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एकस्व/PATENTS|अभिकल्प/DESIGNS|
व्यापार चिह्न/TRADE MARKS|भौगोलिक
उपदर्शन/GEOGRAPHICAL INDICATIONS



सत्यमेव जयते
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सं.संख्या/Ref.No /आवेदन संख्या/Application No/ 201847020374

दिनांक/Date of Dispatch/Email: 15/06/2022

सेवा मे, /To

Saibal Ghosh,

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Email : email@anandandanand.com, archana@anandandanand.com

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 में परीक्षण रिपोर्ट (अर्थात्, 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 05/11/2019 के उत्तर में जारी की गयी है। परीक्षण रिपोर्ट का उत्तर दाखिल करने की अंतिम तिथि (अर्थात्, 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 05/11/2019. 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.

Parvathy S

नियंत्रक पेटेंट/ Controller of Patents

संलग्न/Enclosed: अपरोक्त अनुसार/As above

टिप्पणी: यह इलेक्ट्रॉनिक रूप से उत्पन्न रिपोर्ट है।

NOTE: This is an electronically generated report.

सभी पत्राचार नियंत्रक एकस्व को उपरोक्त लिखित पते पर भेजा जाये।

All communications should be sent to the Controller of Patents at the above mentioned address.

परीक्षण रिपोर्ट / Examination Report

आवेदन संख्या /Application Number	201847020374
दाखिल करने की तिथि /Date of Filing	31/05/2018
पूर्विका दिनांक /Date of Priority	06/11/2015
पीसीटी अंतर्राष्ट्रीय आवेदन की संख्या व दिनांक / PCT International Application No. & Date	US2016060816 -- 07/11/2016
आवेदक /Applicant	IONIS PHARMACEUTICALS, INC.
परीक्षण हेतु अनुरोध की संख्या व दिनांक /Request for Examination No. & Date	R20194034551 05/11/2019
प्रकाशन की तिथि /Date of Publication	08/06/2018

इस परीक्षण रिपोर्ट के चार भाग हैं, अर्थात रिपोर्ट का सारांश, विस्तृत तकनीकी रिपोर्ट, औपचारिक आवश्यकताएँ तथा रिकॉर्ड में 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)(ग) के तहत आविष्कार /Invention u/s 2(1)(j)	नवीनता /Novelty	दावे /Claims: 1-156 हाँ /Yes	
		आविष्कारी कदम / Inventive step	दावे /Claims: हाँ /Yes	
		औद्योगिक उपयोगिता /Industrial Applicability	दावे /Claims: 1-156	हाँ /Yes
			दावे /Claims:	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: (1-112), (113-150 and 154), (151-152), (155 and 156) AND (150 and 154)	हाँ /Yes c, e, d, i and n	
		दावे /Claims:	नहीं /No	
3.	धारा 10(4) के अधीन प्रकटन की दक्षता (हाँ/नहीं निर्दिष्ट करें) /Sufficiency of disclosure u/s 10 (4) (Specify Yes/No)	1-156		
4.	[धारा 10(5) व 10(4) (ग)] के अधीन दावे /Claims [u/s 10(5) & 10(4) (c)]	स्पष्टता/ संक्षिप्तता /Clarity / Conciseness	दावे /Claims: हाँ /Yes	
		परिभाषिकता /Definitive	दावे /Claims: 1-156	नहीं /No
			दावे /Claims:	हाँ /Yes
		क्षेत्र /Scope	दावे /Claims: 149, 155 and 156	नहीं /No
दावे /Claims:	हाँ /Yes			
		दावे /Claims: 1-156	नहीं /No	

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 :

THE PATENT OFFICE

क्र. सं. / Sl.no	दस्तावेजों का विवरण /Details of documents	प्रकाशन तिथि(दिन/माह/वर्ष) / Publication date	उद्धरित दस्तावेज का प्रसंगिक विवरण (पृष्ठ व अनुच्छेद संख्या) / Relevant description (page and paragraph no.) of cited document	उद्धरित दस्तावेज के प्रसंगिक दावे / Relevant claims of cited document	अभिकथित आविष्कार के दावे /Claims of alleged invention
1	D1: US 2015/0126720 A1	07/05/2015	whole document	all claims	1-156

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

क्र. सं. / Sl.no	दस्तावेजों का विवरण /Details of documents	प्रकाशन तिथि(दिन/माह/वर्ष) / Publication date	उद्धरित दस्तावेज का प्रसंगिक 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	D2: SOTIRIOS TSIMIKAS ET AL: "Antisense therapy targeting apolipoprotein(a): a randomized. Double-blind. placebo-controlled phase 1 study". LANCET. vol. 386. no. 10002. Pages 1472-1483.	01/10/2015	whole document	-	1-156

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

(1). आविष्कारी कदम / INVENTIVE STEP:

(I) ऊपर उद्धरित दस्तावेज(जों) के संदर्भ D1 and D2 में स्पष्ट अध्यापन(जों) को ध्यान में रखते हुए, निम्नलिखित कारणों से दावा(वों) (1-156) में आविष्कारी कदम की कमी है

Claim(s) (1-156) lack(s) inventive step, being obvious in view of teaching (s) of cited document(s) above under reference D1 and D2 for the following reasons:

The subject matter of claims 1-156 do not constitute an invention u/s 2(1)(j(a)) of the Patents Act, 1970, as these are not inventive in view of the disclosures in following prior published documents:

D1: US 2015/0126720 A1 &

D2: SOTIRIOS TSIMIKAS ET AL: "Antisense therapy targeting apolipoprotein(a): a randomized. Double-blind. placebo-controlled phase 1 study"

D1 discloses an oligomeric compound (abstract; paragraph [0052]), wherein the oligomeric compound is ISIS 681257 (paragraph [0052]), for use in treating or preventing a disease or condition in a human (to treat, prevent, or ameliorate diseases, disorders or conditions related to apo(a) and/or Lp(a) in a human; abstract; paragraph [0017]), wherein the treatment comprises administering the oligomeric compound to the human during a dosing period (administering the composition to an individual in need thereof; paragraphs [0018], [0023]). Isis does not

disclose administering not more than 500mg of the oligomeric compound. It would have been obvious to a person of ordinary skill in the art, at the time the invention was made, to have disclosed administering not more than 500mg of the oligomeric compound, as the previous disclosure of Isis includes administration of a dose that can be stated in mg/kg (Isis; paragraph [0188]), and since discovering the optimum value of a results effective variable would only involve ordinary skill in the art, and the result would have been an improved dosage regimen treating or preventing a disease or condition in a human. It also discloses a method of treating a disease or condition in a human (a method to treat, prevent, or ameliorate diseases disorders or conditions related to apo(a) and/or Lp(a) in a human; abstract; paragraph [0017]), comprising administering an oligomeric compound to the human during a dosing period (administering the composition to an individual in need thereof; paragraphs [0018]. [0023]) wherein the oligomeric compound is ISIS 681257 (paragraph [0052]). it does not disclose administering not more than 500mg of the oligomeric compound. It would have been obvious to a person of ordinary skill in the art, at the time the invention was made, to have disclosed administering not more than 500mg of the oligomeric compound, as the previous disclosure of D1 includes administration of a dose that can be stated in mg/kg (Isis; paragraph [0188]), and since discovering the optimum value of a results effective variable would only involve ordinary skill in the art, and the result would have been an improved method for treating or preventing a disease or condition in a human.

D2 discloses a phase-I clinical trial, using single dose of 50, 100, 200 and 400 mg or multiple doses of 100,200 and 300 mg. According to D2 single doses of 50-400 mg did not decrease Lp(a) levels at day 30 whereas multi dose cohorts caused significant decreases. D2 also mentions present conjugated compounds in the last paragraph.

Thus, the person skilled in the art would not exercise inventive skills to arrive at the subject-matter of the present invention. Hence, the claims 1-156 are not inventive u/s 2[1(j)(a)] of the Patents Act, 1970.

(2).पेटेंट अयोग्यता /NON PATENTABILITY:

(I) निम्नलिखित कारणों से धारा 3 के खंड (c, e, d, i and n) के प्रावधान के तहत दावा(वे) ((1-112), (113-150 and 154), (151-152), (155 and 156) AND (150 and 154)) सांविधिक रूप से पेटेंट योग्य नहीं हैं /
Claim(s) ((1-112), (113-150 and 154), (151-152), (155 and 156) AND (150 and 154)) are statutorily non-patentable under the provision of clause (c, e, d, i and n) of Section 3 for the following reasons:

1. Claims 1-112 are not patentable u/s 3(c) of the Patents Act, 1970 as the claimed oligomeric compounds are isolated and available in nature.
2. Claims 113-150 and 154 are not patentable u/s 3(e) of the Patents Act 1970, as it is directed to a composition/method. The claims are inadequate in defining the technical aspects of the said composition/method which could hence be presumed to be a mere admixture and in absence of further adequate elaboration on experimental data, it is unclear whether any synergistic effect is produced or not.
3. Claims 151-152 are not patentable u/s 3(d) of the Patents Act, 1970 as the claimed sealed container/syringe is well known from the prior published documents.
4. Claims 155 and 156 are not patentable u/s 3(i) of the Patents Act, 1970 as they claim for method of treatment.
5. Claims 150 and 154 are not patentable u/s 3(n) of the Patents Act, 1970 as it claims for printed information.

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

(I) विनिर्देश आविष्कार की सर्वोत्तम विधि जो आवेदक को ज्ञात है व जिसके लिए वह संरक्षण का दावा करने का हकदार है, उसे निम्नलिखित कारणों से पूरक नहीं करता है।

The specification does not disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection for the following reasons:

claims 1-156 are broad and are not enabled in the specification via working examples in its whole breadth. The applicant is required to restrict the claims in accordance with the enablement in the specification. The complete specification shall, fully and particularly describe the invention and its operation or use and the method by which it is to be performed and disclose the best method of performing the invention, which is known to the applicant and for which he is entitled to claim protection u/s 10(4)(b) of the Patents Act, 1970.

(II) आविष्कार में उपयोग की गयी जैविक सामग्री के स्रोत व भौगोलिक उद्गम की सूचना.

Information of source and geographical origin of biological material used in the invention:

Source and geographical origin of the biological material used should be given in the specification in accordance with section 10(4)(d) of the Patents Act, 1970.

(4).क्षेत्र /SCOPE:

(I) दावा(ते) 1-156 आविष्कार के उस क्षेत्र जिस के लिए संरक्षण का दावा किया गया है उसे निम्नलिखित कारणों से परिभाषित नहीं करता(ते) है।
Claim(s) 1-156 does/do not define the scope of invention for which the protection is claimed for the following reasons:

Claims 1-156 do not meet the requirements of section 10(4)(c) of Patents Act, 1970 as the claim is defined in terms of the achievable end effect.

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

(I) दावा(ते) 1-156 के संबंध में स्पष्ट रूप से परिभाषित नहीं हैं।

Claim(s) 1-156 are not clearly worded in respect of:

1. Claims 1-156 do not meet the requirement of section 10(5) of Patents Act, 1970 as the phrases like "comprises", "comprising", "one or more", "at least", "optionally", "no more than", "not less than" which makes the claim too broad, unclear and vague as it represents an optional feature with no limiting effect, thus introducing ambiguity on the scope of the claim.
2. Claim 1 does not meet the requirement of section 10(5) of Patents Act, 1970 as the term ISIS 681257 is an internal designation and not widely recognized in the art. The claims have to be clear per se without any need to refer to the description. In the absence of the explicit indication of the nucleotide sequence and the modifications of the compound, the scope of claim 1 is not clear

(6).परिभाषिकता /DEFINITIVENESS:

(I) दावा(ते) 149, 155 and 156 निम्नलिखित कारणों से आविष्कार को पर्याप्त रूप से परिभाषित नहीं करता(ते) हैं

Claim(s) 149, 155 and 156 do not sufficiently define the invention for the reasons as follows:

Claims 149, 155 and 156 do not meet the requirement of section 10(4)(a) of Patents Act, 1970 as the claimed method is not well defined with its corresponding process steps.

(7).अन्य आवश्यकताएँ /OTHERS REQUIREMENTS:

(I)

Claim 157 claiming for the use is not an invention within the meaning u/s 2(1)(j) of the Patents Act, 1970.

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

आपत्तियां /Objections	टिप्पणी /Remarks
Statement & Under Taking (Form 3 Details)	<p>(a) Details regarding application for Patents which may be filed outside India from time to time for the same or substantially the same invention should be furnished within Six months from the date of filing of the said application under clause(b) of sub section(1) of section 8 and rule 12(1) of Indian Patent Act.</p> <p>(b) Details regarding the search and/or examination report including claims of the application allowed, as referred to in Rule 12(3) of the Patent Rules, 2003, in respect of the same or substantially the same invention filed in all the major Patent offices along with appropriate translation where applicable, should be submitted within a period of Six months from the date of receipt of this communication as provided under section 8(2) of the Indian Patents Act.</p>

भाग-IV: रिकॉर्ड में 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
31 May 2018	40397	1-New Application For Patent With Provisional /Complete Specification
12 Jun 2018	43141	OTHERS(NON CASH)
08 Nov 2018	80506	3-Statement & Undertaking - Form 3
29 Apr 2019	36702	3-Statement & Undertaking - Form 3
26 Sep 2019	81511	3-Statement & Undertaking - Form 3
05 Nov 2019	92998	28(i)-Request For Examination After 18 months Publication - Form 18
05 Mar 2020	22054	18(iii)-Changing Name/Address/Nationality/Address For Service - Form 13

नियंत्रक का नाम /Name of the Controller: **Parvathy S**

नियंत्रक स्थान /Controller Location: **Mumbai**

टिप्पणी: परीक्षण रिपोर्ट का उत्तर दाखिल करने की अंतिम तिथि / Note: Last date for filing response to the Examination Report: **15/12/2022**

