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095352717

THE CONTROLLER OF PATENTS,  
THE PATENT OFFICE,  
GOVERNMENT OF INDIA  
INTELLECTUAL PROPERTY OFFICE BUILDING,  
PLOT NO. 32, SECTOR 14 DWARKA  
NEW DELHI - 110075  
INDIA

2019, February 1

OUR REF : PN45301 DELHI

**PCT NATIONAL PHASE- CHAPTER I**

Dear Sir,

**THIS NATIONAL PHASE APPLICATION IS BEING FILED ACCORDING TO THE PUBLIC NOTICE DATED 2 JULY 2012 WITH REFERENCE NO. CG/PUBLIC NOTICE/PO/2012/15 ISSUED BY THE CONTROLLER GENERAL OF PATENTS WHICH IS EFFECTIVE FROM 6 JULY, 2012**

**Re: Applicant : SANOFI**

New Patent Application for National Phase entry to International (PCT)

Application No. **PCT/EP2017/066803** with International Filing date of **5th July, 2017**

Title: **"ANTIBODY FORMULATIONS"**

Priority No(s) UNITED STATES OF AMERICA 62/358,404 Dated 05 July 2016  
EUROPE 16306090.8 Dated 30 August 2016

We are submitting herewith the following documents for National Phase Entry into India in respect of the above identified PCT application under Article 22 (1) of the PCT.

- 1) Application
- 2) Front page of PCT Publication No. WO 2018/007456 A1
- 3) Title page on Form 2
- 4) Last claim page 61 with date and signature of Applicant's Agent
- 5) Form PCT/IB/304
- 6) Form PCT/IB/308 (2 Nos.)
- 7) Form PCT/ISA/237
- 8) International Search Report
- 9) Statement and Undertaking on Form 3
- 10) Declaration to inventorship on Form 5
- 11) Sequence Listing
- 12) Copy of Public Notice CG/Public Notice/PO2012/15 dated 2<sup>nd</sup> July 2012 by CGPDTM

Note: The Applicant desires to enter the Indian National Phase with the Specification of the PCT Application as published.

**Fee Rs. 1,04,800/-**

SANOFI

PCT/EP2017/066803

## Documents to follow

- 1) Power of Authority
- 2) Assignment

The fee calculation sheet is given below:

Number of pages 76 (including Form 2, abstract and drawings 13 sheets), Number of claims 22 and Sequence Listing (41 sheets) .

SL.	FEE CALCULATION	ADDITIONAL	AMOUNT ( Rs.)
1	Basic Filing Fee		8000.00
2	Filing Fee for each Priority in excess of one	1	8000.00
3	No. of Pages in excess of 30	46	36800.00
4	No. of Claims in excess of 10	12	19200.00
5	Sequence Listing	41	32800.00
		<b>TOTAL</b>	<b>104800.00</b>

Please acknowledge receipt of this National Phase Application, issue an appropriate receipt and allot a filing number with today's entry date.

Please ensure to quote our reference No. PN45301 in all future correspondence on this application.

Yours faithfully



( SUDHIR D. AHUJA )  
OF D. P. AHUJA & CO  
APPLICANT'S AGENT

Regn. No. IN/PA-122

Email: patents@dpahuja.com

Mobile Phone Number : +919831360050

Encl: 1 - 12

Rs.1,04,800 /-

002/TDR/010219

<b>"Form 1</b> <b>THE PATENTS ACT 1970 (39 of 1970)</b> <b>THE PATENTS RULES, 2003</b> <b>APPLICATION FOR GRANT OF PATENT</b> (See section 7, 54, and 135 and sub-rule (1) of rule 20)		<b>(FOR OFFICE USE ONLY)</b>		
		Application No.		
		Filing date.		
		Amount of fee paid:		
		CBR No:		
		Signature:		
<b>1.APPLICANT'S REFERENCE / IDENTIFICATION NO.</b> <b>(AS ALLOTTED BY OFFICE):</b>				
<b>2.TYPE OF APPLICATION [Please tick(✓)at the appropriate category]</b>				
Ordinary( <input type="checkbox"/> )		Convention( <input type="checkbox"/> )		
		PCT-NP( <input checked="" type="checkbox"/> )		
Divisional( <input type="checkbox"/> )	Patent of Addition( <input type="checkbox"/> )	Divisional( <input type="checkbox"/> )	Patent of Addition( <input type="checkbox"/> )	
<b>3A. APPLICANTS(S)</b>				
Name in Full	Nationality	Country of Residence	Address of the Applicant	
SANOFI	FRANCE	FRANCE	House No.	
			Street	54 RUE LA BOÉTIE
			City	PARIS
			State	
			Country	FRANCE
			Pin code	75008
<b>3B.CATEGORY OF APPLICANT[Please tick(✓)at the appropriate category]</b>				
Natural Person ( <input type="checkbox"/> )		Other than Natural Person( <input checked="" type="checkbox"/> )		
		Small Entity ( <input type="checkbox"/> )	Startup( <input type="checkbox"/> )	
		Others( <input checked="" type="checkbox"/> )		
<b>4.INVENTOR(S)[Please tick(✓)at the appropriate category]</b>				
Are all the inventor(s) same as the applicant(s) named above?		Yes( <input type="checkbox"/> )	No( <input checked="" type="checkbox"/> )	
<b>If "No",furnish the details of the inventor(s)</b>				
Name in Full	Nationality	Country of Residence	Address of the Inventor	
FRANCIS, Donny	GERMANY	GERMANY	House No.	
			Street	C/O SANOFI-AVENTIS DEUTSCHLAND GMBH
			City	FRANKFURT AM MAIN
			State	
			Country	GERMANY
			Pin code	65926

YOUSSEF, Ahmed	GERMANY	GERMANY	House No.	
			Street	C/O SANOFI-AVENTIS DEUTSCHLAND GMBH
			City	FRANKFURT AM MAIN
			State	
			Country	GERMANY
			Pin code	65926
KORUEVA, Stefaniya	GERMANY	GERMANY	House No.	
			Street	C/O SANOFI-AVENTIS DEUTSCHLAND GMBH
			City	FRANKFURT AM MAIN
			State	
			Country	GERMANY
			Pin code	65926
KIRSCH, Martina	GERMANY	GERMANY	House No.	
			Street	C/O SANOFI-AVENTIS DEUTSCHLAND GMBH
			City	FRANKFURT AM MAIN
			State	
			Country	GERMANY
			Pin code	65926

**5. TITLE OF THE INVENTION**

ANTIBODY FORMULATIONS

**6. AUTHORISED REGISTERED PATENT AGENT(S)**

IN/PA No.	122
Name	SUDHIR D.AHUJA
Mobile No.	9831360050

**7. ADDRESS FOR SERVICE OF APPLICANT IN INDIA**

Name	D.P AHUJA & Co.
Postal Address	DLF STAR TOWER, OFFICE NO. 510, SECTOR-30, GURGAON 122 001 NCR, INDIA
Telephone No.	91(33)40177100
Mobile No.	91983136
Fax No.	91(33)40088262
E-mail ID	patents@dpahuja.com

**8. IN CASE OF APPLICATION CLAIMING PRIORITY OF APPLICATION FILED IN CONVENTION COUNTRY, PARTICULARS OF CONVENTION APPLICATION**

Country	Application Number	Filing date	Name of the applicant	Title of the invention	IPC(as classified in the convention country)
UNITED STATES OF AMERICA	62/358,404	05 July 2016	SANOFI	ANTIBODY FORMULATIONS	
EUROPE	16306090.8	30 August 2016	SANOFI	ANTIBODY FORMULATIONS	

**9. IN CASE OF PCT NATIONAL PHASE APPLICATION, PARTICULARS OF INTERNATIONAL APPLICATION FILED UNDER PATENT CO-OPERATION TREATY (PCT)**

International application number	International filing date
PCT/EP2017/066803	05 July 2017

**10. IN CASE OF DIVISIONAL APPLICATION FILED UNDER SECTION 16, PARTICULARS OF ORIGINAL (FIRST) APPLICATION**

Original (first) application no.	Date of filing of original (first) application
NIL	

**11. IN CASE OF PATENT OF ADDITION FILED UNDER SECTION 54, PARTICULARS OF MAIN APPLICATION OR PATENT**

Main application/patent No.	Date of filing of main application
NIL	

**12. DECLARATIONS**

**(i) Declaration by the inventor(s)**

(In case the applicant is an assignee: the inventor(s) may sign herein below or the applicant may upload the assignment or enclose the assignment with this application for patent or send the assignment by post/electronic transmission duly authenticated within the prescribed period.)

I/We, the above named inventor(s) is/are the true & first inventor(s) for this Invention and declare that the applicant(s) herein is/are my/our assignee or legal representative.

- (a) Date
- (b) Signature(s)
- (c) Name(s)

**(ii) Declaration by the applicants(s) in the convention country**

(In case the applicant in India is different than the applicant in the convention country: the applicant in the convention country may sign herein below or the applicant in India may upload the assignment from the applicant in the convention country or enclose the said assignment with this application for patent or send the assignment by post/electronic transmission duly authenticated within the prescribed period)

I/We, the applicant(s) in the convention country declare that the applicant(s) herein is/are my/our assignee or legal representative.

- (a) Date
- (b) Signature(s)
- (c) Name(s) of the signatory

**(iii) Declaration by the applicant(s)**

**We, the applicant(s) hereby declare(s) that :-**

- [Yes] We are in possession of the above-mentioned invention
- [Yes] The provisional/complete specification relating to the invention is filed with this application.
- [No] The invention as disclosed in the specification uses the biological material from India and the necessary permission from the competent authority shall be submitted by me/us before the grant of patent to me/us.
- [Yes] There is no lawful ground of objection(s) to the grant of the Patent to me/us.
- [No] We are the true & first inventor(s).
- [Yes] We are the assignee or legal representative of true & first inventors.
- [Yes] The application or each of the applications, particulars of which are given in Paragraph-8, was the first application in convention country/countries in respect of my/our invention(s).

- [Yes] We claim the priority from the above mentioned application(s) filed in convention country / countries and state that no application for protection in respect of the invention had been made in a convention country before that date by us or by any person from which We derive the title.
- [Yes] Our application in India is based on International application under Patent Cooperation Treaty (PCT) as mentioned in Paragraph-9.
- [No] The application is divided out of our application particulars of which is given in Paragraph-10 and pray that this application may be treated as deemed to have been filed on under sec. 16 of the Act.
- [No] The said invention is an improvement in or modification of the invention particulars of which are given in Paragraph-11.

**13.FOLLOWING ARE THE ATTACHMENTS WITH THE APPLICATION**

Form 2

Item	Details		Fee	Remarks
Complete specification	No. of pages	58		Including Form 2
Claim(s)	No. of claims	22		
	No. of claims	4		
Abstract	No. of pages	1		
Drawing(s)	No. of Drawings	20		
	No. of Pages	13		

a. Front page of PCT Publication No. WO 2018/007456 A1

b. Title page on Form 2

c. Last claim page 61 with date and signature of Applicant's Agent

d. Form PCT/IB/304

e. Form PCT/IB/308 (2 Nos.)

f. Form PCT/ISA/237

g. International Search Report

h. Statement and Undertaking on Form 3

I. Declaration to inventorship on Form 5

j. Sequence Listing

k. Copy of Public Notice CG/Public Notice/PO2012/15 dated 2<sup>nd</sup> July 2012 by CGPDTM

**Total fee Rs. 1,04,800 /-**

We hereby declare that to the best of our knowledge, information and belief the fact and matters slated herein are correct and we request that a patent may be granted to for the said invention.

.Dated this 1st day of February, 2019.

Signature:

Name:

To,  
The Controller of Patents  
The Patent office, at.....Delhi.....

Note:-

- \* Repeat boxes in case of more than one entry.
- \* To be signed by the applicant(s) or by authorised registered patent agent otherwise ehere mentioned.
- \* Tick(✓)/cross(x) whichever is applicable/not applicable in declaration in paragraph-12.
- \* Name of the inventor and applicant should be given in full, family name in the begining.
- \* Strike out the portion which is/are not applicable.
- \* For fee: See First Schedule";



( SUDHIR D. AHUJA )

OF D. P. AHUJA & CO

APPLICANT'S AGENT

Regn. No. IN/PA-122

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Mobile Phone Number : +919831360050

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

(19) World Intellectual Property  
Organization  
International Bureau



(10) International Publication Number

WO 2018/007456 A1

(43) International Publication Date  
11 January 2018 (11.01.2018)

WIPO | PCT

(51) International Patent Classification:

A61K 39/395 (2006.01) C07K 16/28 (2006.01)

(21) International Application Number:

PCT/EP2017/066803

(22) International Filing Date:

05 July 2017 (05.07.2017)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/358,404 05 July 2016 (05.07.2016) US  
16306090.8 30 August 2016 (30.08.2016) EP

(71) Applicant: SANOFI [FR/FR]; 54, rue La Boétie, 75008  
PARIS (FR).

(72) Inventors: FRANCIS, Donny; c/o sanofi-aventis Deutsch-  
land GmbH, 65926 FRANKFURT AM MAIN (DE).  
YOUSSEF, Ahmed; c/o sanofi-aventis Deutschland  
GmbH, 65926 FRANKFURT AM MAIN (DE). KORUE-  
VA, Stefaniya; c/o sanofi-aventis Deutschland GmbH,  
65926 FRANKFURT AM MAIN (DE). KIRSCH, Marti-  
na; c/o sanofi-aventis Deutschland GmbH, 65926 FRANK-  
FURT AM MAIN (DE).

(74) Agent: TISCHNER, Oliver et al.; LAVOIX Munich, Bay-  
erstrasse 83, D-80335 München (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, DJ, DK, DM, DO,  
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,  
HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP,  
KR, KW, 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: ANTIBODY FORMULATIONS

(57) Abstract: High concentration antibody formulations capable of stable long-term storage are disclosed.

WO 2018/007456 A1



## ADVANCE E-MAIL

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING SUBMISSION,  
OBTENTION OR TRANSMITTAL  
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

TISCHNER, Oliver  
Bayerstrasse 83  
D-80335 München  
ALLEMAGNE

Date of mailing ( <i>day/month/year</i> ) 28 August 2017 (28.08.2017)	
Applicant's or agent's file reference BET 17M2507	IMPORTANT NOTIFICATION
International application No. PCT/EP2017/066803	International filing date ( <i>day/month/year</i> ) 05 July 2017 (05.07.2017)
International publication date ( <i>day/month/year</i> ) Not yet published	Priority date ( <i>day/month/year</i> ) 05 July 2016 (05.07.2016)
Applicant SANOFI	

The applicant is hereby notified of the date of receipt (or of obtaining by the International Bureau) of the priority document(s) relating to all earlier application(s) whose priority is claimed. Unless otherwise indicated by the letters "NR", in the right-hand column or by an asterisk appearing next to the date of receipt, **the priority document concerned was submitted or transmitted to or obtained by the International Bureau in compliance with Rule 17.1(a), (b) or (b-bis)**. This Form replaces any previously issued notification concerning submission, transmittal or obtaining of priority documents.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
05 July 2016 (05.07.2016)	62/358,404	US	24 July 2017 (24.07.2017)
30 August 2016 (30.08.2016)	16306090.8	EP	24 August 2017 (24.08.2017)

The letters "NR" denote a priority document which, on the date of mailing of this Form, had not yet been received or obtained by the International Bureau in compliance with Rule 17.1(a), (b) or (b-bis). Where the applicant has failed to either submit, request to prepare and transmit, or to request the International Bureau to obtain the priority document within the applicable time limit under that Rule, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

An asterisk "\*" next to a date of receipt, denotes a priority document submitted or transmitted to or obtained by the International Bureau but not in compliance with Rule 17.1(a), (b) or (b-bis) (the priority document was received after the time limit prescribed in Rule 17.1(a); the request to prepare and transmit the priority document was submitted to the receiving Office after the applicable time limit under Rule 17.1(b) or the request to the International Bureau to obtain the priority document was made after the applicable time limit under Rule 17.1(b-bis)). Even though the priority document was not furnished in compliance with Rule 17.1(a), (b) or (b-bis), the International Bureau will nevertheless transmit a copy of the document to the designated Offices, for their consideration. In case such a copy is not accepted by the designated Office as the priority document, Rule 17.1(c) provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer  Nora Lindner  e-mail pct.team5@wipo.int Telephone No. +41 22 338 74 05
Facsimile No. +41 22 338 89 75	

## ADVANCE E-MAIL

From the INTERNATIONAL BUREAU

## PCT

FIRST NOTICE INFORMING THE APPLICANT OF  
THE COMMUNICATION OF THE INTERNATIONAL  
APPLICATION (TO DESIGNATED OFFICES WHICH  
DO NOT APPLY THE 30 MONTH TIME LIMIT  
UNDER ARTICLE 22(1))

(PCT Rule 47.1(c))

To:

TISCHNER, Oliver  
LAVOIX Munich  
Bayerstrasse 83  
D-80335 München  
ALLEMAGNE

Date of mailing (day/month/year) 08 February 2018 (08.02.2018)			
Applicant's or agent's file reference BET 17M2507		IMPORTANT NOTICE	
International application No. PCT/EP2017/066803	International filing date (day/month/year) 05 July 2017 (05.07.2017)	Priority date (day/month/year) 05 July 2016 (05.07.2016)	
Applicant SANOFI			

1. **ATTENTION:** For any designated Office(s), for which the time limit under Article 22(1), as in force from 1 April 2002 (30 months from the priority date), **does apply**, please see Form PCT/IB/308(Second and Supplementary Notice) (to be issued promptly after the expiration of 28 months from the priority date).

2. Notice is hereby given that the following designated Office(s), for which the time limit under Article 22(1), as in force from 1 April 2002, **does not apply**, has/have requested that the communication of the international application, as provided for in Article 20, be effected under Rule 93bis.1. The International Bureau has effected that communication on the date indicated below:  
11 January 2018 (11.01.2018)

None

In accordance with Rule 47.1(c-bis)(i), those Offices will accept the present notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

3. The following designated Offices, for which the time limit under Article 22(1), as in force from 1 April 2002, **does not apply**, have not requested, as at the time of mailing of the present notice, that the communication of the international application be effected under Rule 93bis.1 :

LU, TZ, UG

In accordance with Rule 47.1(c-bis)(ii), those Offices accept the present notice as conclusive evidence that the Contracting State for which that Office acts as a designated Office does not require the furnishing, under Article 22, by the applicant of a copy of the international application.

#### 4. TIME LIMITS for entry into the national phase

For the designated Office(s) listed above, and unless a demand for international preliminary examination has been filed before the expiration of **19 months** from the priority date (see Article 39(1)), the applicable time limit for entering the national phase will, **subject to what is said in the following paragraph**, be **20 MONTHS** from the priority date.

In practice, **time limits other than the 20-month time limit** will continue to apply, for various periods of time, in respect of certain of the designated Offices listed above. For **regular updates on the applicable time limits** (20 or 21 months, or other time limit), Office by Office, refer to the *PCT Gazette*, the *PCT Newsletter* and the *PCT Applicant's Guide*, Volume II, National Chapters, all available from WIPO's Internet site, at <http://www.wipo.int/pct/en/index.html>.

It is the applicant's **sole responsibility** to monitor all these time limits.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer  Nora Lindner
Facsimile No. +41 22 338 82 70	e-mail: <a href="mailto:pct.team5@wipo.int">pct.team5@wipo.int</a>

## ADVANCE E-MAIL

From the INTERNATIONAL BUREAU

## PCT

SECOND AND SUPPLEMENTARY NOTICE  
INFORMING THE APPLICANT OF THE  
COMMUNICATION OF THE INTERNATIONAL  
APPLICATION (TO DESIGNATED OFFICES  
WHICH APPLY THE 30 MONTH TIME  
LIMIT UNDER ARTICLE 22(1))

(PCT Rule 47.1(c))

To:

TISCHNER, Oliver  
LAVOIX Munich  
Bayerstrasse 83  
D-80335 München  
ALLEMAGNE

Date of mailing (day/month/year) 08 November 2018 (08.11.2018)		
Applicant's or agent's file reference BET 17M2507		IMPORTANT NOTICE
International application No. PCT/EP2017/066803	International filing date (day/month/year) 05 July 2017 (05.07.2017)	Priority date (day/month/year) 05 July 2016 (05.07.2016)
Applicant SANOFI		

- ATTENTION:** For any designated Office(s), for which the time limit under Article 22(1), as in force from 1 April 2002 (30 months from the priority date), **does not apply**, please see Form PCT/IB/308(First Notice) issued previously.
- Notice is hereby given that the following designated Office(s), for which the time limit under Article 22(1), as in force from 1 April 2002, **does apply**, has/have requested that the communication of the international application, as provided for in Article 20, be effected under Rule 93bis.1. The International Bureau has effected that communication on the date indicated below:  
11 January 2018 (11.01.2018)

AZ, BY, CN, EP, HU, KG, KP, KR, MD, MK, MZ, NA, NG, PG, RU, SY, TM

In accordance with Rule 47.1(c-bis)(i), those Offices will accept the present notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

- The following designated Offices, for which the time limit under Article 22(1), as in force from 1 April 2002, **does apply**, have not requested, as at the time of mailing of the present notice, that the communication of the international application be effected under Rule 93bis.1 :

AE, AG, AL, AM, AO, AP, AT, AU, BA, BB, BG, BH, BN, BR, BW, BZ, CA, CH, CL, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EA, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, ID, IL, IN, IR, IS, JO, JP, KE, KH, KN, KW, KZ, LA, LC, LK, LR, LS, LY, MA, ME, MG, MN, MW, MX, MY, NI, NO, NZ, OA, OM, PA, PE, PH, PL, PT, QA, RO, RS, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, TH, TJ, TN, TR, TT, UA, US, UZ, VC, VN, ZA, ZM, ZW

In accordance with Rule 47.1(c-bis)(ii), those Offices accept the present notice as conclusive evidence that the Contracting State for which that Office acts as a designated Office does not require the furnishing, under Article 22, by the applicant of a copy of the international application.

#### 4. TIME LIMITS for entry into the national phase

For the designated or elected Office(s) listed above, the applicable time limit for entering the national phase will, **subject to what is said in the following paragraph**, be **30 MONTHS** from the priority date.

In practice, **time limits other than the 30-month time limit** will continue to apply, for various periods of time, in respect of certain of the designated or elected Office(s) listed above. For **regular updates on the applicable time limits** (30 or 31 months, or other time limit), Office by Office, refer to the *PCT Gazette*, the *PCT Newsletter* and the *PCT Applicant's Guide*, Volume II, National Chapters, all available from WIPO's Internet site, at <http://www.wipo.int/pct/en/index.html>.

It is the applicant's **sole responsibility** to monitor all these time limits.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer  Nora Lindner
Facsimile No. +41 22 338 82 70	e-mail: <a href="mailto:pct.team5@wipo.int">pct.team5@wipo.int</a>

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

## PCT

To:          see form PCT/ISA/220
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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY  
(PCT Rule 43bis.1)

Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet)
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Applicant's or agent's file reference see form PCT/ISA/220	<b>FOR FURTHER ACTION</b> See paragraph 2 below
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International application No. PCT/EP2017/066803	International filing date (day/month/year) 05.07.2017	Priority date (day/month/year) 05.07.2016
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International Patent Classification (IPC) or both national classification and IPC INV. A61K39/395 C07K16/28
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Applicant SANOFI
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**1. This opinion contains indications relating to the following items:**


- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

**2. FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1 bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465	Date of completion of this opinion  see form PCT/ISA/210	Authorized Officer  Page, Michael  Telephone No. +49 89 2399-0
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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/EP2017/066803

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**Box No. 1 Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of:
  - the international application in the language in which it was filed.
  - a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2.  This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3.  With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
  - a.  forming part of the international application as filed:
    - in the form of an Annex C/ST.25 text file.
    - on paper or in the form of an image file.
  - b.  furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
  - c.  furnished subsequent to the international filing date for the purposes of international search only:
    - in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
    - on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
4.  In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/EP2017/066803

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**Box No. IV Lack of unity of invention**

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1.  In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:
- paid additional fees
  - paid additional fees under protest and, where applicable, the protest fee
  - paid additional fees under protest but the applicable protest fee was not paid
  - not paid additional fees
2.  This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- complied with
  - not complied with for the following reasons:  
**see separate sheet**
4. Consequently, this report has been established in respect of the following parts of the international application:
- all parts.
  - the parts relating to claims Nos.

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	<u>7, 14</u>
	No: Claims	<u>1-6, 8-13, 15-22</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-22</u>
Industrial applicability (IA)	Yes: Claims	<u>1-22</u>
	No: Claims	

2. Citations and explanations

**see separate sheet**

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/EP2017/066803

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

1 **Re Item IV**

**Lack of Unity of Invention**

Whereas claims 1-4, 6, 7, 9, 10, 13 and 14 all specify that the antibody is an anti-CXCR5 antibody, claims 5, 8, 11, 12 and 15-22 are open ended and encompass any antibody.

Antibody formulations suitable for subcutaneous administration and having the specific combinations of components are known in the art (see e.g. D3 paragraphs [0011]-[0022] concerning formulations for anti-LIGHT and anti-CXCR5 antibodies).

There is therefore no novel feature linking the subject matter of claims 1-4 and 6-14 to that of claim 5 and the application therefore lacks unity of invention.

2 **Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

2.1 **Reference is made to the following documents:**

- D1 WO 2013/148686 A2 (SANOFI SA [FR]; SCHNIEDERS JULIA [US]) 3 October 2013 (2013-10-03)
- D2 WO 2009/032661 A1 (SANOFI AVENTIS [FR]; LEE RENATA [US]; MIKOL VINCENT [FR]; ALLEN ELIZAB) 12 March 2009 (2009-03-12)cited in the application
- D3 US 2014/004106 A1 (SCHNIEDERS JULIA [DE] ET AL) 2 January 2014 (2014-01-02)
- D4 WANG W ET AL: "ANTIBODY STRUCTURE, INSTABILITY, AND FORMULATION", JOURNAL OF PHARMACEUTICAL SCIENCES, AMERICAN CHEMICAL SOCIETY AND AMERICAN PHARMACEUTICAL ASSOCIATION, vol. 96, no. 1, 1 January 2007 (2007-01-01), pages 1-26, XP009084505, ISSN: 0022-3549, DOI: 10.1002/JPS.20727



- D5 ANN L DAUGHERTY AND RANDALL J MRSNY ED - STEVEN J SHIRE  
ET AL: "Formulation and Delivery Issues for Monoclonal Antibody  
Therapeutics", 1 January 2010 (2010-01-01), CURRENT TRENDS IN  
MONOCLONAL ANTIBODY DEVELOPMENT AND MANUFACTU,  
SPRINGER, US, PAGE(S) 103 - 129, XP009133774,  
ISBN: 978-0-387-76642-3  
[retrieved on 2010-11-11]

**2.2 Novelty - Art.33(1) and (2) PCT:**

D1 concerns formulations for anti-CXCR5 antibodies defined by SEQ ID NOs. 32, 33, 43 and 45 of the application. Said formulations are i.a. for subcutaneous administration (page 1 last paragraph) and comprise antibody at 20-250 mg/ml (page 2 1st paragraph), citrate buffer, 0.01% polysorbate 20, 4.5% sucrose, 1% arginine (57 mM) at pH 6.0 (page 7 1st paragraph). The subject matter of claims 1-4 is therefore anticipated.

Claims 15-22 concern containers, kits, medical use and lyophilised preparations, all of which are likewise anticipated by D1 (see Summary of the Invention).

D3 also concerns stabilised formulations of anti-CXCR5 antibodies (though apparently not the specific antibodies mentioned in the application) and teaches formulations for subcutaneous administration comprising antibody at 5-280 mg/ml, 5-15 mM citrate, 0.001%-0.1% surfactant, 1%-10% sucrose, 0.1%-5% (approx. 6-290 mM) amino acid (e.g. arginine) at pH 6 (D3 paragraphs [0011]-[0020]). Paragraphs [0038]-[0049] disclose two specific formulations. The formulations may be lyophilised (paragraph [0019]). The subject matter of claims 1, 3-6, 8-13 and 15-22 is therefore anticipated.

**2.3 Inventive Step - Art.33(1) and (3) PCT:**

A composition comprising a specific antibody, a buffer, stabilisers and/or surfactants can be considered as being inventive if the concentration ranges of excipients and antibody reflect the stabilising effect shown in the examples. It must be plausible that the results obtained by the stability tests of the examples can be extended to all formulations falling within the scope of the claim.

Because the stability was only shown for one single, specific antibody, the composition must be limited to this specific antibody because one specific stabilisation agent suitable for one antibody is not necessarily suitable for another antibody (D6) and because the interfacial surface of each antibody is unique and requires specific formulation components to provide maximal stability (D7). Consequently the claim must be limited by the full sequence of the tested antibody, including the Fc-region, otherwise the technical effect was not shown over the entire range of possible Fc-variants and the subject-matter is not inventive (claims 1-22 in toto).

**2.4 Industrial Applicability - Art.33(1) and (4) PCT:**

No unified criteria exist in the PCT Contracting States on the question whether methods of treatment are industrially applicable, as they are not considered to be industrially applicable in the EPC. No opinion can be given, therefore on the industrial applicability of claim 21, which claims such a method.

**3 Re Item VIII**

**Certain observations on the international application**

- 3.1 Claim 1 is insufficiently disclosed. The formulation is supposed to be suitable for subcutaneous administration but does not teach an upper limit for the concentration of citrate buffer, surfactant, amino acid or sucrose. The skilled person will need to determine these for themselves. Consequently the application does not meet the disclosure requirements of Article 6 PCT.
- 3.2 Claims 1-16 and 18-20 all concern antibody formulations with defined excipient concentrations. Claims 17 and 22 concern lyophilised compositions for which the concentration is immaterial. This renders claims 17 and 22 unclear (Article 6 PCT).

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference BET 17M2507	<b>FOR FURTHER ACTION</b> see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/EP2017/066803	International filing date (day/month/year) 5 July 2017 (05-07-2017)	(Earliest) Priority Date (day/month/year) 5 July 2016 (05-07-2016)
Applicant  SANOFI		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 7 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- the international application in the language in which it was filed  
 a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b.  This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6**bis**(a)).

c.  With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2.  **Certain claims were found unsearchable** (See Box No. II)

3.  **Unity of invention is lacking** (see Box No III)

4. With regard to the **title**,

- the text is approved as submitted by the applicant  
 the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- the text is approved as submitted by the applicant  
 the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. \_\_\_\_\_  
 as suggested by the applicant  
 as selected by this Authority, because the applicant failed to suggest a figure  
 as selected by this Authority, because this figure better characterizes the invention
- b.  none of the figures is to be published with the abstract

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/EP2017/066803

## Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.c of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of a sequence listing:
  - a.  forming part of the international application as filed:
    - in the form of an Annex C/ST.25 text file.
    - on paper or in the form of an image file.
  - b.  furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
  - c.  furnished subsequent to the international filing date for the purposes of international search only:
    - in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
    - on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
2.  In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/EP2017/066803

## Box No. II Observations where certain claims were found unsearchable (Continuation of Item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**

International application No  
PCT/EP2017/066803

**A. CLASSIFICATION OF SUBJECT MATTER**  
INV. A61K39/395 C07K16/28  
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
A61K C07K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data, Sequence Search

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2013/148686 A2 (SANOFI SA [FR]; SCHNIEDERS JULIA [US]) 3 October 2013 (2013-10-03) page 2, paragraph 4 - page 5, paragraph 3 page 6, paragraph 3 - page 8, paragraph 1 examples 12,20 claims 1,6,17,22,23,35,47,49,54,58,61,62,68 sequences 21,22,28,29 -----	1-22
X	WO 2009/032661 A1 (SANOFI AVENTIS [FR]; LEE RENATA [US]; MIKOL VINCENT [FR]; ALLEN ELIZAB) 12 March 2009 (2009-03-12) cited in the application	1-22
Y	paragraphs [0005], [0236], [0239], [0242], [0243], [0245], [0261] - [0263]; claim 1; example 2 ----- -/--	2,7,14

Further documents are listed in the continuation of Box C.

See patent family annex.

\* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

13 September 2017

Date of mailing of the international search report

22/09/2017

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040,  
Fax: (+31-70) 340-3016

Authorized officer

Page, Michael

## INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2017/066803

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014/004106 A1 (SCHNIEDERS JULIA [DE] ET AL) 2 January 2014 (2014-01-02)	1,3-6, 8-13, 15-22
Y	paragraphs [0011] - [0020], [0038] - [0049], [0210] - [0229], [0251] - [0265], [0275], [0277]	2,7,14
A	<p>-----</p> <p>WANG W ET AL: "ANTIBODY STRUCTURE, INSTABILITY, AND FORMULATION", JOURNAL OF PHARMACEUTICAL SCIENCES, AMERICAN CHEMICAL SOCIETY AND AMERICAN PHARMACEUTICAL ASSOCIATION, vol. 96, no. 1, 1 January 2007 (2007-01-01), pages 1-26, XP009084505, ISSN: 0022-3549, DOI: 10.1002/JPS.20727 pages 14-20, paragraph Antibody Formulation</p> <p>-----</p>	1-22
A	<p>-----</p> <p>ANN L DAUGHERTY AND RANDALL J MRSNY ED - STEVEN J SHIRE ET AL: "Formulation and Delivery Issues for Monoclonal Antibody Therapeutics", 1 January 2010 (2010-01-01), CURRENT TRENDS IN MONOCLONAL ANTIBODY DEVELOPMENT AND MANUFACTURE, SPRINGER, US, PAGE(S) 103 - 129, XP009133774, ISBN: 978-0-387-76642-3 [retrieved on 2010-11-11] the whole document</p> <p>-----</p>	1-22

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2017/066803

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
WO 2013148686	A2	03-10-2013	CA 2868401 A1	03-10-2013
			EP 2830658 A2	04-02-2015
			JP 2015514090 A	18-05-2015
			RU 2014142990 A	20-05-2016
			WO 2013148686 A2	03-10-2013
-----				
WO 2009032661	A1	12-03-2009	AR 068354 A1	11-11-2009
			AU 2008296538 A1	12-03-2009
			CA 2698203 A1	12-03-2009
			CN 101842115 A	22-09-2010
			CN 104017078 A	03-09-2014
			CN 104017079 A	03-09-2014
			CO 6270238 A2	20-04-2011
			CR 11293 A	23-03-2010
			CR 20150054 A	06-04-2015
			DO P2010000069 A	31-03-2010
			EC SP109985 A	31-03-2010
			EP 2195023 A1	16-06-2010
			IL 204173 A	30-06-2015
			JP 5743543 B2	01-07-2015
			JP 6129152 B2	17-05-2017
			JP 2010537636 A	09-12-2010
			JP 2015096075 A	21-05-2015
			JP 2017123866 A	20-07-2017
			KR 20100061815 A	09-06-2010
			KR 20140117638 A	07-10-2014
			KR 20140121486 A	15-10-2014
			KR 20150082692 A	15-07-2015
			MA 31821 B1	01-11-2010
			MX 338395 B	15-04-2016
			MX 338397 B	15-04-2016
			MX 338474 B	18-04-2016
			MX 346172 B	10-03-2017
			MY 159201 A	30-12-2016
			NZ 583605 A	26-10-2012
			PA 8794201 A1	23-07-2009
			PE 09932009 A1	08-07-2009
			RU 2010111751 A	10-10-2011
			SG 10201407388X A	29-01-2015
			SV 2010003494 A	25-01-2011
			TN 2010000092 A1	26-09-2011
			TW 200918558 A	01-05-2009
			TW 201425337 A	01-07-2014
			TW 201630939 A	01-09-2016
			UA 104715 C2	11-03-2014
			US 2011027266 A1	03-02-2011
			US 2013236476 A1	12-09-2013
			US 2013243783 A1	19-09-2013
			US 2013243793 A1	19-09-2013
			US 2013246035 A1	19-09-2013
			US 2013251714 A1	26-09-2013
			US 2017044263 A1	16-02-2017
			UY 31309 A1	31-03-2009
			WO 2009032661 A1	12-03-2009
-----				
US 2014004106	A1	02-01-2014	US 2014004106 A1	02-01-2014
			US 2017232104 A1	17-08-2017
-----				



**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-22

Antibody formulations

1.1. claims: 1-4, 6, 7, 9, 10, 13, 14(completely); 5, 8, 11, 12, 15-22(partially)

Antibody formulation comprising an anti-CXCR5 antibody

1.2. claims: 5, 8, 11, 12, 15-22(all partially)

Antibody formulation suitable for subcutaneous administration.

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**INTELLECTUAL  
PROPERTY INDIA**  
PATENTS/DESIGNS/  
TRADE MARKS/  
GEOGRAPHICAL  
INDICATIONS.



सत्यमेव जयते

Government of India  
Office of The Controller General,  
Patents, Designs & Trade Marks,  
Boudhik Sampada Bhavan,  
S.M. Road, Antop Hill,  
Mumbai-400 037 (India)

(Tel): ☎ 022-24132735  
022-24123388  
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(Website): [www.ipindia.nic.in](http://www.ipindia.nic.in)

CG/ Public Notice/PO/2012/15

Dated:02.07.2012

**PUBLIC NOTICE**

**on filing of PCT National Phase Applications in India**

Indian Patent Office (IPO) continuously endeavors to improve its efficiency so as to render better services to the public. In an effort to simplify the process of filing of a PCT National Phase Application, the IPO has, in coordination with the International Bureau (IB) of the World Intellectual Property Organization (WIPO), acquired online access to the PCT International Applications and related documents available with the IB. The benefits of this coordination will be passed on to the stakeholders as redundant processes will be eliminated. An Applicant will no more be required to file multiple copies of documents already available with IB, as IPO will be able to utilize such documents accessed electronically from IB. This would also result in more efficient usage of the valuable resources of IPO and reduce errors in data entry, thereby obviating the need for corrections in many cases.

In order to operationalise the simplified process of filing of PCT National Phase Applications, the following instructions are issued. It may be noted that these instructions apply only to PCT National Phase Applications entering India which do not claim priority of any PCT National Phase Application filed previously in India.

**Instructions**

- 1) a. For filing a PCT National Phase Application in India, which does not claim priority of any PCT National Phase Application filed previously in India, only the following contents are required to be populated in Form 2:
  - i) Column 1, 2 and 3; and

**RECEIVED**  
- 5 JUL 2012




BY:.....

- ii) The last page of claims (first page, if claims comprise of only one page) with date and signature.
- b. It is clarified that if an Applicant, for the aforementioned category of Applications, submits a Form 2 in which columns other than 1, 2 and 3 are also populated, the IPO will consider the contents accessed from IB.
- c. All other applicable documents are still required to be filed.

**Note:**

- i. For the applications of the type referred to above, columns 7 and 8 of Form I need not be populated in any case.
- ii. It is clarified that the IPO does not allow an Applicant to amend the specification or the related documents before he actually enters National Phase in India. These directions are in consonance with the aforementioned practice.
- 2) The documents filed by the Applicant should exactly correspond with the up-to-date information available on the record of IB on the date of filing of the PCT National Phase Application in India. The said information must have been notified / published by the IB in accordance with the PCT and the Regulations made thereunder. Any request pending with the IB shall be of no consequence and should not be reflected in the documents. If any such request is reflected in the documents, the information notified/published by IB shall prevail.
- 3) The requirement of filing complete specification and abstract in Form 2 at the time of filing of a PCT National Phase Application in India is being dispensed with for the Applications under reference, as explained in (1) above. However, where the international application was either not filed or has not been published in English, the Applicant shall file translation of the Application in English, duly verified by the Applicant or the person duly authorized by him that the contents thereof are correct and complete.
- 4) The Applicants will be required to comply with all other requirements in accordance with the Patents Act, 1970 and the Patents Rules, 2003.
- 5) These instructions shall come into effect on 6<sup>th</sup> July, 2012.

  
2/7/2012

(Chaitanya Prasad)  
Controller General of Patents, Designs & Trade Marks