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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 December 2006 (21.12.2006)

PCT

(10) International Publication Number
WO 2006/133835 A3

(51) International Patent Classification:
A61K 9/16 (2006.01) *A61K 31/4439* (2006.01)

(21) International Application Number:
PCT/EP2006/005423

(22) International Filing Date: 7 June 2006 (07.06.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/151,459 14 June 2005 (14.06.2005) US

(71) Applicants *(for all designated States except US)*: **BAXTER INTERNATIONAL INC.** [US/US]; One Baxter Parkway, Deerfield, IL 60015 (US). **BAXTER HEALTHCARE S.A.** [CH/CH]; Hertistrasse 2, CH-8304 Wallisellen (CH).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **ROESSLER, Berthold** [DE/DE]; Kluskamp 3, 33790 Halle (DE). **RAAB, Gerhard** [DE/DE]; Birkenstrasse 76a, 63549 Ronneburg (DE). **REISSMANN, Thomas** [DE/DE]; Massbornstrasse 44, 60437 Frankfurt am Main (DE).

(74) Agent: **HOCK, Joachim**; Müller-Boré & Partner, Grafinger Strasse 2, 81671 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, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, 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.

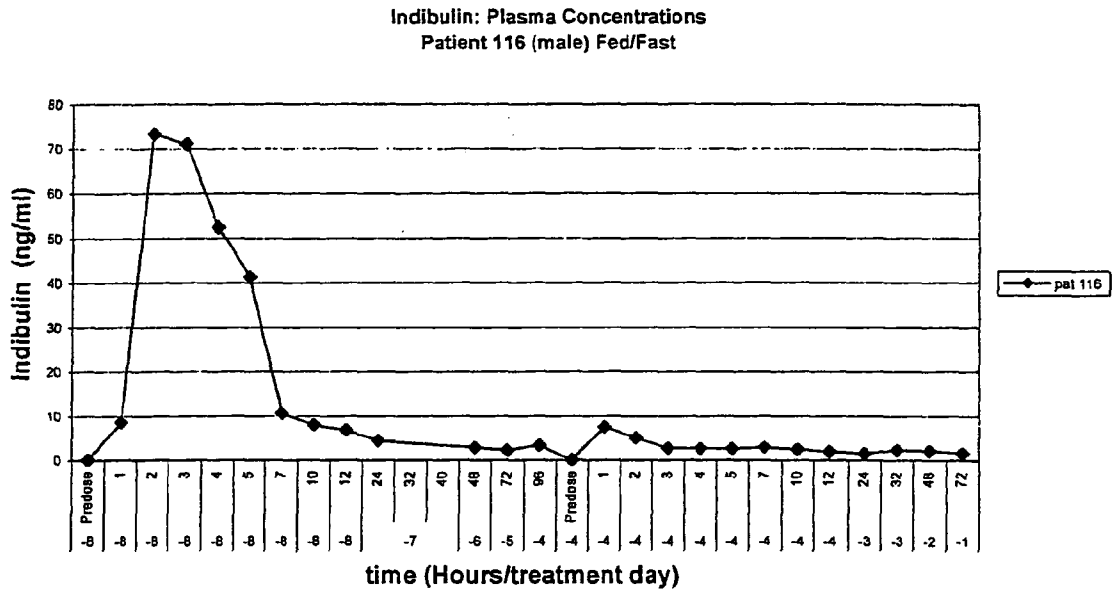
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, 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*

(88) Date of publication of the international search report:
19 July 2007

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: ORAL SOLID PHARMACEUTICAL FORMULATION OF THE TRIBULIN INHIBITOR INDIBULIN



(57) Abstract: The present invention relates to a pharmaceutical formulation for oral administration of the poorly soluble and therefore hardly bioavailable tubulin inhibitor Indibulin and a process for its manufacture. In particular, there is provided a pharmaceutical formulation of Indibulin for oral administration comprising a granulate containing micronized Indibulin having a particle size of less than 20 µm for at least 99 vol.-% of the particles, at least one hydrophilic surfactant, and one or more capsulation excipients.

WO 2006/133835 A3