FORM 3

THE PATENT ACT, 1970
(39 of 1970)
and
THE PATENTS RULES,2003

STATEMENT AND UNDERTAKING UNDER SECTION 8

(See section 8; rule 12)

1. Name, address and nationality of the applicant(s).	We, SANOFI Nationality : FRANCE 54 RUE LA BOETIE PARIS 75008 FRANCE
	..... hereby declare:
	~~(i) that we have not made any application for the same/ substantially the same invention outside India~~ or (ii) that we who have made this application No 201917004058 dated 01 February 2019 , made for the same/substantially same invention, application(s) for patent in the other countries, the particulars of which are given below :

Inventor:	Applicant:	CPC:	IPC:	Publication info:	Priority date:
D·弗朗西斯, A·优素福, (+2)	赛诺菲	A61K39/395 A61K39/3955 A61K39/39591 (+14)	A61K39/395 A61K47/12 A61K47/18 (+6)	CN115998858 (A) 2023-04-25 ??????	2016-07-05
8. ANTIBODY FORMULATIONS					
Inventor:	**Applicant:**	**CPC:**	**IPC:**	**Publication info:**	**Priority date:**
ドニー・フランシス, アーメッド・ユーセフ, (+2)	サノフイＳＡ ＮＯＦＩ	A61K39/395 A61K39/3955 A61K39/39591 (+14)	A61K39/395 A61K47/12 A61K47/18 (+6)	JP2019520390 (A) 2019-07-18 JP7028855 (B2) 2022-03-02 ??????	2016-07-05
9. ANTIBODY FORMULATIONS					
Inventor:	**Applicant:**	**CPC:**	**IPC:**	**Publication info:**	**Priority date:**
FRANCIS DONNY YOUSSEF AHMED (+2)	SANOFI SA [FR]	A61K39/395 A61K39/3955 A61K39/39591 (+14)	A61K39/00 A61K39/395 A61K47/14 (+8)	KR20190027375 (A) 2019-03-14 KR102450280 (B1) 2022-10-04 ??????	2016-07-05
10. ANTIBODY FORMULATIONS					
Inventor:	**Applicant:**	**CPC:**	**IPC:**	**Publication info:**	**Priority date:**
FRANCIS DONNY YOUSSEF AHMED (+2)	SANOFI SA [FR]	A61K39/395 A61K39/3955 A61K39/39591 (+14)	A61K39/395 A61K47/12 A61K47/18 (+5)	KR20220137159 (A) 2022-10-11 ??????	2016-07-05
11. ANTIBODY FORMULATIONS.					
Inventor:	**Applicant:**	**CPC:**	**IPC:**	**Publication info:**	**Priority date:**
DONNY FRANCIS [DE] AHMED YOUSSEF (+2)	SANOFI SA [FR]	A61K39/395 A61K39/3955 A61K39/39591 (+14)	A61K39/395 C07K16/28	MX2019000177 (A) 2019-06-20	2016-07-05
12. ANTIBODY FORMULATIONS					
Inventor:	**Applicant:**	**CPC:**	**IPC:**	**Publication info:**	**Priority date:**
ФРАНЦИС, Донни, ЮССЕФ, Ахмед, (+2)	САНОФИ	A61K39/395 A61K39/3955 A61K39/39591 (+14)	A61K39/395	RU2019102943 (A) 2020-08-05 RU2019102943 (A3) 2020-11-11 RU2769326 (C2) 2022-03-30	2016-07-05
13. ANTIBODY FORMULATIONS					
Inventor:	**Applicant:**	**CPC:**	**IPC:**	**Publication info:**	**Priority date:**
FRANCIS DONNY [DE] YOUSSEF AHMED [DE] (+2)	SANOFI SA [FR]	A61K39/395 A61K39/3955 A61K39/39591 (+14)	A61K39/395 C07K16/28	SG11201900043T (A) 2019-02-27	2016-07-05
14. Antibody formulations					

Inventor: FRANCIS DONNY [DE] YOUSSEF AHMED [DE] (+2)	**Applicant:** SANOFI SA [FR]	**CPC:** A61K39/39591 C07K16/2866 C07K2317/24 (+1)	**IPC:** A61K39/395 A61K47/12 A61K47/18 (+1)	**Publication info:** TW201806618 (A) 2018-03-01 TWI760345 (B) 2022-04-11	**Priority date:** 2016-07-05
15. ANTIBODY FORMULATIONS					
Inventor: FRANCIS DONNY [DE] YOUSSEF AHMED [DE] (+2)	**Applicant:** SANOFI SA [FR]	**CPC:** A61K39/395 A61K39/3955 A61K39/39591 (+14)	**IPC:** A61K39/395 A61K47/12 A61K47/18 (+4)	**Publication info:** US2019255173 (A1) 2019-08-22 US11207407 (B2) 2021-12-28 ??????	**Priority date:** 2016-07-05
16. ANTIBODY FORMULATIONS					
Inventor: FRANCIS DONNY [DE] YOUSSEF AHMED [DE] (+2)	**Applicant:** SANOFI SA [FR]	**CPC:** A61K39/395 A61K39/3955 A61K39/39591 (+14)	**IPC:** A61K39/395 A61K47/12 A61K47/18 (+5)	**Publication info:** US2022111048 (A1) 2022-04-14 ??????	**Priority date:** 2016-07-05
17. ANTIBODY FORMULATIONS					
Inventor: FRANCIS DONNY [DE] YOUSSEF AHMED [DE] (+2)	**Applicant:** SANOFI SA [FR]	**CPC:** A61K39/39591 C07K16/2866 C07K2317/24 (+1)	**IPC:** A61K39/395 C07K16/28	**Publication info:** WO2018007456 (A1) 2018-01-11 ??????	**Priority date:** 2016-07-05

(iii) that the rights in the application(s) has/have been assigned to us

(iv) that we undertake that upto the date of grant of the patent by the Controller, I/We would keep him informed in writing the details regarding corresponding applications for patents filed outside India within six months from the date of filing of such application.

Dated this 4th May, 2023

2. To be signed by the applicant or his authorized registered patent agent

3. Name of the natural person who has signed

(RUPSA GUPTA)
OF D. P. AHUJA & CO
APPLICANT'S AGENT
Regn. No. IN/PA-1613
Email: patents@dpahuja.in
Mobile Phone Number : +919831360050

To
The Controller of Patents,
The Patent Office,
DELHI

WE CLAIM :

~~1. An antibody formulation suitable for subcutaneous administration to a patient, the formulation comprising:~~

~~a) about 50 to about 250 mg/mL of an anti-CXCR5 antibody or a fragment thereof;~~

~~b) a citrate buffer;~~

~~c) greater than about 0.01% (w/v) surfactant;~~

~~d) greater than about 50 mM amino acid; and~~

~~e) greater than about 1% sucrose,~~

~~wherein the pH of the formulation is about pH 6.~~

~~2. The antibody formulation of claim 1, wherein the anti-CXCR5 antibody or a fragment thereof comprises:~~

~~(a) a light chain variable domain comprising the amino acid sequence of SEQ ID NO: 11, and a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO: 12;~~

~~(b) the amino acid sequences of RSSKSLLHSSGKTYLY (SEQ ID NO: 58), RMSNLAS (SEQ ID NO: 59), MQHLEYPYT (SEQ ID NO: 60), GFSLIDYGVN (SEQ ID NO: 61), VIWGDGTTY (SEQ ID NO: 62), and IVY (SEQ ID NO: 63);~~

~~(c) a light chain variable domain comprising the amino acid sequence of SEQ ID NO: 13, SEQ ID NO: 14, or SEQ ID NO: 15, and a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO: 16;~~

~~(d) the amino acid sequences of RSSKSLLHSSGKTYLY (SEQ ID NO: 58), RLSNLAS (SEQ ID NO: 64), MQHLEYPYT (SEQ ID NO: 60), GFSLIDYGVN (SEQ ID NO: 61), VIWGDGTTY (SEQ ID NO: 62), and IVY (SEQ ID NO: 63);~~

~~(e) the amino acid sequences of RSSKSLLHSSGKTYLY (SEQ ID NO: 58), RLSSNLAS (SEQ ID NO: 65), MQHLEYPYT (SEQ ID NO: 60), GFSLIDYGVN (SEQ ID NO: 61), VIWGDGTTY (SEQ ID NO: 62), and IVY (SEQ ID NO: 63);~~

~~(f) a variable light chain (VL) comprising the amino acid sequence of SEQ ID NO: 17, SEQ ID NO: 19, or SEQ ID NO: 21, and a variable heavy chain (VH) comprising the amino acid sequence of SEQ ID NO: 23;~~

~~(g) a variable light chain comprising the amino acid sequence of SEQ ID NO: 30, SEQ ID NO: 31, or SEQ ID NO: 32, and a variable heavy chain comprising the amino acid sequence of SEQ ID NO: 33 or SEQ ID NO: 34;~~

~~(h) the amino acid sequences of RSSKSLLHSSGKTYLY (SEQ ID NO: 58), RMSNLA (SEQ ID NO: 66), MQHLEYPYT (SEQ ID NO: 60), GFSLIDYGVN (SEQ ID NO: 61), VIWGDGTTY (SEQ ID N: 62), and IVY (SEQ ID NO: 63);~~

~~(i) the amino acid sequences of RSSKSLLHSSGKTYLY (SEQ ID NO: 58), RLSNLA (SEQ ID NO: 67), MQHLEYPYT (SEQ ID NO: 60), GFSLIDYGVN (SEQ ID NO: 61), VIWGDGTTY (SEQ ID NO: 62), and IVY (SEQ ID NO: 63);~~

~~(j) the amino acid sequences of RSSKSLLHSSGKTYLY (SEQ ID NO: 58), RLSSLA (SEQ ID NO: 68), MQHLEYPYT (SEQ ID NO: 60), GFSLIDYGVN (SEQ ID NO: 61), VIWGDGTTY (SEQ ID NO: 62), and IVY (SEQ ID NO: 63);~~

~~(k) a variable light chain comprising the amino acid sequence of SEQ ID NO: 35, and a variable heavy chain comprising the amino acid sequence of SEQ ID NO: 37;~~

~~(l) a variable light chain comprising the amino acid sequence of SEQ ID NO: 39, SEQ ID NO: 41, or SEQ ID NO: 43, and a variable heavy chain comprising the amino acid sequence of SEQ ID NO: 45 or SEQ ID NO: 47;~~

~~(m) a variable light chain comprising the amino acid sequence of SEQ ID NO: 55, and a variable heavy chain comprising the amino acid sequence of SEQ ID NO: 56 or SEQ ID NO: 57; or~~

~~(n) the amino acid sequences of RSSKSLLHSSGKTYLYW (SEQ ID NO: 69), RMSNLA (SEQ ID NO: 66), MQHLEYPYT (SEQ ID NO: 60), GFSLIDYGVN (SEQ ID NO: 61), VIWGDGTTY (SEQ ID NO: 62), and IVY (SEQ ID NO: 63).~~

~~3. The antibody formulation of claim 1, wherein the amino acid is arginine or methionine.~~

~~4. The antibody formulation of claim 1, wherein the surfactant is a polysorbate.~~

~~5~~1. An antibody formulation suitable for subcutaneous administration to a patient, the formulation comprising:

a) about 100 to about 175 mg/mL of an antibody;

b) about 10 mM citrate buffer;

c) about 0.1% (w/v) surfactant;

d) about 200 mM arginine; and

e) about 4.5 to 9% sucrose,

wherein the pH of the formulation is about pH 6, wherein the antibody is a fully human anti-CXCR5 antibody, and wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 33 and a light chain comprising the amino acid sequence of SEQ ID NO: 32.

~~6. The antibody formulation of claim 5, wherein the antibody is a fully human anti-CXCR5 antibody.~~

~~7. The antibody formulation of claim 6, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 33 and a light chain comprising the amino acid sequence of SEQ ID NO: 32.~~

~~8~~2. The antibody formulation ~~of~~ as claimed in claim ~~5~~1, wherein the antibody comprises a single chain Fv.

~~9~~3. The antibody formulation ~~of~~ as claimed in claim ~~5~~1, wherein the antibody is an isolated antibody or an antigen-binding fragment thereof that specifically binds to the extracellular domain of human CXCR5.

~~104~~. The antibody formulation ~~of~~ as claimed in claim ~~93~~, wherein the isolated antibody or the antigen-binding fragment thereof comprises the amino acid sequences of RSSKSLLHSSGKTYLY (SEQ ID NO: 58), RLSSLA (SEQ ID NO: 68), MQHLEYPYT (SEQ ID NO: 60), GFSLIDYGVN (SEQ ID NO: 61), VIWGDGTTY (SEQ ID NO: 62), and IVY (SEQ ID NO: 63).

~~115~~. The antibody formulation ~~of~~ as claimed in claim ~~51~~, wherein the surfactant is a polysorbate.

~~126~~. The antibody formulation ~~of~~ as claimed in claim ~~115~~, wherein the polysorbate is polysorbate 20 or polysorbate 80.

~~137~~. An antibody formulation, comprising:

a) about 175 mg/mL of a humanized IgG4 anti-CXCR5 antibody;

b) about 10 mM citrate buffer;

c) about 1.0 mg/mL polysorbate 80;

e) about 200 mM arginine ~~HCl~~; and

f) about 45 mg/mL sucrose,

wherein the pH of the formulation is about pH 6, wherein the humanized IgG4 anti-CXCR5 antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 33 and a light chain comprising the amino acid sequence of SEQ ID NO: 32.

~~14. The antibody formulation of claim 13, wherein the humanized IgG4 anti-CXCR5 antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 33 and a light chain comprising the amino acid sequence of SEQ ID NO: 32.~~

~~158~~. A container comprising the antibody formulation ~~of~~ as claimed in any of claims 1-~~147~~.

~~16~~9. The container ~~of~~ as claimed in claim ~~15~~8, wherein the container is a prefilled syringe, a vial, or an autoinjector.

~~17~~10. A container comprising the antibody formulation ~~of~~ as claimed in any of claims 1-~~14~~7 in a lyophilized form.

~~18~~11. A kit, comprising the container ~~of~~ as claimed in claim ~~15~~8 and a label or instructions for the administration and use of the antibody formulation.

~~19~~12. The kit ~~of~~ as claimed in claim ~~18~~11, wherein administration is by injection.

~~20~~13. The antibody formulation ~~according to~~ as claimed in any one of claims 1-~~14~~7 for use in a method of diagnosis or treatment of a CXCR5 (C-X-C chemokine receptor type 5)-mediated disease or disorder of the human or animal body.

~~21. The antibody formulation according to any one of claims 1-14 for use in a method for treating rheumatoid arthritis.~~

~~22~~14. A lyophilized form of the antibody formulation ~~of~~ as claimed in any one of claims 1-~~14~~7.