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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
26 November 2015 (26.11.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/177057 A1

(51) International Patent Classification:
A61K 9/00 (2006.01) *A61K 9/19* (2006.01)
A61K 47/10 (2006.01) *C07K 16/24* (2006.01)
A61K 47/26 (2006.01)

(21) International Application Number:
PCT/EP2015/060816

(22) International Filing Date:
15 May 2015 (15.05.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
14169753.2 23 May 2014 (23.05.2014) EP

(71) Applicant: **ARES TRADING S.A.** [CH/CH]; Zone Industrielle de l'Ouriettaz, CH-1170 Aubonne (CH).

(72) Inventors: **RINALDI, Gianluca**; Via Silvestrini 9, I-00015 Monterotondo RM (IT). **FRATARCANGELI, Silvia**; C.so Risorgimento 3, I-03024 Ceprano FR (IT). **DEL RIO, Alessandra**; Via Ildebrando Vivanti 108, I-00144 Roma RM (IT).

(74) Agents: **HOLMES, Michael Anthony** et al.; HGF Limited, 4th Floor, Merchant Exchange, 17-19 Whitworth Street West, Manchester M1 5WG (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, 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 2015/177057 A1

(54) Title: LIQUID PHARMACEUTICAL COMPOSITION

(57) Abstract: The present invention relates to novel liquid pharmaceutical compositions of adalimumab, which include adalimumab or a biosimilar thereof, an acetate buffering agent/system such as sodium acetate/acetic acid, and a sugar stabiliser such as trehalose. Such a combination of components furnishes formulations having a stability (e.g. on storage and when exposed to stress) which is comparable to or an improvement upon those known in the art, and with fewer ingredients. Such advances will help adalimumab treatments to become more widely available at lower cost, and prolong the viability of pre-loaded delivery devices (e.g. pre-filled syringes) to reduce unnecessary waste of the drug.