

República Argentina - National Executive BranchYEAR FOR THE DEFENSE OF LIFE, FREEDOM AND PROPERTY

Provision

Number: DI-2024-442-APN-ANP#INPI

CIUDAD DE BUENOS AIRES Friday, December 27th, 2024

Reference: Rejected by Art. 29 S/I.-

ACCORDING to the invention patent applications detailed in the list in the ANNEX to this document and; CONSIDERING:

That the article 29 of the Invention Patent and Utility Model Law No. 24,481 (of 1996), with its amendments Law No. 24,572, Law No. 25,859 and Law No. 27,444, establishes that: "If the observations made by the NATIONAL PATENT ADMINISTRATION are not accepted by the applicant, the patent application will be rejected upon written notification to the applicant, indicating the reasons and grounds for the resolution."

That the article 29 of Decree No. 260/96, Annex II, provides that: "When the objections raised are not satisfactorily resolved by the applicant, the examiner, after a reasoned report, which will be brought to the applicant's attention, may advise the NATIONAL PATENT ADMINISTRATION to reject the application, in accordance with its article 29."

That the hearing under article 29 has a term of THIRTY (30) days from the date of notification of the corresponding hearing, which was instituted by this NATIONAL PATENT ADMINISTRATION under the terms of the article 29 of Decree No. 260/96, Annex II.

That compliance with deadlines is mandatory so that the principles of promptness, economy and efficiency in procedures are not limited to a mere programmatic statement.

That the verification of the fact described in the standard entails the consequences foreseen by the legislator, without the need for any interpellation by this Administration.

That, therefore, it is appropriate that this NATIONAL PATENT ADMINISTRATION declare the rejection of the applications detailed in the ANNEX.

That the legal advisory body of this NATIONAL PATENT ADMINISTRATION has taken the appropriate measures.

That this is issued in accordance with the attributions conferred by the current legal regulation.

Therefore:

THE NATIONAL PATENT ADMINISTRATION PROVIDES:

ARTICLE 1 - Declare the rejection of the applications for invention patents contained in the list attached in the ANNEX, under the registration numbers indicated therein, in accordance with the provisions of article 29 of the Invention Patents and Utility Models Law No. 24,481 (of 1996) and its amendments Law No. 24,572, Law No. 25,859 and Law No. 27,444 and their respective regulatory article, and taking into account the considerations set forth in this provision.

ARTICLE 2 - To inform that this administrative act may be appealed through an Administrative Appeal provided for in article 72 of Law No. 24,481 (of 1996), which provides for its regulations and amendments, within thirty (30) calendar days from the date of notification; or, alternatively, within twenty (20) calendar days from the notification of the Reconsideration Appeal provided for in article 84 of the Administrative Procedures Regulation Decree 1759/72 (of 2017) and amendments, or within thirty (30) calendar days from the notification thereof, of the Hierarchical Appeal provided for in articles 89 and 90 of the aforementioned regulatory body. It is also reported that, in accordance with art. 1 of INPI Resolution No. 191/2020 (B.O. 11/25/2020): "(...) In all cases, the calculation of terms will begin after THIRTY (30) calendar days, counted from the publication of the list of Act numbers in the Patent Notification Bulletin, (...) made available to the public on the agency's website."

Likewise, according to art. 1 of INPI Resolution No. 191/2020 (B.O. 11/25/2020): "(...) In all cases, calculation of terms will begin after THIRTY (30) calendar days, counted from the publication of the list of Act numbers in the Patent Notification Bulletin, (...) made available to the public on the agency's website."

ARTICLE 3 - Notify, register and archive. -

Digitally signed by ARIAS Eduardo Ricardo Date: 2024.12.27 08:19:58 ART Location: Ciudad Autónoma de Buenos Aires

Eduardo Ricardo Arias Commissioner National Patent Administration Instituto Nacional de la Propiedad Industrial

INSTITUTO NACIONAL DE LA PROPIEDAD INDUSTRIAL

NATIONAL PATENT ADMINISTRATION

Av. Paseo Colón 717 (C1063ACH)-Ciudad de Bs.As.-República Argentina www.inpi.gov.ar



REPORT BEFORE FINAL RESOLUTION	APPLICATION NUMBER: 20170102299
APPLICANT: GILEAD SCIENCES, INC.	AGENT :1342
EXAMINER: MVIGO	DATE: 06/11/2024
PREVIOUS INF. DATE: 09/10/2019	DATE OF RESPONSE: 12/16/2019
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Int. Cl.⁷: CIP(2024.01) C07D 401/14, A61K 31/4439, A61P 31/18

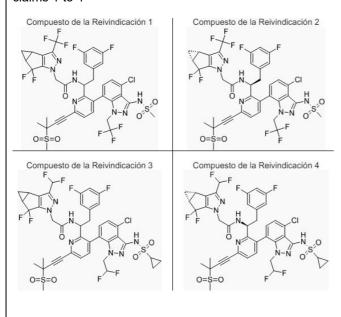
BASIS OF THE REPORT

ORIGINAL SUBMISSION DATE: 08/17/2017

DESCRIPTION, PAGES: 1 to 114 **ORIGINALLY SUBMITTED** DESCRIPTION, PAGES: 1 to 114 SUBMITTED IN: 07/12/2019 DESCRIPTION, PAGES: 1 to 122, cover SUBMITTED IN: 12/16/2019 CLAIMS: 88 **ORIGINALLY SUBMITTED** CLAIMS: 16 SUBMITTED IN: 07/12/2019 CLAIMS: 7 SUBMITTED IN: 12/16/2019 **ORIGINALLY SUBMITTED** DRAWINGS, FIGURE(S): 13 DRAWINGS, FIGURE(S): 13 SUBMITTED IN: 07/12/2019

NOTES:

On 12/16/2019, the applicant responds to the view of the background examination presenting a new cover page; "Substitution of 1-H-indazole compounds and 1-H-indazol-3-amine compounds useful as intermediates in their synthesis." Copy of the report and new statement of 7 claims, where compound (Ia), (Ib), (IIa) are claimed. (IIb), claims 1 to 4



IF-2024-62035222-APN-ANP#I¹NPI

REPORT BEFORE FINAL RESOLUTION

APPLICATION NUMBER: 20170102299

A compost from claims 1 to 4 for use in therapy, claim 5. A 1H-indazol-3-amine compost useful as an intermediate in the synthesis of two compounds from claims 1 to 4 of the formulas, claims 6 and 7

In the background examination, 2 documents were contested:

D1 US20140303164 (AR 094990) of which the undersigned did not make the correct observation of z 2 and the novelty was recognized, but due to the analysis presented in the notice, the lack of novelty of the claimed compounds is observed and D3 US20140296266 (AR 094990) which, because it shares priorities with D1, has a similar content.

On 06/05/2020, a request for attention was filed in the digital process, whose observations are pertinent where 2 documents D1: US20140296266 and D2: US20140303164 are mentioned (mentioned in the background examination). A summary of what was observed is made:

the formula IIIh of D2 is mentioned in particular

$$\begin{array}{c|c} & z^{\xi a} & \\ \hline \\ c & \\ N & \\ N & \\ Z^{2} & \\ A^{1} = A^{2} & \\ Z^{1w} & \\ N & \\ N & \\ \end{array}$$

Where Z2 can be (C2-C8)alkyne substituted by Z2C which can be - (SO2)R

p4 where R p4 can be methyl.

Therefore, it affects the novelty of the compounds claimed by art. 4 of law 24,481 and amendments to art. 4 b). Likewise, any invention that does not include the state of the art will be considered new. c) State of the art is understood as the set of technical knowledge made public before the date of filing of the patent application or, where applicable, of the recognized priority, by means of oral or written description, by exploration or by any other means of disclosure or information, in the country or abroad.

In full agreement with the "Guidelines for Examination of Patentability of Patent Applications for Chemical-Pharmaceutical Inventions", Joint Resolution MI No. 118 / MS No. 546 / INPI No. 107, of May 2, 2012, establish the following::

...2) Considering generic structures (iv) "Markush" Formula type structures

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1. The disclosure of a group of chemical compounds, even in a generic form, reveals all the components of that group, which become part of the state of the art.

Also considering art. 4 b) of law 24481 and amendments

What is claimed here would be a selection of what is disclosed in the aforementioned document. Therefore, the requirements of Novelty and Inventive Activity established in article 4 of Law 24,481/96 are not met.

In this sense, Joint Ministerial Resolution MI No. 118/MS No. 546/INPI No. 107, of May 2, 2012, clarifies (v) selection patents:

"There is nothing new in the selection of an element or elements already revealed by the state of the art, even when they present differential or superior properties, not previously demonstrated. The discovery of a differentiated or superior characteristic or property for a given element or group of elements, already known from the state of the art, does not represent novelty for the product or process."

Therefore, document US 20140303164 affects the novelty of formulas (Ia), (Ib), (IIa) and (IIb), violating art. 4 of Law 24481 and amendments.

Still in the call for attention, observations are made about the intermediate compounds of claims 6 and 7, considering them non-inventive, because

"The processes by which the compounds disclosed in D2 are obtained show similar intermediates with the structure adapted to the compound to be obtained. For example, the intermediate compounds of example 1 (page 96), example 3 (page 97), example 4 (page 98), example 5 (page 99), example 8 (page 101), example 9 (page 102), example 10 (page 103), example 14 (page 105), example 16 (page 106), example 19 (page 108), example 21 (page 111), example 22 (page 112), example 23 (page 113), and I could go on listing each of the intermediates used in many of the examples of synthesis of compounds disclosed by D2"...

"The compounds of claim 6 are obvious to any person skilled in the art based on what is disclosed by D2. Just as certain intermediates must be used to obtain the molecules intended to be patented in application P20170102299 (AR109364 A1), other intermediates must be used to obtain the compounds disclosed in D2, such as those selected in the respective examples and which have a logical structure with the final compound intended to be obtained."

According to the above, claims 6 and 7 are not inventive and violate art. 4d) of Law 24,481 and amendments.

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On 05/19/2022, a new call for attention was presented where documents D1: WO2014134566 equivalent to US 20140303164, mentioned in the call for attention of 06/05/2020, are described, reaching the same conclusion that compounds Ia and Ib are included in document WO 2014134566 and, therefore, are not new, violating art. 4 of law 24481 and amendments. It also refers to document D2 WO 2016033243, where the claimed compounds are included in formula I. It concludes that compounds Ia/Ib and IIa/IIb are disclosed in D1 and D2.

Makes observations on the intermediate compounds, considering them non-inventive, according to document D1 WO 2014134566.

The requested compound is Lenacapavir.

Therefore, it is concluded that the claimed compounds Ia/Ib, IIa/IIb and subordinate claims are not new and violate art. 4 of Law 24481 and amendments. Claims 6 and 7 referring to intermediate compounds are not inventive, violating art. 4d of Law 24481 and amendments.

Note 1: For the purposes of complying with art. 32 of Law 24,481 (of 1996), it is requested, for better provision, that whenever modifications are introduced in the claim document, a copy of the 1st claim be attached, adding the phrase: "x claims follow".

Note 2: For any questions regarding registration, it is necessary to schedule an appointment in advance by telephone with the examiner responsible (PHONE: 4344-4923 - 27).

Important:

In compliance with the requirement set out in Article 29 of Regulation of Law 24481 (Decree 260/96-Annex II), this latest report is issued prior to the issuing of the final resolution.

REPORT BEFORE FINAL RESOLUTION	APPLICATION NUMBER: 20170102299	
DICTAMEN: REJECT (IRF)		
Examiner's signature:		
MVIGO		
NOTIFICATION:		
	the process, the interested party shall be given a period	
From the report prior to the final resolution of the process, the interested party shall be given a period of 30 calendar days to comply with the observations made.		
	ended (without the need for an express request) for three atic extensions are used, at the time of responding to the the extensions used.	
If the applicant does not respond to the hearing within the stipulated period (hearing period + 3 extensions of 30 calendar days each), the application will be considered withdrawn, in accordance with article 29 of the Regulation of Law No. 24,481 (of 1996) and amendments.		



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Additional signature sheet Graphic report

Number: IF-2024-62035222-APN-ANP#INPI

CIUDAD DE BUENOS AIRES

Wednesday, June 12th, 2024

Reference: 20170102299

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Digitally signed by GESTION DOCUMENTAL ELECTRONICA - GDE Date: 2024.06.12 15:08:39 -03:00

Maria Ines Vigo Technical Analyst National Patent Administration Instituto Nacional de la Propiedad Industrial