Remarks/arguments

Claims 1-5 and 7-32 are pending.

I. Rejection under 35 U.S.C. § 102(b)

Claims 1-5, 7-23, 25, and 26 have been rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,605,300. The Examiner states that the '300 patent discloses a formulation comprising a combination of immediate release and delayed release amphetamine beads. The Examiner contends that the '300 discloses that: "[a] single immediate release bead can be coated with a delayed release bead coating solution and combined with a second delayed release formulation so that the immediate and delayed release portions are present in the same bead and on different beads (Example 4)." Office Action, p. 3.

Applicants respectfully traverse this rejection. The instant claims are directed to a 3-bead pharmaceutical composition comprising (a) an immediate release bead, (b) a first delayed release bead providing pulsed release, and (c) a second delayed release bead providing sustained release. The '300 patent discloses a 2-bead pharmaceutical formulation comprising an immediate release bead and a delayed pulsed release bead. Example 1 of the '300 patent, titled "Immediate Release Formulation," discloses an immediate release amphetamine bead. Examples 2 and 3 of the '300 patent disclose embodiments of a delayed pulsed release bead wherein the immediate release bead of Example 1 was sprayed with enteric coatings. The release profile of the Example 2 bead is shown in Figure 4, which illustrates a delay of 2 hours prior to a nearly complete release of drug within 1 hour, i.e., delayed pulsed release. The release profile of the Example 3 bead is shown in Figure 5, which illustrates a delay of 3 hours prior to a nearly complete release of drug within about 30 minutes, i.e., delayed pulsed release. The '300 patent teaches that the "lag time"

(delay until release begins) of the delayed pulsed release component can be increased by applying a coating of, e.g., SURELEASE, over the enteric coating. See, '300 patent, col. 8, 58 – col. 9, l. 22. Example 4 of the '300 patent exemplifies this teaching by coating the delayed pulsed release beads "from Example 2 *or* from Example 3 (2 kg *of either*)" with SURELEASE. '300 patent, col. 11, l. 60 – col. 12, l. 26 (emphasis added). Example 5 of the '300 patent discloses a pulsatile delivery system "achieved by combining the immediate release pellets [beads] (Example 1) with delayed release pellets (Example 2 *or* Example 3)." '300 patent, col. 12, ll. 28-48 (emphasis added). Thus, the '300 patent discloses a 2-bead composition comprising an immediate release bead and a delayed pulsed release bead. The '300 patent discloses different embodiments of immediate release beads and delayed pulsed release beads, but the only disclosure of combining beads with different release profiles is the 2-bead pulsatile delivery system which includes an immediate release bead and a delayed pulsed bead. There is no disclosure of a 3-bead composition.

In sum, the '300 patent does not disclose a pharmaceutical composition comprising 3 beads (much less a 3-bead composition comprising an immediate release bead, a bead providing delayed pulsed release, and a bead providing sustained release). Thus, this rejection should be withdrawn.

II. Rejection under 35 U.S.C. § 103(a)

Claims 1-5 and 7-32 have been rejected under 35 U.S.C. § 103(a) as obvious over the '300 patent. The Examiner states that: "[t]he general conditions of the claim have been met, namely a pharmaceutical dosage form comprising immediate release and sustained release beads coated with enteric polymers." Office Action p. 5. According to the Examiner, "the instant

claims recite that the enteric polymers are the same. As such the coated beads of the '300 patent would act as the second and third beads, since their only difference is the intended use of a pulse release or a sustained release. Since the coating materials would be the same, the collection of enteric coated controlled release beads found in the '300 patent would meet this limitations [sic]." Office Action, p. 6. Thus, the Examiner contends that an enteric coating may only be used to create a bead with one type of profile. The '300 patent teaches that this profile is delayed pulsed release.

Applicants respectfully traverse this rejection. Even if the '300 patent discloses the instantly claimed first delayed release bead and second delayed release bead (it does not), and the first and second delayed release beads have the same release profile (they do not), the '300 patent does not disclose or suggest a pharmaceutical composition comprising 3-beads. The '300 patent teaches immediate release and delayed pulsed release amphetamine beads. According to the '300 patent, sustained release delivery is not suitable for amphetamines. See, e.g., col. 1, ll. 14-63; col. 4, ll. 29-61. As stated in (I) above, the '300 patent discloses a 2-bead delivery system. There would have been no motivation for one of ordinary skill in the art to include an immediate release bead and two different delayed pulsed release beads in a pharmaceutical delivery system, nor a reasonable expectation that such a composition would work in a pharmaceutical composition according to the instant claims:

> The addition of a second delayed pulsed release formulation, having a lag time of about 8 hours, to ADDERALL XR® cannot, as one might expect, meet the recognized need for a once-daily long-acting amphetamine composition .... A delayed pulsed formulation having a lag time of about 8 hours would be unsuitable because it would release the active agent in the distal gastrointestinal tract (the colon), resulting in decreased absorption of the active agent.

Instant specification, para. 22.

Thus, the '300 patent does not disclose or suggest the claimed 3-bead amphetamine pharmaceutical composition. For the reasons stated above, this rejection should be withdrawn.

Conclusion

This application is believed to be in condition for allowance. If any issues remain which may be addressed by an Examiner's amendment of or a supplemental amendment, the Examiner is respectfully requested to contact the undersigned.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP

Paul M. Zagar
Registration No. 52,392

600 13th Street, N.W.
Washington, DC 20005-3096
Phone: 212.547.5400 PMZ:MWE
Facsimile: 202.756.8087
Date: July 28, 2010

Please recognize our Customer No. 20277 as our correspondence address.