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सं.संख्या/Ref.No /आवेदन संख्या/Application No/ 201917004058 दिनांक/Date of Dispatch/Email: 24/11/2022

सेवा मे,/To
SUDHIR D. AHUJA,
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विषय: एकस्व अधिनियम, 1970 की धारा 12 व 13 तथा एकस्व नियम, 2003 के अधीन परीक्षण रिपोर्ट
Subject: Examination report under sections 12 & 13 of the Patents Act, 1970 and the Patents Rules, 2003.

1. उपर्युक्त आवेदन के संदर्भ मे परीक्षण रिपोर्ट (अर्थात, एकस्व नियम, 2003 (यथा संशोधित) के नियम 24-ख(3) में विनिर्दिष्ट आपत्तियों का प्रथम कथन) इसके साथ संलग्न है। यह रिपोर्ट परीक्षण हेतु अनुरोध दिनांक 22/06/2020 के उत्तर मे जारी की गयी है। परीक्षण रिपोर्ट का उत्तर दाखिल करने की अंतिम तिथि (अर्थात, इस रिपोर्ट में लगाई गयी सभी आवश्यकताओं के अनुपालन की अवधि) आवेदक को आपत्तियों का प्रथम कथन जारी होने की तिथि से छः माह है।
   Please find enclosed herewith an Examination Report (i.e. a first statement of objections as specified in Rule 24-B(3) of The Patents Rules, 2003 (as amended)) in respect of above-mentioned application. This report is issued with reference to a request for examination dated 22/06/2020.The last date for filing a response to the Examination Report (i.e. a period to comply with all the requirements raised in this examination report) is six months from the date on which the first statement of objections is issued to the Applicant.

2. यदि रिपोर्ट के अंतर्गत लगाई गयी आवश्यकताओं का अनुपालन एकस्व नियम, 2003 (यथा संशोधित) के नियम 24 ख(5) में विनिर्दिष्ट अवधि के भीतर अंदर अनुपालन नहीं किया गया तो एकस्व अधिनियम 1970 की धारा 21(1) के अधीन वर्तमान आवेदन को परित्यक्त माना जाएगा।
   The instant application shall be deemed to have been abandoned under Section 21(1) of The Patents Act, 1970, unless all the requirements raised in this report are complied with in the period as specified in Rule 24-B (5) of The Patents Rules, 2003 (as amended).

3. आपका ध्यान एकस्व नियम, 2003 के नियम 24 ख(6) के प्रावधानों की ओर भी आमंत्रित किया जाता है।
   Your attention is also invited to the provisions of Rule 24-B (6) of the Patents Rules 2003.

4. आपको सलाह दी जाती है कि शीघ्र निपटान हेतु अपना उत्तर शीघ्र प्रस्तुत करें।
   You are advised to file the reply at the earliest for early disposal.

Saravana Ram Prasad V G
नियंत्रक पेटेंट/ Controller of Patents

संलग्न/Enclosed: अपरोक्त अनुसार/As above

टिप्पणी: यह इलेक्ट्रोनिक रूप से उत्पन्न रिपोर्ट है।
NOTE: This is an electronically generated report.

सभी पत्राचार नियंत्रक एकस्व को उपरोल्लिखित पते पर भेजा जाये।
All communications should be sent to the Controller of Patents at the above mentioned address.

THE PATENT OFFICE

परीक्षण रिपोर्ट /Examination Report

आवेदन संख्या /Application Number	201917004058
दाखिल करने की तिथि /Date of Filing	01/02/2019
पूर्विक्ता दिनांक /Date of Priority	05/07/2016
पीसीटी अंतर्राष्ट्रीय आवेदन की संख्या व दिनांक / PCT International Application No. & Date	EP2017066803 -- 05/07/2017
आवेदक /Applicant	SANOFI
परीक्षण हेतु अनुरोध की संख्या व दिनांक /Request for Examination No. & Date	R20201018542 22/06/2020
प्रकाशन की तिथि /Date of Publication	29/03/2019

इस परीक्षण रिपोर्ट के चार भाग हैं, अर्थात रिपोर्ट का सारांश, विस्तृत तकनीकी रिपोर्ट, औपचारिक आवश्यकताएँ तथा रिकॉर्ड मे दस्तावेज़ /
This examination report consists of four parts, namely summary of the report, detailed technical report, formal requirements and documents on record.

भाग -1: रिपोर्ट का सारांश
PART-I: SUMMARY OF THE REPORT

क्र. सं. /Sl. No.	अधिनियम के तहत आवश्यकताओं पर विस्तृत टिप्पणियां /Requirements under the Act		दावों की संख्या /Claim Numbers	टिप्पणी /Remarks
1.	धारा 2(1)(ज) के तहत आविष्कार /Invention u/s 2(1)(j)	नवीनता /Novelty	दावे /Claims:	हाँ /Yes
			दावे /Claims: 1-6, 8-13 and 15-22	नहीं /No
		आविष्कारी कदम / Inventive step	दावे /Claims:	हाँ /Yes
			दावे /Claims: 1-22	नहीं /No
2.	धारा 3 के अधीन पेटेंट-अयोग्यता (यदि हाँ, खंड 3(क-त) /Non-patentability u/s 3 (if yes, specify section3(a-p))		दावे /Claims: (1-6, 8-13 and 15-22); (1-14 and 20); (21);	हाँ /Yes 3 (d); 3 (e); 3 (i);
			दावे /Claims:	नहीं /No
3.	धारा 10 (5) के अधीन आविष्कार की एकलता /Unity of invention u/s 10 (5)		दावे /Claims:	हाँ /Yes
			दावे /Claims: 1-22	नहीं /No
4.	[धारा 10(5) व 10(4) (ज)] के अधीन दावे /Claims [u/s 10(5) & 10(4) (c)]	स्पष्टता/ संक्षिप्तता /Clarity / Conciseness	दावे /Claims:	हाँ /Yes
			दावे /Claims: 20	नहीं /No
		परिभाषिकता /Definitive	दावे /Claims:	हाँ /Yes
			दावे /Claims: 1	नहीं /No
		विवरण द्वारा समर्थित /Supported by description	दावे /Claims:	हाँ /Yes
			दावे /Claims: 1-22	नहीं /No
		क्षेत्र /Scope	दावे /Claims:	हाँ /Yes
			दावे /Claims: 1-22	नहीं /No
5.	अन्य आवश्यकता (एँ) /Other requirement(s): 1. Claim 21 as drafted is clearly and explicitly drawn to a method of treatment and is not patentable u/s 3(i) of the Act. Said claims are hence not considered for examination in the present report and no opinion on any aspect of patentability is established for the same. 2. Claim 20 of the instant application intended for the use cannot be considered as an invention within the meaning u/s 2(1) (j) of the Act. The characterization of the product by use as characterized in claims (specifically in claim 1) is not patentable u/s 3(i) of the Patents Act, 1970. 3. Claim 18 and 19 refers to “kit” which is not an invention u/s 2(1) (j) of The Patents Act 1970 as it lacks any functional feature. It is a mere combination of components and instructions for use with no novelty or inventive step whatsoever in the said way of placement.			

भाग –II विस्तृत तकनीकी रिपोर्ट
PART-II: DETAILED TECHNICAL REPORT

क. उद्धरित दस्तावेजों की सूची /A.List of documents cited:

(क) पेटेंट साहित्य / (a). Patent Literature :

क्र. सं. / Sl.no	दस्तावेज़ों का विवरण /Details of documents	प्रकाशन तिथि(दिन/माह/वर्ष) / Publication date	उद्धरित दस्तावेज़ का प्रासंगिक विवरण (पृष्ठ व अनुच्छेद संख्या) / Relevant description (page and paragraph no.) of cited document	उद्धरित दस्तावेज़ के प्रासंगिक दावे / Relevant claims of cited document	अभिकथित आविष्कार के दावे /Claims of alleged invention
1	D1. WO 2013/148686 A2	03/10/2013	whole document		1-22
2	D2. WO 2009/032661 A1	12/03/2009	whole document		1-22
3	D3. US 2014/004106 A1	02/01/2014	whole document		1-22

(ख) गैर-पेटेंट साहित्य /(b).Non-patent literature

क्र. सं. / Sl.no	दस्तावेज़ों का विवरण /Details of documents	प्रकाशन तिथि(दिन/माह/वर्ष) /Publication date	उद्धरित दस्तावेज़ का प्रासंगिक विवरण (पृष्ठ व अनुच्छेद संख्या) /Relevant description (page and paragraph no.) of cited document	अभिकथित आविष्कार के दावे /Relevant claims of cited document	अभिकथित आविष्कार के दावे /Claims of alleged invention
1	D4. WANG WET AL: "ANTIBODY STRUCTURE, INSTABILITY, AND FORMULATION", JOURNAL OF PHARMACEUTICAL SCIENCES, AMERICAN CHEMICAL SOCIETY AND AMERICAN PHARMACEUTICAL ASSOCIATION, val. 96, no. 1, 1 January 2007 (2007-01-01), pages 1-26.	01/01/2007	whole document		1-22
2	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 (201 0-01-01), CURRENT	01/01/2010	whole document		1-22

	TRENDS IN MONOCLONAL ANTIBODY DEVELOPMENT AND MANUFACTU, SPRINGER, US, PAGE(S) 103-129.				

ख. अधिनियम के तहत आवश्यकताओं पर विस्तृत टिप्पणियां /B. Detailed observations on the requirements under the Act:

(1).नवीनता / NOVELTY:

(I) ऊपर उद्धरित दस्तावेज़ के संदर्भ (1-6, 8-13 and 15-22) मे दिये गए प्रकटन के पूर्वानुमान को ध्यान मे रखते हुए, निम्नलिखित कारणों से दावा(वों) (1-6, 8-13 and 15-22) मे नवीनता की कमी है /
Claim(s) (1-6, 8-13 and 15-22) lack(s) novelty, being anticipated in view of disclosure in the document cited above under reference D1/D3 for the following reasons:

The instant application describes about an antibody formulation comprising anti-CXCR5 antibody, citrate buffer, surfactant, an amino acid and sucrose.

The subject matter of the claims 1-6, 8-13 and 15-22 of the instant application is not novel over the document D1/D3, as the documents independently discloses all the essential features of claims.

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 21st paragraph), citrate buffer, 0.01% polysorbate 20, 4.5% sucrose, 1% arginine (57 mM) at pH 6.0 (page 71st paragraph). The subject matter of claims 1-4 is therefore not novel.

Claims 15-22 concern containers, kits, medical use and lyophilized preparations, all of which are likewise anticipated by D1.

D3 also concerns stabilized formulations of anti-CXCR5 antibodies 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 lyophilized (paragraph [0019]). The subject matter of claims 1, 3-6, 8-13 and 15-22 is therefore not novel.

Hence the subject matter of the claims 1-6, 8-13 and 15-22 of the instant application is not novel over the cited document D1/D3.

(2).आविष्कारी कदम / INVENTIVE STEP:

(I) ऊपर उद्धरित दस्तावेज़(जों) के संदर्भ D1-D5 मे स्पष्ट अध्यापन(नों) को ध्यान मे रखते हुए, निम्नलिखित कारणों से दावा(वों) (1-22) मे आविष्कारी कदम की कमी है
Claim(s) (1-22) lack(s) inventive step, being obvious in view of teaching (s) of cited document(s) above under reference D1-D5 for the following reasons:

The claims 1-6, 8-13 and 15-22 of the alleged invention are not novel, hence it is also not inventive under section 2 (1) (j).

As it is already objected in novelty of claim 1-6, 8-13 and 15-22 considering the prior art document D1/D3, the said document also considered for the lack of inventive step.

The subject matter of the claims 1-22 are obvious to a person skilled in the art, and do not constitute an invention as per the section 2(1)(j) of The Patents Act, 1970, as they do not involve an inventive step, in view of the documents D1-D5.

A composition comprising a specific antibody, a buffer, stabilizers and/or surfactants can be considered as being inventive if the concentration ranges of excipients and antibody reflect the stabilizing 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 stabilization agent suitable for one antibody is not necessarily suitable for another antibody and because the interfacial surface of each antibody is unique and requires specific formulation components to provide maximal stability. 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.

Hence, in view of the documents D1-D5, the subject matter of the instant application do not constitute an invention as per the section 2 (1) (ja) of The Patents Act, 1970.

(3).पेटेंट अयोग्यता /NON PATENTABILITY:

(I) निम्नलिखित कारणों से धारा 3 के खंड (3 (d); 3 (e); 3 (i);)के प्रावधान के तहत दावा(वे) ((1-6, 8-13 and 15-22); (1-14 and 20); (21);) सांविधिक रूप से पेटेंट योग्य नहीं हैं /
Claim(s) ((1-6, 8-13 and 15-22); (1-14 and 20); (21);) are statutorily non-patentable under the provision of clause (3 (d); 3 (e); 3 (i);) of Section 3 for the following reasons:

1. Subject matter of the claims 1-6, 8-13 and 15-22 attracts section 3(d) of The Patents Act, 1970, in view of the cited prior art.

2. Subject matter of the claim 1-14 and 18-20 attracts section 3(e), of The Patents Act, 1970, as it is a substance/composition obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof.

3. The subject matter of the claim 21 attracts the section 3(i) of The Patents Act, 1970, as it is related to a method of treatment.

(4).आविष्कार की एकलता /UNITY OF INVENTION:

(I) दावा(वों) 1-22 मे आविष्कार की एकलता की कमी है क्योंकि दावे किसी एक आविष्कार या आविष्कारों का समूह जो मिलकर एक आविष्कारी संकल्पना की संरचना करें उससे संबन्धित नहीं हैं। Claim(s) 1-22 lack(s) unity of invention as the claims do not relate to a single invention or to a group of inventions linked so as to form a single inventive concept:

The instant application lacks unity since the claims cover three inventions which are not linked by the same or corresponding special technical features thereby defining three different inventions which are not linked by a single general inventive concept.

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 (D3 paragraphs [0011]-[0022] concerning formulations for anti-LIGHT and antiCXCR5 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.

Group I: claims 1-22, are directed to Antibody formulations.

Group II: claims 1-4, 6, 7, 9, 10, 13, 14 (completely); 5, 8, 11, 12, 15-22 (partially) are directed to Antibody formulation comprising an anti-CXCR5 antibody.

Group III: claims 5, 8, 11, 12, 15-22 (all partially) are directed to Antibody formulation suitable for subcutaneous administration.

The above said three separate groups of inventions do not have single general inventive concept as required under S.10 (5) of the Act. Hence the claims contain plurality of distinct inventions and were objected.

(II) इस आवेदन का दावा (के दावे) सह-लंबित आवेदन संख्या के दावे के परस्पर विरोध मे है।
Claim(s)of the instant application conflict(s) with claim(s) of co-pending application no.

(6).प्रकटन की दक्षता /SUFFICIENCY OF DISCLOSURE:

(I) दावा(वे) 1-22 विनिर्देश मे प्रकट विषय पर आधारित नहीं है अथवा निम्नलिखित कारणों से विनिर्देश मे प्रकटन द्वारा समर्थित नहीं है।
Claim(s)'1-22' are not fairly based on the matter disclosed in the specification or not supported by the disclosure in the specification for the following reasons:

The scope of protection sought in claims is much broad compared to the provided disclosure in the description. In view of this, claims 1-22 are not fairly based on the subject matter disclosed in the specification [u/s 10(5) of the Act].

The claims 1-22 are not fully and particularly described with working example and hence the description provided does not full fill the requirements of section 10(4) (a), (b) & (c) of the Patents Act, 1970.

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.

Claims 17 and 22 concern lyophilized compositions for which the concentration is immaterial. This renders claims 17 and 22 unclear.

(7).क्षेत्र /SCOPE:

(I) दावा(वे) 1-22 आविष्कार के उस क्षेत्र जिस के लिए संरक्षण का दावा किया गया है उसे निम्नलिखित कारणों से परिभाषित नहीं करता(ते) है.
Claim(s) 1-22 does/do not define the scope of invention for which the protection is claimed for the following reasons:

1. Principal/independent claims must contain all the essential technical features, based on which novelty and inventive step can be established. Also, claims 18 and 19 do not define the specific components of the claimed kit.

2. Subject matter of the claims 9, 15-19 and 22 do not define a technical feature.

3. The terms and expressions "about", “any one of claims” and "greater than about", used in claims are vague and makes the scope of claims indefinite / unclear for which protection is sought and hence not allowable.

4. The subject matter of claims 1-22 is much broader than justified in the complete specification. The limitation of said claims shall be restricted to what is exemplified in the complete specification. Hence the instant application does not fulfill the requirement of section 10(4)(a) of the Patents Act, 1970 (as amended).

5. Claim 20 is very broad in scope & also does not clearly define the composition, the entire novel inventive concept in terms of its % or proportion of components as should be defined clearly & incorporated in claim.

6. Claims 1-22 have been drafted in vague and broad manner, which makes the scope of claims indefinite /unclear for which protection is sought and hence not allowable.

(8).स्पष्टता एवं संक्षिप्तता /CLARITY AND CONCISENESS:

(I) दावा(वे) 20 के संबंध मे स्पष्ट रूप से परीभाषित नहीं हैं.
Claim(s) 20 are not clearly worded in respect of:

1. Subject matter of claim 20 lacks clarity u/s 10(5) of The Patents Act, 1970 as the amount/ratio of the components of the composition are not clearly and succinctly defined.

2. Claim 20 recites use, which is not considered as an invention under section 2(1)(j) of the Patents Act, 1970 as it is neither a product nor a process.

(9).परिभाषिकता /DEFINITIVENESS:

(I) दावा(वे)1 निम्नलिखित कारणों से आविष्कार को पर्याप्त रूप से परीभाषित नहीं करता(ते) हैं
Claim(s) 1 do not sufficiently define the invention for the reasons as follows:

Independent claim should contain the subject matter related to a product or process defined by its essential technical features. Product defined by use or intended use lack definiteness u/s 10(5) of The Patents Act, 1970. Claims shall clearly characterize the structural features of the product, a functional/purpose limitation will not define the product.

(10).अन्य आवश्यकताएँ /OTHERS REQUIREMENTS:

(I)

The applicant is required to provide a marked up copy of all amendments made in the description and claims to meet the requirements of the objections raised.

भाग – III: औपचारिक आवश्यकताएँ /PART-III: FORMAL REQUIREMENTS

आपत्तियां /Objections	टिप्पणी /Remarks
Statement & Under Taking (Form 3 Details)	Details of the corresponding foreign applications filed should be updated as per section 8(1) (b) read with u/r 12(1),(2) of the Patents Act and Rules. Detail prosecutions of the corresponding foreign applications should be filed u/s 8(2) read with u/r 12(3) of the Patents Act and rule.

भाग-IV: रिकॉर्ड मे दस्तावेज़ /PART-IV: DOCUMENTS ON RECORD

निम्नलिखित दस्तावेज़ों के आधार पर यह परीक्षण रिपोर्ट तैयार की गयी है
The examination report has been prepared based on the following documents:

कार्यसूची तिथि / Docket Date	कार्यसूची संख्या /Docket Number	प्रविष्टि संख्या विवरण /Entry Number Description
01 Feb 2019	10446	1-New Application For Patent With Provisional /Complete Specification
19 Apr 2019	38599	Proof of Right
19 Apr 2019	38599	45-Form Of Authorisation Of Patent Agent - Form 26

25 Apr 2019	40230	OTHERS(NON CASH)
25 Apr 2019	40230	OTHERS(NON CASH)
19 Jul 2019	70016	3-Statement & Undertaking - Form 3
22 Jun 2020	63781	28(i)-Request For Examination After 18 months Publication - Form 18

नियंत्रक का नाम /Name of the Controller: Saravana Ram Prasad V G

नियंत्रक स्थान /Controller Location: Chennai

टिप्पणी: परीक्षण रिपोर्ट का उत्तर दाखिल करने की अंतिम तिथि / Note: Last date for filing response to the Examination Report: 24/05/2023