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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
16 July 2015 (16.07.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/104311 A1

(51) **International Patent Classification**:
A61K 9/00 (2006.01) *A61K 47/10* (2006.01)
A61K 9/08 (2006.01) *A61K 38/28* (2006.01)
A61K 47/02 (2006.01) *A61P 3/10* (2006.01)

(21) **International Application Number**:
PCT/EP2015/050217

(22) **International Filing Date**:
8 January 2015 (08.01.2015)

(25) **Filing Language**: English

(26) **Publication Language**: English

(30) **Priority Data**:
14305024.3 9 January 2014 (09.01.2014) EP
61/925,484 9 January 2014 (09.01.2014) US

(71) **Applicant**: **SANOFI** [FR/FR]; 54 rue La Boétie, F-75008 Paris (FR).

(72) **Inventors**: **BLEY, Oliver**; c/o Sanofi-Aventis Deutschland GmbH, 65926 Frankfurt am Main (DE). **LOOS, Petra**; c/o Sanofi-Aventis Deutschland GmbH, 65926 Frankfurt am Main (DE). **BIDLINGMAIER, Bernd**; c/o Sanofi-Aventis Deutschland GmbH, 65926 Frankfurt am Main (DE). **KAMM, Walter**; c/o Sanofi-Aventis Deutschland GmbH, 65926 Frankfurt am Main (DE). **BERCHTOLD, Harald**; c/o Sanofi-Aventis Deutschland GmbH, 65926 Frankfurt am Main (DE).

(74) **Agent**: **TIMMERBEIL, Björn**; c/o Sanofi-Aventis Deutschland GmbH, Global Intellectual Property Department, Industriepark Höchst, Geb. K 703, 65926 Frankfurt am Main (DE).

(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, BN, BR, BW, BY, BZ, CA, CH, CL, 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, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, 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, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

WO 2015/104311 A1

(54) **Title**: STABILIZED GLYCEROL FREE PHARMACEUTICAL FORMULATIONS OF INSULIN ANALOGUES AND/OR INSULIN DERIVATIVES

(57) **Abstract**: Stabilized pharmaceutical formulations of insulin analogues and/ or insulin derivatives are disclosed. In particular, the application is directed to a pharmaceutical formulation comprising (a), at least one analogue and/or derivative of insulin; and (b). Zn(ll); and (c). optionally protamine; wherein the pharmaceutical formulation is free of glycerol.