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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
28 August 2008 (28.08.2008)

PCT

(10) International Publication Number
WO 2008/102264 A3

(51) International Patent Classification:
A61K 9/16 (2006.01) *A61K 9/50* (2006.01)
A61K 9/48 (2006.01)

(21) International Application Number:
PCT/IB2008/000770

(22) International Filing Date:
20 February 2008 (20.02.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/902,091	20 February 2007 (20.02.2007)	US
60/902,092	20 February 2007 (20.02.2007)	US
60/902,093	20 February 2007 (20.02.2007)	US

(71) Applicant *(for all designated States except US)*: **EURAND PHARMACEUTICALS LIMITED** [IE/IE]; The Yard House, Killruddery Estate, Southern Cross Road, County Wicklow (IE).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **ORTENZI, Giovanni** [IT/IT]; Via Tiziano Vecellio 6, I-20052 Monza (IT). **MARCONI, Marco** [IT/IT]; Via Abramo Lincoln 22, I-20092 Cinisello Balsamo (IT). **MAPELLI, Luigi** [IT/IT]; Via Bettino da Trezzo 14, I-20125 Milano (IT).

(74) Agents: **KREMER, Simon** et al.; Mewburn Ellis LLP, 33 Gutter Lane, London EC2V 8AS (GB).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, 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, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:
— *of inventorship (Rule 4.17(iv))*

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*

(88) Date of publication of the international search report:
23 July 2009

(15) Information about Correction:
Previous Correction:
see Notice of 16 October 2008

(54) Title: STABLE DIGESTIVE ENZYME COMPOSITIONS

(57) Abstract: Compositions of the present invention, comprising at least one digestive enzyme (e.g., pancrelipase) are useful for treating or preventing disorders associated with digestive enzyme deficiencies. The compositions of the present invention can comprise a plurality of coated particles, each of which is comprised of a core coated with an enteric coating comprising at least one enteric polymer and 4-10% of at least one alkalinizing agent, or have moisture contents of about 3% or less, water activities of about 0.6 or less, or exhibit a loss of activity of no more than about 15% after six months of accelerated stability testing.

WO 2008/102264 A3