

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
15 September 2005 (15.09.2005)

PCT

(10) International Publication Number
WO 2005/084640 A1

- (51) International Patent Classification⁷: **A61K 9/12**, 31/4704, A61M 15/00, B65D 83/14
- (21) International Application Number: PCT/EP2005/002042
- (22) International Filing Date: 25 February 2005 (25.02.2005)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/547,798 27 February 2004 (27.02.2004) US
04011424.1 13 May 2004 (13.05.2004) EP
- (71) Applicant (for all designated States except US): **CHIESI FARMACEUTICI S.p.A.** [IT/IT]; Via Palermo 26/A, I-43100 Parma (IT).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **LEWIS, David** [GB/IT]; c/o Chiesi Farmaceutici S.p.A., Via Palermo 26/A, I-43100 Parma (IT). **GANDERTON, David** [GB/IT]; c/o Chiesi Farmaceutici S.p.A., Via Palermo 26/A, I-43100 Parma (IT). **MEAKIN, Brian** [GB/IT]; c/o Chiesi Farmaceutici S.p.A., Via Palermo 26/A, I-43100 Parma (IT). **DELCANALE, Maurizio** [IT/IT]; c/o Chiesi Farmaceutici S.p.A., Via Palermo 26/A, I-43100 Parma (IT). **PIVETTI, Fausto** [IT/IT]; c/o Chiesi Farmaceutici S.p.A., Via Palermo 26/A, I-43100 Parma (IT).
- (74) Agent: **ADAM, Holger**; KRAUS & WEISERT, Thomas-Wimmer-Ring 15, 85039 München (DE).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, 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, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (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.*

(54) Title: STABLE PHARMACEUTICAL SOLUTION FORMULATIONS FOR PRESSURIZED METERED DOSE INHALERS

(57) Abstract: Aerosol solution formulations for use in an aerosol inhaler which comprise 8-hydroxy-5-[(1R)-1-hydroxy-2-[[[(1R)-2-(4-methoxyphenyl)-1-methylethyl]amino] ethyl]-2(1H)-quinolinone or a salt thereof, in particular the hydrochloride salt (TA 2005), as an active ingredient, a propellant containing a hydrofluoroalkane, and a cosolvent, stabilized by addition of a specific small amount of a high concentrated phosphoric acid and optionally by the use of a suitable can having part or all of its internal metallic surfaces lined with an inert organic coating.



WO 2005/084640 A1