(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 July 2003 (24.07.2003)

PCT

(10) International Publication Number
WO 03/059349 A1

(51) International Patent Classification[7]: A61K 31/437, 9/16, 47/14, 47/44, 9/00, A61P 25/20

(21) International Application Number: PCT/IE03/00001

(22) International Filing Date: 9 January 2003 (09.01.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/346,613 10 January 2002 (10.01.2002) US

(71) Applicant *(for all designated States except US)*: **BIOVAIL LABORATORIES INC.** [BB/BB]; Chlston Park, Building 1, Ground Floor, Collymore Rock, St. Michael (BB).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **O'TOOLE, Edel** [IE/IE]; 70 Philipsburgh Terrace, Marino, Dublin 3 (IE). **FOGARTY, Siobhan** [IE/IE]; 88 Temple Road, Blackrock, County Dublin (IE).

(74) Agents: **LANE, Cathal, Michael** et al.; Tomkins & Co., 5 Dartmouth Road, Dublin 6 (IE).

(81) Designated States *(national)*: AE, AG, AL, AM, AT (utility model), AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ (utility model), CZ, DE (utility model), DE, DK (utility model), DK, DM, DZ, EC, EE (utility model), EE, ES, FI (utility model), FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK (utility model), SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 03/059349 A1

(54) Title: SEDATIVE NON-BENZODIAZEPINE FORMULATIONS

(57) Abstract: The invention provides for an enhanced absorption pharmaceutical composition comprising a plurality of microparticles, each microparticle comprising at least one sedative non-benzodiazepine, at least one spheronization aid and at least one solubility enhancer. The microparticles of the invention are further incorporated into an oral fast-dispersing dosage form.