

P- 2021/40373

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

DIRECCIÓN DE NUEVAS CREACIONES

E. S. D.

Re: Expediente No. NC2021/0017479

Solicitud de patente a nombre de VIIV HEALTHCARE UK (NO 5) LIMITED

Yo, CAROLINA DAZA MONTALVO identificada como aparece al pie de mi firma, domiciliada en la Carrera 11 No. 86-53, obrando como apoderada de la sociedad VIIV HEALTHCARE UK (NO 5) LIMITED, domiciliado en Middlesex, Gran Bretaña, solicitante de la patente de la referencia, en respuesta al oficio No. **3042** notificado electrónicamente el 26 de febrero de 2026, relacionado con los requerimientos de fondo de la solicitud, atentamente me permito presentar la siguiente información:

1. Modificación al capítulo reivindicatorio

Con fundamento en la facultad que confiere el artículo 34 de la Decisión 486 al solicitante para modificar la solicitud de patente en cualquier momento del trámite, presento junto a este memorial un nuevo capítulo reivindicatorio que consta de cinco (5) reivindicaciones, el cual reemplaza completamente el documento presentado el 4 de agosto de 2025. Específicamente, se realizaron las siguientes modificaciones:

1.1 Las reivindicaciones 6 a 8 fueron eliminadas del capítulo reivindicatorio.

Estas modificaciones no amplían de ninguna manera el objeto de la presente solicitud, y se realizan con el fin de definir la materia reclamada de forma clara, superando las objeciones planteadas por el examinador en su concepto técnico, por lo que el capítulo reivindicatorio presentado junto a este memorial se ajusta a las disposiciones del Artículo 34 de la Decisión 486 de 2000.

2. Pago de tasas

Considerando que el presente memorial se presenta junto con modificaciones a las reivindicaciones, se adjunta recibo por concepto de pago de tasa de modificación a la solicitud, según lo establecido en la Resolución 59669 de 2020.

Ahora, en relación con el número de reivindicaciones, atentamente me permito resaltar que junto a la presente respuesta no se realiza el pago de la tasa por concepto de reivindicaciones adicionales, toda vez que el nuevo capítulo reivindicatorio tiene un número de cláusulas menor que el presentado anteriormente.

3. Reivindicaciones relativas a uso

El examinador asevera que la reivindicación 6 no sería patentable de acuerdo con el Art. 14 de la Decisión 486, dado que la expresión *"adecuada para la administración oral, para la inyección intramuscular, o para la inyección subcutánea"* se considera como una referencia implícita al uso de la composición.

Al respecto, me permito manifestar que la reivindicación objetada no hace parte del capítulo reivindicatorio presentado junto a este memorial, superando así las objeciones del examinador.

4. Descripción

El Examinador sostiene que la descripción no proporciona soporte suficiente para la materia reclamada en las reivindicaciones 7 y 8, señalando que no se describe de manera clara cómo obtener una composición farmacéutica que contenga los agentes adicionales allí mencionados, no se especifican las proporciones en que dichos agentes deben combinarse, ni tampoco se aportan ejemplos ilustrativos.

Al respecto, el Solicitante manifiesta, en primer lugar, que no comparte dicha apreciación, toda vez que la descripción, considerada en su conjunto y a la luz de los conocimientos generales de la persona versada en la materia, proporciona información suficiente para llevar a cabo la invención sin esfuerzo indebido.

No obstante, es relevante destacar que el alcance de la solicitud ha sido sustancialmente restringido, y que las reivindicaciones objetadas (reivindicaciones 7 y 8) han sido eliminadas y no forman parte del pliego presentado junto a este memorial.

En consecuencia, la objeción formulada ha quedado sin objeto, puesto que se refería exclusivamente a materia que ya no es reivindicada. El conjunto actual de reivindicaciones no ha sido cuestionado por falta de soporte, y mantiene plena correspondencia con la descripción originalmente presentada.

Por ende, el Solicitante sostiene que la memoria descriptiva soporta de manera adecuada y suficiente la materia actualmente reivindicada, permitiendo a la persona normalmente versada en la materia reproducir la invención. En tal virtud, la solicitud cumple cabalmente con los requisitos de suficiencia descriptiva y soporte exigidos por la Decisión Andina 486.

5. Nivel inventivo

El examinador ha indicado que las reivindicaciones 1 a 5, 7 y 8 carecerían de nivel inventivo en vista de las enseñanzas del documento D1 (WO/2018/203235).

Con respecto a lo anterior, que *"se considerará que la invención tiene nivel inventivo, si para una persona del oficio normalmente versada en la materia técnica correspondiente, esa invención no hubiese resultado obvia ni se hubiese derivado de manera evidente del estado de la técnica"*.

Lo anterior implica que el análisis de nivel inventivo no debe limitarse a una comparación directa entre los objetos de las anterioridades y la solicitud en estudio. Por el contrario, el análisis de nivel inventivo requiere justificar técnicamente la supuesta obviedad de la invención, estableciendo cómo esta carecería de un salto cualitativo y hubiese sido obvia para una persona versada en la materia.

5.1 El análisis del examinador

El examinador señala que el documento D1 es el más cercano al estado de la técnica ya que divulga una serie de compuestos derivados de piridopirimidinas como inhibidores de la replicación del virus de la inmunodeficiencia humana (VIH) (Pág. 1).

De acuerdo con el examinador, la diferencia entre de la presente invención y D1 es la presencia del grupo trifluorometilo unido al sustituyente etoxi.

No obstante, en el Oficio se concluye que dicha modificación no se traduce en una mejora del efecto terapéutico ni de la potencia, argumentando que la inhibición de la replicación del VIH ya está descrita en D1. Además, el examinador afirma que D1 contempla ampliamente los sustituyentes etoxi fluorados (por ejemplo, *"-O-C₁-C₅ alquilo opcionalmente sustituido con 1-3 átomos de flúor"*) y, por lo tanto, considera que el compuesto reivindicado se encuentra dentro de su alcance y representa una modificación obvia.

5.2 La materia reclamada cumple con el requisito de nivel inventivo

a. La presente solicitud constituye una invención de selección

El solicitante manifiesta respetuosamente que la presente invención se enmarca plenamente dentro del concepto de invención por selección, tal como se define en la Sección 4.7.6.1 de la *Guía para examen de patente de invención y modelo de utilidad*, emitida por la SIC.

Según estas Directrices, una invención por selección implica la elección de un compuesto específico o un subgrupo restringido de una clase conocida más amplia, y se considera inventiva cuando la materia seleccionada presenta un efecto técnico no divulgado en el estado de la técnica y, además, inesperado.

De este modo, las Directrices de su despacho establecen explícitamente que:

- Una selección es inventiva cuando proporciona una ventaja imprevista, y
- Conforme a las Directrices de la SIC, la actividad inventiva no puede negarse únicamente porque el compuesto seleccionado pertenezca a un género previamente divulgado en el estado de la técnica, si demuestra efectos técnicos inesperados.

Asimismo, la actividad inventiva solo puede denegarse si se demuestra que la materia reivindicada no presenta el efecto que se alega, lo cual no ocurre en el presente caso.

Como consta en los documentos del trámite, en la presente solicitud, el compuesto reivindicado representa una selección específica y con propósito de la divulgación estructuralmente amplia y diversa de D1. Como se demuestra en la solicitud, este compuesto presenta mejoras inesperadas en estabilidad, perfil farmacocinético, biodisponibilidad y reducción de dosis, las cuales no se divulgan ni se sugieren en D1.

Por lo tanto, se cumplen plenamente los criterios establecidos por las Directrices para la identificación de una selección patentable.

b. Aplicación incorrecta de los criterios para estudiar una invención de selección

El solicitante manifiesta respetuosamente que el examinador no ha aplicado correctamente los criterios que rigen el estudio de las invenciones de selección.

En lugar de centrarse en si la selección reivindicada produce un efecto técnico inesperado, el examinador parece exigir comparaciones entre múltiples realizaciones distantes dentro de D1, sin importar su distancia con el compuesto de la presente solicitud. El solicitante respetuosamente sostiene que este enfoque es incompatible con la práctica establecida.

Contrariamente a lo que afirma el examinador, las Directrices colombianas para el examen no exigen demostrar superioridad sobre todos los compuestos dentro de una divulgación amplia, sino establecer que la materia seleccionada proporciona una ventaja inesperada sobre el estado de la técnica más cercano o una realización representativa. El solicitante ha cumplido claramente este requisito mediante los datos comparativos que obran en autos.

Además, en el expediente no se identifican elementos probatorios que desvirtúen los efectos técnicos alegados para el compuesto reivindicado. Por consiguiente, no existe fundamento para denegar la actividad inventiva por este motivo ni para solicitar información adicional.

c. Efecto Técnico y método Problema-Solución

Además, a diferencia del análisis del examinador, según el método problema-solución, al momento de evaluar la actividad inventiva, la cuestión relevante es si la característica estructural distintiva está causalmente vinculada a un efecto técnico.

En el presente caso, el solicitante ha demostrado claramente que la introducción del grupo trifluorometilo en el sustituyente etoxi es directamente responsable de las mejoras observadas en:

- estabilidad metabólica,
- Perfil farmacocinético superior,
- Biodisponibilidad y exposición sistémica ($AUC_{0-\infty}$)y

- reducción de la dosis.

Los resultados que demuestran dichas propiedades se explicaron en detalle en la respuesta al oficio anterior.

Asimismo, dada la amplia variabilidad estructural de D1, evidenciada por las múltiples selecciones necesarias para llegar al compuesto reclamado que realiza el mismo examinador, los datos comparativos proporcionados son apropiados y suficientes para establecer esta relación causal.

d. Ausencia de Motivación y Análisis Retrospectivo

En vista de lo anterior, el solicitante sostiene que el razonamiento expuesto presenta características propias de un análisis ex post facto, contrario a los lineamientos del método problema-solución, lo que invalida el análisis y las conclusiones con respecto a la ausencia de actividad inventiva en su totalidad.

Si bien la solicitud D1 divulga de forma genérica una amplia clase de compuestos que abarcan numerosas posibilidades estructurales, no contiene ninguna enseñanza, sugerencia o motivación específica que hubiera llevado al experto en la materia a seleccionar el compuesto reivindicado, y mucho menos a tener una expectativa razonable de lograr las ventajas técnicas demostradas en la presente solicitud.

En efecto, la única razón aparente por la que el examinador llega a la materia reivindicada a partir de la divulgación de D1 es porque la invención ya le es conocida. Este conocimiento ha llevado al examinador a identificar y aislar retrospectivamente fragmentos particulares de D1 que, sacados de su contexto original y combinados selectivamente, parecen aproximarse a la estructura reivindicada. Este enfoque no resulta compatible con la práctica de examen establecida en la Guía de la SIC ni con el método problema-solución.

En otras palabras, el examinador está realizando una reconstrucción selectiva y artificial del estado de la técnica, eligiendo divulgaciones específicas de una enseñanza genérica

amplia e indiferenciada únicamente porque se alinean, a posteriori, con la invención reivindicada. Este tipo de razonamiento no refleja la perspectiva de la persona normalmente versada en la materia en la fecha de prioridad, sino una perspectiva basada en la divulgación del solicitante.

Los principios establecidos de actividad inventiva prohíben estrictamente esta metodología. La cuestión relevante no es si la invención reivindicada *puede* reconstruirse a posteriori, sino si el estado de la técnica anterior habría proporcionado una indicación clara y directa hacia la materia reivindicada, junto con una expectativa razonable de éxito. Sin embargo, D1 no proporciona tal orientación.

Además, la mera existencia de una divulgación amplia que abarca innumerables variaciones teóricas no constituye una enseñanza específica ni una motivación para llegar a la selección reivindicada. Esto es particularmente cierto en el presente caso, donde **el compuesto seleccionado presenta propiedades técnicas inesperadas y ventajas que no se divulgan ni se anticipan en D1.**

Por consiguiente, la conclusión del examinador sobre la obviedad no se basa en una evaluación objetiva del estado de la técnica anterior, sino en una racionalización a posteriori impulsada por el conocimiento de la invención, y por lo tanto debe ser rechazada.

e. Carácter arbitrario de la objeción

Además, el solicitante manifiesta respetuosamente que la objeción elevada por el examinador es arbitraria e incompatible con la práctica de examen establecida en las directrices locales y comunitarias.

En efecto, el análisis del examinador parece ignorar la evidencia comparativa del expediente e impone un umbral probatorio más alto que el requerido por las Directrices de examen establecidas en la Guía de examen previamente citada. Como se ha señalado, no es necesario demostrar superioridad sobre cada realización divulgada en

D1, sino solo demostrar que la selección reivindicada proporciona una ventaja técnica, lo cual ha sido claramente establecido.

f. Conformidad con la práctica de examen internacional

Es igualmente relevante que la presente solicitud haya sido concedida en varias jurisdicciones importantes, incluyendo Australia, Europa, Japón, Estados Unidos, China e Israel, donde se examinó cuidadosamente el mismo estado de la técnica (D1).

En particular, el solicitante desea señalar que:

- La USPTO reconoció expresamente que la solicitud demuestra propiedades farmacocinéticas inesperadas en comparación con el compuesto más similar a D1 (Ejemplo 60.2) y, en consecuencia, concluyó que la materia reivindicada no es obvia.
- La OEP, tanto en su calidad de Autoridad Internacional de Búsqueda (IPRP) como durante el examen regional, confirmó la existencia de actividad inventiva, incluso tras revisar observaciones de terceros que cuestionaban la patentabilidad.
- La JPO también concedió la solicitud sin presentar objeciones respecto a la actividad inventiva, a pesar de tener conocimiento de la D1.

Para una mejor referencia se presentan dichos documentos como anexos. Estos resultados, aportados con carácter meramente persuasivo y no vinculante, muestran que diversas oficinas de patentes, aplicando estándares reconocidos internacionalmente, particularmente en relación con las invenciones de selección, han concluido que el compuesto reivindicado cumple con el requisito de actividad inventiva.

Dicho esto, el solicitante desea aclarar expresamente que esta referencia al trámite en otras jurisdicciones no pretende en modo alguno cuestionar, menoscabar ni desacreditar la autoridad o independencia de la Oficina de Patentes de Colombia, ni sugerir que su examen deba estar sujeto a decisiones extranjeras. Por el contrario, dichas referencias se proporcionan únicamente como evidencia persuasiva e ilustrativa de que la invención reivindicada ha sido reconocida consistentemente, bajo estándares legales comparables, como una invención con actividad inventiva.

En efecto, la convergencia de estos exámenes independientes indica claramente que la objeción planteada se deriva de una interpretación excesivamente restrictiva de los criterios aplicables, la cual se aparta tanto de la práctica internacional como de los principios del marco jurídico andino.

En vista de lo anterior, y en estricta aplicación del Artículo 18 de la Decisión 486, el Solicitante respetuosamente sostiene que la invención reivindicada no puede considerarse obvia para una persona normalmente versada en la materia.

De hecho, la evidencia proporcionada durante el trámite demuestra claramente que:

- el compuesto reivindicado constituye una selección no obvia de una amplia divulgación del estado de la técnica;
- dicha selección está asociada con efectos inesperados y técnicamente significativos; y
- no existe en D1 ninguna enseñanza, sugerencia o motivación que hubiera llevado al experto en la materia a la invención reivindicada con una expectativa razonable de éxito.

Por consiguiente, al evaluarse de acuerdo con el estándar jurídico apropiado bajo el régimen andino, la materia reivindicada cumple con el requisito de actividad inventiva, y la objeción planteada no se encuentra suficientemente sustentada desde el punto de vista fáctico ni jurídico.

Por estos motivos, el solicitante solicita respetuosamente que se retire íntegramente la objeción por falta de actividad inventiva.

6. Conclusión

Con las modificaciones introducidas y los argumentos presentados puede concluirse que:

- i) El nuevo pliego reivindicatorio se ajusta a las disposiciones del Artículo 34 de la Decisión 486/00,

- ii) La invención de la presente solicitud es clara y cuenta con el debido sustento en el capítulo descriptivo, a la vez que se encuentra divulgada de manera suficientemente completa, cumpliendo así con los requerimientos de los Artículos 30 y 28 de la Decisión 486;
- iii) La invención de la presente solicitud no resulta obvia ni se derivada de manera evidente del estado de la técnica, cumpliendo así con los requerimientos del Artículo 18 de la Decisión 486.

Por tanto, atentamente me permito solicitar a ese Despacho otorgar el privilegio de patente solicitado a la solicitud en estudio, toda vez que cumple a cabalidad con los requerimientos de la Decisión 486 de 2000.

Asimismo, respetuosamente solicito a ese Despacho pronunciarse en relación con todos los argumentos presentados en este memorial dando estricta aplicación al principio del debido proceso consagrado en el artículo 29 de la Constitución Nacional.

7. Anexos

- Capítulo reivindicatorio modificado, compuesto por 5 reivindicaciones.
- Recibo de pago por concepto de modificación a la solicitud.
- Copia de la decisión de concesión emitida por la USPTO, OEP, JPO, en su idioma original.

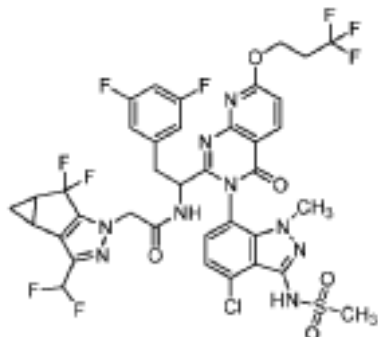
Señora Directora,



CAROLINA DAZA MONTALVO
C.C. 66.783.790 de Palmira Valle
TP-141563 CSJ
notificaciones@clarkemodet.com.co

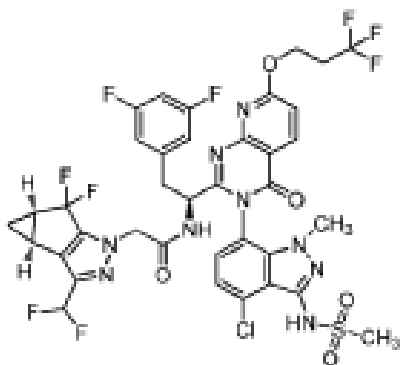
REIVINDICACIONES MODIFICADAS

1.El compuesto:



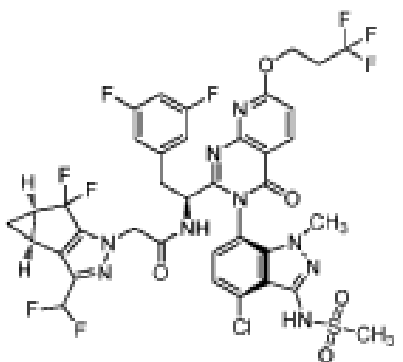
o una sal farmacéuticamente aceptable del mismo.

2.El compuesto de conformidad con la reivindicación 1 que tiene la estereoquímica que se ilustra a continuación



o una sal farmacéuticamente aceptable del mismo.

3.El compuesto de conformidad con la reivindicación 2 que tiene la estereoquímica que se ilustra a continuación



o una sal farmacéuticamente aceptable del mismo.

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Reivindicaciones Modificadas en respuesta a Oficio 3042

28 de mayo de 2026

4. Una composición farmacéutica que comprende un compuesto o sal de conformidad con cualquiera de las reivindicaciones 1-3.

5. Una composición de conformidad con la reivindicación 4 que comprende además un excipiente farmacéuticamente aceptable.



**Superintendencia de
Industria y Comercio**

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT: 800.176.089-2

COMPROBANTE DE RECAUDO SISTEMA SIPI

Radicado: NC2021/0017479

Recibo: 26-261703

Fecha: 26/05/2026

CAROLINA MERCEDES DAZA MONTALVO

CC: 66.783.790

Pago PSE No: 1263521

CUS: 336843298

Patente PCT

DERIVADOS DE PIRIDO [2,3-D] PIRIMIDINA COMO INHIBIDORES DE LA REPLICACIÓN DEL VIRUS DE INMUNODEFICIENCIA HUMANA

Detalle del pago

Id.	Rentístico	Concepto y Servicio	Cant.	Val. Unit.	Subtotal
1	50005-01-03	Modificaciones / Correcciones al registro Patente PCT (DESCUENTO INTERNET)	1	\$ 236,000	\$ 236,000
TOTAL					\$ 236,000



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NOTICE OF ALLOWANCE AND FEE(S) DUE

20462 7590 06/20/2024
GlaxoSmithKline
Global Patents UP4110
1250 South Collegeville Road
Collegeville, PA 19426

EXAMINER	
CREWS, JARET JAMES	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 06/20/2024

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/268,107	02/12/2021	Eric P. GILLIS	PU66776	6192

TITLE OF INVENTION: PYRIDO[2,3-D]PYRIMIDINE DERIVATIVES AS INHIBITORS OF HUMAN IMMUNODEFICIENCY VIRUS REPLICATION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	09/20/2024

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

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Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via the USPTO patent electronic filing system or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	09/20/2024

EXAMINER	ART UNIT	CLASS-SUBCLASS
CREWS, JARET JAMES	1623	514-258100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required)

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via the USPTO patent electronic filing system ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/268,107	02/12/2021	Eric P. GILLIS	PU66776	6192
20462	7590	06/20/2024	EXAMINER	
GlaxoSmithKline Global Patents UP4110 1250 South Collegeville Road Collegeville, PA 19426			CREWS, JARET JAMES	
			ART UNIT	PAPER NUMBER
			1623	
DATE MAILED: 06/20/2024				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).

<https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf>

Routine uses of the information in this record may include disclosure to:

- 1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;
- 2) a federal, state, local, or international agency, in response to its request;
- 3) a contractor of the USPTO having need for the information in order to perform a contract;
- 4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;
- 5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;
- 6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;
- 7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;
- 8) another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c));
- 9) the Office of Personnel Management (OPM) for personnel research purposes; and
- 10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Notice of Allowability	Application No. 17/268,107	Applicant(s) GILLIS et al.	
	Examiner JARET J CREWS	Art Unit 1623	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's Amendment filed on 02/08/2024.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 3-4,6-12 and 16-27. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892) 2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date ____. 3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material ____. 4. ☒ Interview Summary (PTO-413), Paper No./Mail Date. <u>06/04/2024.</u>	5. ☒ Examiner's Amendment/Comment 6. ☒ Examiner's Statement of Reasons for Allowance 7. ☐ Other ____
--	---

/JARET J CREWS/ Examiner, Art Unit 1623	/YIH-HORNG SHIAO/ Primary Examiner, Art Unit 1623
--	--

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in an interview with Nora Stein on June 4, 2024.

The application has been amended as follows:

In the most recent claim set filed February 8, 2024:

Claim 3, the recitation "which is" (line 2) is now changed to "of".

Claim 6, the phrase "A composition according to Claim 4" is now changed to "The pharmaceutical composition according to Claim 4, wherein the composition is".

Claim 7, the recitation "administration of a compound" is now changed to "administration of an effective amount of a compound".

Claim 18, the phrase "A pharmaceutical composition according to claim 17" is now changed to "The pharmaceutical composition according to claim 17, wherein the composition is".

Claims 7 and 19, immediately after the phrase “according to Claim 3” in claim 7 and “according to claim 16” in claim 19, insert the phrase “to the human”.

Priority

This application is a 371 of PCT/IB2020/055653 06/17/2020 which claims benefit to provisional application 62/863,406 06/19/2019.

Claim Status

The claim set filed February 8, 2024 has been entered. Claims 1-2, 5 and 13-15 have been canceled. Claims 16-27 are new. Therefore, claims 3-4, 6-12 and 16-27 as amended are examined on the merits herein and allowed in this Office Action.

Response to Arguments

Applicant's Remarks filed February 8, 2024 have been entered. Applicant's amendment has overcome all claim objections in the non-final office action mailed November 8, 2023.

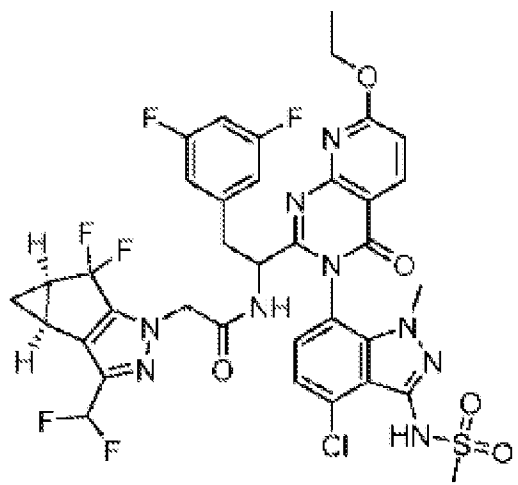
The rejection of claims 11-12 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as indefinite is withdrawn as Applicant has deleted the compounds S-648414, GSK3640254, and GSK373993/VH3739937.

The provisional rejection of claims 1-5 on the ground of non-statutory double patenting as being unpatentable over claims 1-2 of co-pending application 17/918,654; The provisional rejection of claims 1-12 on the ground of non-statutory double patenting as being unpatentable over claims 1-2 of co-pending application 17/918,654 in view of

Graupe et al.; The provisional rejection of claims 1-7 and 9-12 on the ground of non-statutory double patenting as being unpatentable over claims 1, 18-19 and 24 of co-pending application 17/756,971; and The provisional rejection of claims 1-12 on the ground of non-statutory double patenting as being unpatentable over claims 1, 18-19 and 24 of co-pending application 17/756,971 in view of Graupe et al. are withdrawn as the specification presents data supporting unexpected pharmacokinetic properties of compounds of claims 3 and 16 compared to compound 60.2 of Babu, the closest structural compound, as detailed below.

Closest Prior Art

The closest prior art to the compound according to claims 3 and 16 or a pharmaceutically acceptable salt thereof as claimed in claim 3 is Babu et al. (Published 11/08/2018, WO 2018203235, IDS filed 02/12/2021).



Babu teaches exemplary compound 60.2, see pg. 229, example C1103.1. The compound of Babu is considered to be the closest structural compound, since it differs from the compounds recited in claims 3 and 16 through the fact that it contains an extra CF₃ group on the ethoxy chain. However, the

present application discloses data supporting unexpected pharmacokinetic properties compared to compound 60.2 disclosed on pg. 229 of Babu, see pg. 229, compound 60.2.

The present application provides pharmacokinetic parameters including drug clearance, where example 1 of the present invention was compared directly to example 60.2 of Babu, and showed a greater than 2-fold lowering of clearance rates in all four species tested relative to example 60.2, see specification pg. 42, tables 2 and 3, and thus would mean a lower dose of example 1 would be required to achieve a high concentration of drug in circulation, see specification, pg. 42, lines 14-20.

Therefore, the exemplary compound of Babu does not anticipate nor render obvious the compound as claimed in claims 3 and 16 and the compound of claims 3 and 16 are free of the prior art.

Notice of Allowability

Claims 3-4, 6-12 and 16-27 are allowed. The following is an examiner's statement of reasons for allowance: The teachings of Babu do not anticipate nor render obvious the compounds of claims 3 and 16 for the reasons stated above.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 3-4, 6-12 and 16-27 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JARET J CREWS whose telephone number is (571)270-0962. The examiner can normally be reached Monday-Friday: 9:00am-5:30pm EST.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 17/268,107
Art Unit: 1623

Page 7

/JARET J CREWS/
Examiner, Art Unit 1623

/YIH-HORNG SHIAO/
Primary Examiner, Art Unit 1623

Decision to Grant a Patent (PatentsApplication2021-575482)

* NOTICES *

JPO and INPIT are not responsible for any damages caused by the use of this translation.

1. This document has been translated by computer. So the translation may not reflect the original precisely.
2. **** shows the word which can not be translated.

Decision to Grant a Patent

Patent Application Number: Japanese Patent Application No. 2021-575482

Date proposed: January 6, 2025

Examiner, Japan Patent Office: Keisuke Tsuchihashi 3839 4P00

Title of the invention: pyrido[2,3-D]pyrimidine derivatives as inhibitors of human immunodeficiency virus replication

Number of Claims: 10

Patent Applicant: Bebe, Healthcare, UK, (Number 5), Limited

Representative: Yukitaka Nakamura (and three others)

This application is to be granted a patent, since no reason for refusal has been found.

, Chief Examiner / Deputy, Examiner, Assistant Examiner, Classification Judge: Rie ICHINOMIYA, Keisuke DOBASHI, Tomomi SAOTOME 3441 3839, 3759

- Distinction of Patent: Usually

- Reference: see below

- Application of Patent Act Article 30: not applicable

- Change of the Title of the Invention: No

- Deposit of Microorganisms

References

Patent Application Number: Japanese Patent Application No. 2021-575482

- FI

C07D 471/04 116,C07D 471/04 CSP,A61K 31/52,A61K 31/537,A61K 31/4985,A61K 31/5365,A61K 31/635,A61K 31/4545,A61K 31/675,A61K 31/513,A61K 31/439,A61K 31/519,A61P 31/18,A61P 43/00 121,A61K 45/00, A61K 31/451

-Field investigated (IPC, DB name)

C07D

A61K CAlus/REGISTRY(STN)

- Reference patent documents

WO 2018/203235 (WO, A1)

- Reference books and magazines

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference PU66776	FOR FURTHER ACTION		See item 4 below
International application No. PCT/IB2020/055653	International filing date (<i>day/month/year</i>) 17 June 2020 (17.06.2020)	Priority date (<i>day/month/year</i>) 19 June 2019 (19.06.2019)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant VIIV HEALTHCARE UK (NO.5) LIMITED			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*. I(a).
2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☒	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☒	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application
4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 21 December 2021 (21.12.2021)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Cécile Chatel e-mail ro.ib@wipo.int

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/IB2020/055653

International filing date (day/month/year)
17.06.2020

Priority date (day/month/year)
19.06.2019

International Patent Classification (IPC) or both national classification and IPC
INV. A61P31/18 C07D471/04 A61K31/519

Applicant
VIIV HEALTHCARE UK (NO.5) LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0
Fax: +49 89 2399 - 4465

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Gavriliu, Daniela

Telephone No. +49 89 2399-0



Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. ☐ forming part of the international application as filed:
 - ☐ in the form of an Annex C/ST.25 text file.
 - ☐ on paper or in the form of an image file.
 - b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
 - ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).
 - ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-15</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	<u>1-15</u>
	No: Claims	
Industrial applicability (IA)	Yes: Claims	<u>1-15</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D1 WO 2018/203235 A1 (VIIV HEALTHCARE UK NO 5 LTD [GB]) 8
November 2018 (2018-11-08)

2 Industrial applicability(Article 33(4)PCT).

For the assessment of the present claims 7-12 on the question whether they are industrial applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may also allow, however, claims to a known compound for the manufacture of a medicament for a new medical treatment.

3 Independent claims

- compounds as claimed claim 1
- their pharmaceutical composition (claim 4)
- their pharmaceutical uses (claims 7 and 13-15)

4 Novelty (Article 33(1) and (2) PCT)

The compound of claim 1 is a selection from the generic formula (I) of D1. Thus, the present claimed subject-matter directed to a compound as depicted in claim 1 in all its stereochemical structures and the corresponding pharmaceutical salts, compositions and uses is considered to fulfill the requirements of Article 33(1) and (2) PCT.

5 Inventive step (Article 33(1) and (3) PCT)

The subject-matter of claim 1 can be considered as a selection of a formula (I) from the compounds of formula (I) disclosed in document D1 for the same use, namely the inhibition of HIV. The present application discloses data supporting unexpected pharmacokinetic properties compared to compound 60.2 disclosed on page 229 of D1. Compound 60.2 of D1 is considered as being the closest structural compound since it differs from the one of the current claim 1 only through the fact that it contains an extra CF₃ group on the ethoxy chain. The skilled person did not have any hint in D1 to arrive at the present substitution with the expectation that such improved activity will be present.

Thus, on account of the data present on pages 36-45 of the application an inventive step could be acknowledged.

Re Item VI

Certain documents cited

D2 WO 2020/157692 A1 (VIIV HEALTHCARE UK LTD [GB]) 6 August
 2020 (2020-08-06)

A compound substituted by fluorine atoms on the alkoxy chain is disclosed in D2. The present compound differs from the one of claim 1 of D1 on account of the specific substitution on the ethoxy chain (i.e. 3 fluorine atoms instead of 2 fluorine). D2 is not relevant for assessing inventive step since it is published after the present filing date.