



भारत सरकार GOVERNMENT OF INDIA

एकस्व कार्यालय/THE PATENT OFFICE बौद्धिक सम्पदा भवन/ I.P.O. BUILDING एंटोप हिल/Antop Hill, एस.एम.रोड/ S.M.Road, मुंबई/ Mumbai- 400037 दुरभाष/Tel. No.: (091)(022)24153651

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सं.संख्या/Ref.No /आवेदन संख्या/Application No/ 38/MUM/2013

दिजांक/Date of Dispatch/Email: 23/05/2019

सेवा मे,/To

VIHITA CHEM PVT. LTD.,

VIHITA CHEM PVT. LTD. 305, GIDC, ANKLESHWAR, 393002, GUJARAT, INDIA

Email: patent@infinventip.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 (अर्थात, एकस्व नियम, 2003 (यथा संशोधित) के नियम 24-ख(3) में विनिर्दिष्ट आपत्तियों का पूथम कथन) इसके साथ संलग्न हैं। यह रिपोर्ट परीक्षण हेतु अनुरोध दिनांक 19/09/2015 के उत्तर में जारी की गयी हैं। परीक्षण रिपोर्ट का उत्तर दाखिल करने की अंतिम तिथि (अर्थात, इस रिपोर्ट में लगाई गयी सभी आवश्यकताओं के अनुपालन की अविधि) आवेदक को आपत्तियों का पथम कथन जारी होने की तिथि से छः माह हैं।

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 19/09/2015. 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 स्व(5) में विनिर्दिष्ट अविध 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 स्व(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 सताह दी जाती है कि शीघू निपटान हेतु अपना उत्तर शीघू पूस्तुत करें।
 You are advised to file the reply at the earliest for early disposal.

Ramesh Vanaparthi

नियंतूक पेटेंट/ Controller of Patents

संलग्न/Enclosed: अपरोक्त अनुसार/As above

टिप्पणी: यह इलेक्ट्रोनिक रूप से उत्पन्न रिपोर्ट हैं।

NOTE: This is an electronically generated report.

सभी पत्राचार नियंतुक एकस्व को उपरोटिलिस्वित 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	38/MUM/2013
दाखिल करने की तिथि /Date of Filing	07/01/2013
पूर्विक्ता दिलांक /Date of Priority	
पीसीटी अंतर्राष्ट्रीय आवेदन की संख्या व दिनांक / PCT International Application No. & Date	
आवेदक /Applicant	VIHITA CHEM PVT. LTD.
परीक्षण हेतु अनुरोध की संख्या व दिनांक /Request for Examination No. & Date	3798/RQ-MUM/2015 19/09/2015
पूकाशन की तिथि /Date of Publication	26/12/2014

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

-1. SUMMART OF TE	IL KLFOK I		
अधिनियम के तहत आवश्यकताओं पर विस्तृत टिप्पणियां /Requirements under the Act		दावों की संख्या /Claim Numbers	टिप्पणी /Remarks
धारा 2(1)(त्र) के तहत आविष्कार /Invention u/s 2(1)(j)	/ Inventive step	द्रावे /Claims:	ਗ਼ੱ /Yes
	आविष्कारा कदम / Inventive Steb	द्रावे /Claims: 1-8	नहीं /No
	औद्योगिक उपयोगिता /Industrial	द्रावे /Claims: 1-8	ਰ਼ĭ /Yes
	Applicability	द्रावे /Claims:	नहीं /No
धारा 3 के अधीन पेटेंट-अयोग्यता (यदि हाँ, खंड 3(क-त) /Non- patentability u/s 3		द्रावे /Claims: 1-8	हाँ /Yes d
	3(a-p))	द्रावे /Claims:	नहीं /No
धारा 10(4) के अधीन पूकटन की दक्षता (हाँ/नहीं निर्दिष्ट करें)/Sufficiency of disclosure u/s 10 (4) (Specify Yes/No)		yes	
[धारा 10(5) ਰ 10(4) (ग)] के अधीन दावे /Claims [u/s 10(5) & 10(4) (c)]	स्पष्टता/ संक्षिप्तता /Clarity /	द्रावे /Claims:	ਗ਼ੱ /Yes
	Conciseness	ਫ਼ਾਰੇ /Claims: 1-8	नहीं /No
	Definitive	द्रावे /Claims:	ਰ਼ĭ /Yes
	uismidodi /Delinilive	ਫ਼ਾਰੇ /Claims: 1-9	नहीं /No
	विवरण द्वारा समर्थित /Supported by	द्रावे /Claims:	ਗ਼ੱ /Yes
	description	द्रावे /Claims: 1-8	नहीं /No
	≥ /Coope	द्रावे /Claims:	ਗ਼ੱ /Yes
	ଞ୍ଚନ୍ଦୁ / Scope	द्रावे /Claims: 9	नहीं /No
	अधिनियम के तहत आवश्यक /Requirements under full 2(1)(ग) के तहत आविष्कार /Invention u/s 2(1)(j) धारा 3 के अधीन पेटेंट-अयोग्य patentability u/s 3 (if yes, specify section धारा 10(4) के अधीन प्रकटन करें)/Sufficiency of disc (Specify Yes/No)	/Requirements under the Act हारा 2(1)(त्र) के तहत आविष्कार /Invention u/s 2(1)(j) आहोगिक उपयोगिता /Industrial Applicability हारा 3 के अधीन पेटेंट-अयोग्यता (यदि हाँ, खंड 3(क-त) /Non- patentability u/s 3 (if yes, specify section3(a-p)) हारा 10(4) के अधीन प्रकटन की दक्षता (हाँ/नहीं निर्दिष्ट करें)/Sufficiency of disclosure u/s 10 (4) (Specify Yes/No) हारा 10(5) व 10(4) (ग)] के अधीन दावे /Claims [धारा 10(5) & 10(4) (c)] हिवदण द्वारा समर्शित /Supported by	রাষ্টানিব্যন ক নৱন आवश्यकनाओं पर विस्तृत टिप्पणियां /Requirements under the Act আব (2(1)(ন) ক নৱন রাষ্ট্রিকান্ত ব্যথানিব্যালা ব্যর্থা /Claims:

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 :

उद्धरित दस्तावेज़ का	
गारांशिक विवस्ता /गाउँ व	



क्. सं. / SI.no	दस्तावेज़ों का विवरण /Details of documents	पूकाशन तिथि(दिज/माह/वर्ष) / Publication date	अनुत्छेद संख्या) / Relevant description (page and paragraph no.) of cited document	उद्घरित दस्तावेज़ के प्रायंगिक दावे / Relevant claims of cited document	अभिकथित आविष्कार के दावे /Claims of alleged invention
1	D1 CN101759666 (B) 2012-09-05	05/09/2012			1-8
2	D2 WO 2005/028434 31/03/2005	31/03/2005			1-8

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

क्. सं. / Sl.no	दस्तावेज़ों का विवरण /Details of documents	पूकाशन तिथि(दिन/माह/वर्ष) /Publication date	उद्घरित दस्तावेज़ का प्रासंगिक विवरण (पृष्ठ व अनुद्छेद 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	D3 Sudip Mukhopadhyay,*,† S. Ananthakrishnan, and Sampatraj B. Chandalia Org. Proc. Res. Dev., 1999, 3 (6), pp 451–454 DOI: 10.1021/op990035n Publication Date (Web): November 2, 1999				1-8
2	D4 Minkin, V. I.; Dorofeenko, G. N. Russ. Chem. Rev. 1960, 599 30/11/1960	30/11/1960			1-8

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

(1).आविष्कारी कदम / INVENTIVE STEP:

(I) ऊपर उद्घरित दस्तावेज़(जों) के संदर्भ में स्पष्ट अध्यापन(नों) को ध्यान में रखते हुए, निम्नलिखित कारणों से दावा(वों) (1-8) में आविष्कारी कदम की कमी हैं

Claim(s) (1-8) lack(s) inventive step, being obvious in view of teaching (s) of cited document(s) above under reference for the following reasons:

The invention relates to novel process for the preparation of (2-bromo-4,5-dimethoxyphenyl) methyl bromide of formula (I), which is a key intermediate for the preparation of pinaverium bromide.

The process involved the reacting of dimethoxy phenyl with the brominating agent gives mono bromo compound followed by the treating with formaldehyde and followed by bromination to give phenyl substituted methyl bromide compound.

D1 teaches Preparation method of pinaverium bromide. The key intermediate in this process is (2-bromo-4,5-dimethoxyphenyl) methyl bromide prepared from the bromination of 4,5-dimethoxyphenyl) methyl bromide.



See the claim 1-12, chemical transformation reaction from compound 4 to compound 5.

D2 teaches the heterocyclic compounds, particularly heterocyclic compounds and related analogues that show broad utility, e.g., by inhibiting HSP90 and treating and preventing diseases that are HSP90-dependent.

In one aspect, the invention comprises the heterocyclic compounds and related analogues as specified below in Formulae A, I, IA-E, II, HA-D, III, IIIA-B, and TV an IVA and heterocyclic compounds that are produced by a process of the invention. Also included in the scope of the present invention are stereoisomeric forms, including the individual enantiomers and diastereomers, racemic mixtures, and diastereomeric mixtures, as well as polymorphs, solvates, esters, tautomers, pharmaceutically acceptable salts and prodrugs of these compounds. Stereoisomers of the compounds of the present invention may be isolated by standard resolution techniques such as, for example, fractional crystallization and chiral column chromatography.

In one aspect, the invention provides compounds of Formula A, or a polymorph, solvate, ester, tautomer, diastereomer, enantiomer, pharmaceutically acceptable salt or prodrug thereof, which show utility for inhibiting HSP90 and/or treating and preventing diseases that are HSP90-dependent.

See the claim 1-5.

D3 teaches the An alternative manufacturing process-scheme was developed

to synthesize 2-bromophenol and 2,6-dibromophenol involving oxidative bromination of a substrate protected in the para position in a two-phase system followed by deprotection involving

decarboxylation. Thus, selective oxidative bromination of 4-hydroxybenzoic acid in ethylene dichloride with HBr-H2O2 and subsequent decarboxylation in quinoline gave 90-95%

yield to the mono- or bromophenol depending upon the mol ratio of HBr: H2O2 employed in the oxidative bromination. Similarly, 4-methylphenol under identical reaction conditions

gave 99.6% selectivity to 2-bromo-4-methylphenol at 89% conversion ratio of 4-methylphenol.

See the abstract and scheme 1.

D4 teaches the veratraldehyde formation from the veratrol using a formylating agent DMF, POCI3.

See table 2. Entry 5

From the combined teachings of D1-D4 the process for the preparation of (2-bromo-4,5-dimethoxyphenyl) methyl bromide which is key reactant or intermediate used in the process of preparation of pinaverium bromide. The reaction disclosed are bromination of dimethoxy phenyl methyl bromide using NBS as brominating agent was disclosed in the said prior art. The claims 1-9, of alleged invention is obvious for a person skilled in the art to perform the invention form the teachings of the prior art. Therefore the said claims 1-9 of the alleged invention lacks inventive step in view of prior art documents u/s 2(1)(ja) of the Patents Act.

(2).पेटेंट अयोग्यता /NON PATENTABILITY:

(I) निम्नितियत कारणों से धारा 3 के खंड (d)के प्रावधान के तहत दावा(वे) (1-8) सांविधिक रूप से पेटेंट योग्य नहीं हैं / Claim(s) (1-8) are statutorily non-patentable under the provision of clause (d) of Section 3 for the following reasons:

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THE PATENT OFFICE

The argumentation/reasoning as provided under the clause of inventive step is also applies to section 3(d) of the Patents Act. in view of D1-D4, the process for the preparation of (2-bromo-4,5-dimethoxyphenyl) methyl bromide from reactant dimethoxybenzene is merely repetitive of known process without any advantageous effect over the process shown in the prior art. Therefore the claims 1-9 attracts the section 3d of the Patents Act.

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

(I) दावा(ते) 1-8 विनिर्देश में पूकट विषय पर आधारित नहीं हैं अथवा निम्नितियत कारणों से विनिर्देश में पूकटन द्वारा समर्थित नहीं हैं। Claim(s)'1-8' 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 claims in the alleged invention are not supported by the example in the complete specification both are different in the reaction process, the reagents. The complete specification not disclosed in the best way that was performed. Therefore the said complete specification attracts Section 10(4)(b) of the Patents Act.

(4).क्षेत् /SCOPE:

(I) दावा(वे) 9 आविष्कार के उस क्षेत्र जिस के लिए संरक्षण का दावा किया गया है उसे निम्नलिखित कारणों से परिभाषित नहीं करता(ते) हैं. Claim(s) 9 does/do not define the scope of invention for which the protection is claimed for the following reasons:

Claim 9 is referring to the description & example. Hence It is an omnibus claim, which does not have any legal basis under the Patents Act. In fact, as the claim is unclear, vague and unsearchable, such a claim cannot be allowed as per Section 10(4)(c) and 10(5) of the Patents Act.

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

(I) दावा(वे) 1-8 के संबंध में स्पष्ट रूप से परीभाषित नहीं हैं. Claim(s) 1-8 are not clearly worded in respect of:

The process claims are unclear they did not give any process parameters like temperature and other reaction conditions. Therefore the said claim attracts Section 10(4)(c) and 10(5) of the Patents Act.

(6).परिभाषिकता /DEFINITIVENESS:

(I) द्रावा(वे)1-9 निम्नतिखित कारणों से आविष्कार को पर्याप्त रूप से परीभाषित नहीं करता(ते) हैं Claim(s) 1-9 do not sufficiently define the invention for the reasons as follows:

- 1. Claim 3 is defined N-bromosuccinimide, the same do not have support from examples. The same should be deleted.
- 2. Solvents of claim 5 do not have support from the specification. The same should be deleted.

(७).अन्य आवश्यकताएँ /OTHERS REQUIREMENTS:



(I)

While making any amendments to complete specifications a marked/highlighted copy should be provided to show and understand how the amendments are carried in the original claims. Further, the support for the subject matter added should be submitted by pointing out the corresponding page(s) and paragraph(s) in the complete specifications and the subject matter of the amendments should be in compliance with section 59 of the Act. Any type of voluntary amendments should be made in only in a prescribed manner (form-13).

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

आपत्तियां /Objections	टिप्पणी /Remarks
	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 subsection(1) of section 8 and rule 12(1) of Indian Patents Act and rules;
Under Taking (Form 3 Details)	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 same or substantially the same invention filed in all the major Patent offices such as USPTO, EPO and JPO etc., 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 and rules.
Other Deficiencies	All the forms, claim sheet, drawings and other documents shall be duly signed by the applicant as per the Patent rules, 2003.

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

निम्नितिखत दस्तावेज़ों के आधार पर यह परीक्षण रिपोर्ट तैयार की गयी हैं

The examination report has been prepared based on the following documents:

कार्यसूची तिथि / Docket Date	कार्यसूची संख्या /Docket Number	पूर्विष्टि संख्या विवरण /Entry Number Description
07 Jan 2013	268	1-New Application For Patent With Provisional /Complete Specification
07 Jan 2013	268	2-Complete After Provisional Specification - Form 2 Check For No. OF Pages & Claims
07 Jan 2013	268	OTHERS(NON CASH)
07 Jan 2013	268	3-Statement & Undertaking - Form 3
07 Jan 2013	268	5-Declaration As To Inventorship - Form 5
19 Sep 2015	20195	45-Form Of Authorisation Of Patent Agent - Form 26
19 Sep 2015	20196	FORM 28
19 Sep 2015	20198	28(i)-Request For Examination After 18 months Publication - Form 18
04 Jan 2016	121	OTHERS(NON CASH)
04 Jan 2016	121	OTHERS(NON CASH)



िवयंतूक का जाम /Name of the Controller: Ramesh Vanaparthi

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:

23/11/2019