



(51) International Patent Classification:

A61K 39/395 (2006.01) A61K 47/26 (2006.01)
A61K 9/00 (2006.01) C07K 16/28 (2006.01)
A61K 47/18 (2006.01)

(21) International Application Number:

PCT/EP2015/070091

(22) International Filing Date:

2 September 2015 (02.09.2015)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/045,338 3 September 2014 (03.09.2014) US

(71) Applicant: **MEDIMMUNE LIMITED** [GB/GB]; Milstein Building, Granta Park, Cambridge, Cambridgeshire CB21 6GH (GB).

(72) Inventors: **ERIKSSON, Per-Olof**; c/o AstraZeneca R&D Lund, SE-221 87 Lund (SE). **VON WACHENFELDT, Karin**; c/o AstraZeneca R&D Lund, SE-221 87 Lund (SE). **COHEN, Suzanne**; c/o MedImmune Limited, Granta Park, Cambridge, Cambridgeshire CB21 6GH (GB). **DOBSON, Claire**; c/o MedImmune Limited, Granta Park, Cambridge, Cambridgeshire CB21 6GH (GB). **LANE, Deborah**; c/o MedImmune Limited, Granta Park, Cambridge, Cambridgeshire CB21 6GH (GB). **DAY, Katrina**; c/o MedImmune Limited, Granta Park, Cambridge, Cambridgeshire CB21 6GH (GB).

(74) Agent: **TTOFI, Evangelia**; Milstein Building, Granta Park, Cambridge, Cambridgeshire CB21 6GH (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.

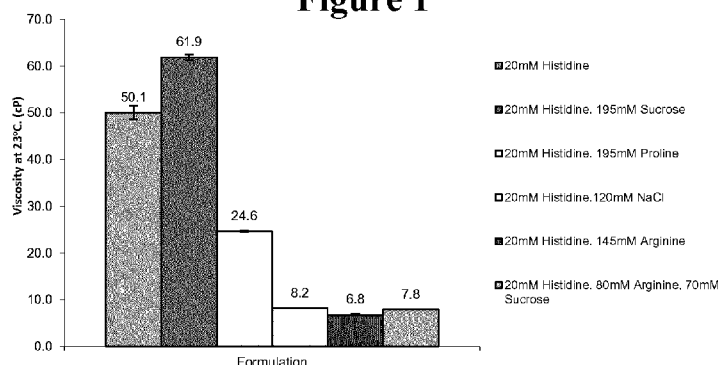
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU,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

Published:

- with international search report (Art. 21(3))
- with sequence listing part of description (Rule 5.2(a))

(54) Title: STABLE ANTI-IL-4R-ALPHA ANTIBODY FORMULATION

Figure 1



(57) **Abstract:** The present invention relates to a stable, low viscosity antibody formulation, wherein the formulation comprises a high concentration of anti-IL4R antibody. In some embodiments, the invention relates in general to a stable antibody formulation comprising about 100 mg/mL to about 200 mg/mL of an antibody or fragment thereof that specifically binds human interleukin-4 receptor alpha (hIL-4R α), about 50 mM to about 400 mM of a viscosity modifier; about 0.002% to about 0.2% of a non-ionic surfactant; and a formulation buffer. In some embodiments, the formulation buffer is essentially free of phosphate. In some embodiments, the invention is directed to a container, dosage form and/or kit. In some embodiments, the invention is directed to a method of making and using the stable antibody formulation.