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सं.संख्या/Ref.No /आवेदन संख्या/Application No/ 202117000064 दिनांक/Date of Dispatch/Email: 07-08-2023

सेवा मे,/To
HARI HARAN SUBRAMANIAM,
SUBRAMANIAM & ASSOCIATES, Attorneys - at – law, 7th Floor, M3M Cosmopolitan, Sector 66, Golf Course Extension Road, Gurugram – 122001, National Capital Region, India Tel: +91-124-4849700 Fax: +91-124-4849798 / 4849799 Mobile Nos.: +91 7042499356; 9205965311
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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 30-06-2022 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 30-06-2022.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.

Brindha Shali Arulanandham
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	202117000064
दाखिल करने की तिथि /Date of Filing	01-01-2021
पूर्विक्ता दिनांक /Date of Priority	06-07-2018
पीसीटी अंतर्राष्ट्रीय आवेदन की संख्या व दिनांक / PCT International Application No. & Date	US2019040257 -- 02-07-2019
आवेदक /Applicant	AGIOS PHARMACEUTICALS, INC.
परीक्षण हेतु अनुरोध की संख्या व दिनांक /Request for Examination No. & Date	R20221023993 30-06-2022
प्रकाशन की तिथि /Date of Publication	19-03-2021

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: 1-16	हाँ /Yes
			दावे /Claims:	नहीं /No
		आविष्कारी कदम / Inventive step	दावे /Claims:	हाँ /Yes
			दावे /Claims: 1-16	नहीं /No
		औद्योगिक उपयोगिता /Industrial Applicability	दावे /Claims: 1-16	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: 1-16	हाँ /Yes 3(d)
			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: Group I: Claims 1-3; Group II: Claims: 4-6; Group III: Claims: 7-16	नहीं /No
4.	धारा 10(4) के अधीन प्रकटन की दक्षता (हाँ/नहीं निर्दिष्ट करें)/Sufficiency of disclosure u/s 10 (4) (Specify Yes/No)		1-16	
5.	[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
			दावे /Claims: 1-16	नहीं /No
		परिभाषिकता /Definitive	दावे /Claims:	हाँ /Yes
			दावे /Claims: 1-16	नहीं /No
		विवरण द्वारा समर्थित /Supported by description	दावे /Claims:	हाँ /Yes
			दावे /Claims: 1-16	नहीं /No
		क्षेत्र /Scope	दावे /Claims:	हाँ /Yes
			दावे /Claims: 1-16	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 :

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 2015138839 A1	17/09/2015	page 51, example 1, page 53-54, example 2, and Fig. 1-3; page 54, example 3 and Fig. 4-6	See claim 1-20	1-16

(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	D2: MINOR CAIRA ED-MONTCHAMP JEAN-LUG: "CRYSTALLINE POLYMORPHISM OF ORGANIC COMPOUNDS", TOPICS IN CURRENT CHEMISTRY; [TOPICS IN CURRENT CHEMISTRY], SPRINGER, BERLIN, DE, vol. 198, 1 January 1998 (1998-01-01), pages 163-208, XP001156954, DOI: 10.1007/3-540-69178-2_5.		chapter 3.1, pages 165-166		1-16

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 दस्तावेज़(जों) के संदर्भ D1 and D2 मे स्पष्ट अध्यापन(नों) को ध्यान मे रखते हुए, निम्नलिखित कारणों से दावा(वों) (1-16) मे आविष्कारी कदम की कमी है
Claim(s) (1-16) 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 1-16 of the present application lacks an inventive step in view of the cited prior art document:

D1: WO 2015138839 A1 (PD- 17/09/2015)

D2: MINOR CAIRA ED- MONTCHAMP JEAN-LUG: "CRYSTALLINE POLYMORPHISM OF ORGANIC COMPOUNDS", TOPICS IN CURRENT CHEMISTRY; [TOPICS IN CURRENT CHEMISTRY], SPRINGER, BERLIN, DE, vol. 198, 1 January 1998 (1998-01-01), pages 163-208, XP001156954, DOI: 10.1007/3-540-69178-2_5.

Document D1 discloses a compound namely, (S)-N-((S)-l-(2-chlorophenyl)-2-((3,3-difluorocyclobutyl)amino)-2-oxoethyl)-1-(4-cyanopyridin-2-yl)-N-(5-fluoropyridin-3-yl)-5-oxopyrrolidine-2-carboxamide (Compound 1) i.e. Ivosidenib or its pharmaceutically acceptable salts as anti-cancer drug.

The present application relates to various solid-state forms of Ivosidenib of formula (I)

D1 is considered to be the most relevant state of the art. The problem to be solved by the current application is considered to be the provision of an alternative solid state form of Ivosidenib. The biological activity of a compound depends primarily on its molecular structure. To reach its target it will be at some point in solution, e.g. in body fluids, where all differences among solid state forms disappear. The skilled person would thus expect that all solid state forms of Ivosidenib possess the same activity, at least to a certain extent. From common general knowledge it is known that the systematic investigation of a compound to determine whether it is prone to polymorphism is routine practice in the pharmaceutical industry. It is also known that most substances when investigated for a sufficiently long time will reveal more than one polymorph (D2, paragraph bridging pages 165-166). Furthermore, the methods to screen for polymorphs are well-known in the art (D2, chapter 3.1). The skilled person being interested in the therapeutic application of Ivosidenib would thus routinely screen for polymorphs of Ivosidenib. If such routine work yields another polymorph, e.g. the present Form E, then its provision is an obvious solution of the problem as defined above. In the absence of any substantiated unexpected property of the claimed form, which is relevant for its technical application, in comparison with the closest related form of Ivosidenib, no inventive step in the sense of section 2(1)(ja) of The Patents Act, 1970. This also holds true for any specific mixture of forms.

Claim 7 discloses a process for the preparation of a specific polymorphic form of Ivosidenib (identified as form L in the current application and Form 1 in D1). The process includes no technical features other than the conversion of a solid state form into form L. In D1 (page 54, second paragraph) Form 1 is obtained via a series of re-crystallization of a product purified by chromatography.

D1 is considered the most relevant state of the art. The problem to be solved by the current application is considered to be the provision of an alternative process for the preparation of Form L (Form 1) of Ivosidenib. It is common knowledge that one solid state form can be converted into another. This is how Form 2 is prepared in D1. In the absence of any technical features in claim 7 and a link between said features and an unexpected effect, it will not be possible to acknowledge an inventive step in the sense of section 2(1)(ja) of The Patents Act, 1970.

Hence, claims 1-16 of the alleged invention lack an inventive step in view of the cited art and do not meet the requirements of section 2(1)(ja) of The Patents Act, 1970.

(2).पेटेंट अयोग्यता /NON PATENTABILITY:

(I) निम्नलिखित कारणों से धारा 3 के खंड (3(d))के प्रावधान के तहत दावा(वे) (1-16) सांविधिक रूप से पेटेंट योग्य नहीं हैं /
Claim(s) (1-16) are statutorily non-patentable under the provision of clause (3(d)) of Section 3 for the following reasons:

A. The subject matter of claims1-6 of the present application attracts the provision of section 3(d) of The Patents Act, 1970 since the claimed compounds (Formula I) are considered to be the mere discovery of a new form (polymorphs) of a known substance which does not result in the enhancement of the known efficacy of that substance.

B. The subject matter of claims 7-16 of the present application attracts the provision of section 3(d) of The Patents Act, 1970 since the claimed process is considered to be the mere use of a known process that does not result in a new product or employs at least one new reactant.

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

(I) दावा(वों) Group I: Claims 1-3; Group II: Claims: 4-6; Group III: Claims: 7-16 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) Group I: Claims 1-3; Group II: Claims: 4-6; Group III: Claims: 7-16 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:

Claims 1-16 lack unity of invention u/s 10(5) of the Patents Act, 1970 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 following groups of invention are identified:

The current application discloses the solid state form of a methyl isobutyl ketone (MIBK) solvate of Ivosidenib (Form E) and a process for the preparation of Form L of ivosidenib. Document D1 discloses three solid state forms of Ivosidenib (a. the amorphous form [page 51, example 1], b. Form 1[page 53-54, example 2, claims 11-15 and Fig. 1-3], and c. Form 2 [page 54, example 3, claims 16-20 and Fig. 4-6]). Forms 1 and 2 correspond to forms L and B of the current application respectively. The common matter linking the inventions (Ivosidenib in solid state form) is therefore known from D1. The current application, therefore, solves two completely unrelated problems. On the one hand the provision of an alternative process for the preparation of form L and, on the other, the provision of alternative solid state forms of Ivosidenib each of which is not linked by a common technical feature. As the process and the separate claims do not share the same or corresponding special technical features, the requirements of unity according to Sec. 10(5) of The Act are not fulfilled. The current application is therefore considered to cover 13 separate inventions identified below:

Group I: Claims 1-3 relates to a solid state form E of methyl isobutyl ketone (MIBK) solvate of Ivosidenib.

Group II: Claims: 4-6 relate to an anhydrous solid state form M of Ivosidenib.

Group III: Claims: 7-16 relate to a process for making Form L of Ivosidenib comprising making one or more meta-stable forms of Ivosidenib in anhydrous, hydrated, or solvated form, and allowing such one or more meta-stable forms of Ivosidenib to convert to Form L, wherein the meta-stable forms are selected from: Form A, C, D, E, F, G, H, I, J, M, N.

The above groups of inventions are not so linked as to form a single general inventive concept as required under section 10(5) of the Act, in the present application on a priori basis, hence they lack unity of invention. However, the examination is done without prejudice to unity objection. The applicant may file divisional applications for the remaining groups of claims if necessary.

(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.

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

(I) दावा(वे) 1-16 विनिर्देश मे प्रकट विषय पर आधारित नहीं है अथवा निम्नलिखित कारणों से विनिर्देश मे प्रकटन द्वारा समर्थित नहीं है।
Claim(s)'1-16' are not fairly based on the matter disclosed in the specification or not supported by the disclosure in the specification for the following reasons:

claims 1-16 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) विनिर्देश पूर्णतयाः व विशेषकर आविष्कार तथा इसके संचालन तथा विधि के निष्पादन के संबंध मे विवरण नहीं देते हैं।
The complete specification does not fully and particularly describe the invention and its operation and the method by which it is to be performed in respect of:

There is no procedure in the application for the preparation of Form E. The person skilled in the art, therefore, has not been provided with sufficient information in order to carry out the invention as claimed and therefore lacks support [Section 10(4)(c) and 10(5) of The Act]. It is clear from the XRPD diffractogram for form E (Fig. 20), which has a noisy skewed baseline and very few discernible peaks, that the product has a low degree of crystallinity. The DSC scan (Fig. 21) includes a number of small peaks indicative of a mixture of solid states. The fact that form E is clearly a complex mixture not only means that it is questionable if it can be reproduced, leading to a further objection under section 10(4)(c) and 10(5) of The Act but also means that with the current data, it is not clear what is actually meant by form E [Section 10(4)(c) and 10(5) of The Act].

(III) आविष्कार का शीर्षक /Title of Invention:

Title to be amended to be in confirmity with the subject matter claimed.

(IV) आविष्कार मे 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.

(6).क्षेत्र /SCOPE:

(I) दावा(वे) 1-16 आविष्कार के उस क्षेत्र जिस के लिए संरक्षण का दावा किया गया है उसे निम्नलिखित कारणों से परिभाषित नहीं करता(ते) है.
Claim(s) 1-16 does/do not define the scope of invention for which the protection is claimed for the following reasons:

The terms Form A, C, D, E, F, G, H, I, J, M, N are each associated with a specific XRPD diffractogram. A hydrate or solvate would have a different diffractogram. The inclusion of hydrates and solvates in the claims therefore lacks clarity [Section 10(4)(c) and 10(5) of The Act]

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

(I) दावा(वे) 1-16 के संबंध मे स्पष्ट रूप से परीभाषित नहीं हैं.
Claim(s) 1-16 are not clearly worded in respect of:

1. The preamble of claim 7 relates to a process, however, the body of the claim represents the characterization of different solid Forms of Ivosidenib. No process steps are described in claim 7. The technical process steps for the conversion of one or more meta-stable Forms of Ivosidenib into Form L are not properly disclosed.

2. Again, the characterization of Forms A, G, H, and I are referred to figures showing the XRD pattern, DSC, and TGA profile, hence, referring to drafts like an omnibus claim.

Hence, the subject matter for which protection is sought is unclear. Therefore, claim 7 lacks clarity under section 10(4)(c) and 10(5) of The Patents Act, 1970. The same argument is also applicable to claims 8-16.

3. 1-16 do not meet the requirement of section 10(5) of Patents Act, 1970 as the phrases like "one or two or three or four or five", "comprising", "comprises", "one or more", "two or more" which makes the claim too, unclear

and vague as it represents an optional feature with no limiting effect, thus introducing ambiguity on the scope of the claim.

(8).परिभाषिकता /DEFINITIVENESS:

(I) दावा(वे)1-16 निम्नलिखित कारणों से आविष्कार को पर्याप्त रूप से परीभाषित नहीं करता(ते) हैं
Claim(s) 1-16 do not sufficiently define the invention for the reasons as follows:

The terms Form A, C, D, E, F, G, H, I, J, M, and N are arbitrary designations that have no commonly accepted meaning. Claims 1-16 in which the subject matter for which protection sought is defined using these terms therefore lack clarity [Section 10(4)(c) and 10(5) of The Act].

(9).अन्य आवश्यकताएँ /OTHERS REQUIREMENTS:

(I)

Claims 3, 6 and 7 are referring to the Figures. Hence it is an omnibus claim, which does not have any legal basis under The Patents Act. In fact, as the claims are unclear, vague, and unsearchable, such a claim cannot be allowed as per sections 10(4)(c) and 10(5) of the Act.

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

आपत्तियां /Objections	टिप्पणी /Remarks
Endorsement by /Assignment from Inventor	The proof of right in the form of endorsement or assignment from the inventors has not yet been filed. Therefore, the same should be filed in the prescribed manner as per section 7(2) of The Patents Act, 1970 along with petition.
Statement & Under Taking (Form 3 Details)	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 section 8(1) and Rule 12(1) of The Patents Act, 1970. B. Details regarding the search and/or examination report including claims of the application allowed, as referred to in Rule 12(3) of the Patents Rules, 2003, in respect of the same or substantially the same invention filed in all the major Patent office 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 Patents Act, 1970
Form 13	Form-13 dated 30-06-2022 to amend claims 1-50 to 1-16 by way of correction and explanation may be allowed.
Power of Attorney (Whether GPA, SPA, Stamped, requisite fee etc.)	On scrutiny it is found that the Power of Attorney [Ref Number E-45/11462/2023/DEL] is submitted dated 06/07/2023 as appeared from cash details, is beyond the extended timeline as provided by the Honourable Supreme Court guideline “Miscellaneous Application No.21/2022 in MA 665/2021 in SMW(C) No.3/2020 with Miscellaneous Application No.29/2022 in MA 665/2021 in SMW(C) No.3/2020”.

fee etc.)	Hence, the said Power of Attorney shall not be considered as a record. Fresh PA/GPA shall be submitted as per Rule 135 of The Patents Rules, 2003 with petition.

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 Jan 2021	80	1-New Application For Patent With Provisional /Complete Specification
23 Aug 2021	85297	3-Statement & Undertaking - Form 3
30 Jun 2022	67590	18(i)-Amendment Of Application Before Grant - Form 13
30 Jun 2022	67709	28(i)-Request For Examination After 18 months Publication - Form 18
31 Aug 2022	92090	3-Statement & Undertaking - Form 3
02 May 2023	50646	3-Statement & Undertaking - Form 3
06 Jul 2023	77169	45-Form Of Authorisation Of Patent Agent - Form 26

नियंत्रक का नाम /Name of the Controller: Brindha Shali Arulanandham

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: 07-02-2024