Third Party Observations (TPOs) filed between January and December 2025

Note:

TPO No. refers to the publisher's internal reference number.

Appl. No. provides information on the International Application No. and the Publication Number.

National phase reflects information provided on WIPO's PATENTSCOPE database as at the date of preparing this document. However, this data is dynamic and may not provide accurate information on the actual status of the patent application.

<table>
<tr><td>TPO No.</td><td>267</td></tr>
<tr><td>Appl. No.</td><td>WO2024076915 (WO’915): Small Molecule: HIV</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024076915</td></tr>
<tr><td>Applicants</td><td>GILEAD SCIENCES, INC.</td></tr>
<tr><td>Priority Date</td><td>63/413,192 04.10.2022 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’915 claims 4’-ethynyl-thionucleoside analogues (substituted thiophene ring instead of the ribose sugar ring) as HIV reverse transcriptase inhibitors (NRTI) and compositions and methods thereof for the treatment and prevention of HIV. It specifically claims the following:
1. compounds of formulae I-IX
2. specifically claimed compounds being derivatives such as phosphate metabolites, ProTide prodrugs, etc of thionucleoside analogues.
WO915 claims (i) thionucleoside analogues of Compounds of Formulae I-IX (such as phosphate derivatives, ProTide prodrugs, etc), salts and stereoisomers thereof, wherein the 2-alkynyl-tetrahydrothiophen-3-ol ring (thiofuranose) is attached to a Het moiety (analogues of adenine, guanine, cytosine), which has peripheral substitutions; (ii) Specific 2-ethynyl-2-(hydroxymethyl)-tetrahydrothiophen-3-ol thionucleoside compounds (with cyclopropylamino, ethoxyl, fluoro substitutions on the Het moiety); triphosphate derivatives thereof; ProTide prodrug thereof (with phenoxy and 2-ethyl-1-butyl alanyl ester as the masking groups); (iii) pharmaceutical compositions comprising the claimed compound and additional therapeutic agents and method of treating HIV therewith.
<u>TPO filed:</u> The TPO observed through the prior art documents that the claims in WO’915 lacks inventive step, as the thionucleoside analogues of compounds of formulae I–IX claimed in the Application as the compounds have been already disclosed, and only peripheral substitutions have been made that are also known in the art. The compounds of the present Application, WO’915 was compared to the compounds in the prior art to emphasize the similarity in the structures, and to show that the claims lack inventive step.
<u>No. of prior art documents used in No. of notes.:</u> 8 prior art documents through 7 notes to assail inventive step. One of the prior art documents was a PX document that is it was published after the priority date but before the filing date of the present Application WO’915.
<u>Additional comment filed:</u> to point out the (i) Interchangeable nomenclature for chemical compounds, (ii) lack of inventive step of the claims of the present Application, WO’915 by comparative tables to show the similarity between the present Application and the prior art.
<u>Importance of Application:</u> WO915 relates to 4-thionucleoside analogues (compounds, its phosphate derivatives and protide prodrugs thereof) as inhibitors of HIV reverse transcriptase (NRTI) for treatment/prevention of HIV as long-acting compounds.</td></tr>
<tr><td>Date of Filing of TPO</td><td>04/02/2025</td></tr>
<tr><td>National Phase</td><td><table><tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr></table></td></tr>
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	European Patent Office	06.05.2025	2023798056	Published 13.08.2025

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<tr><td>TPO No.</td><td>268</td></tr>
<tr><td>Appl. No.</td><td>WO2024094690 (WO’690): Biologic: HIV</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024094690</td></tr>
<tr><td>Applicants</td><td>VIIV HEALTHCARE UK (NO.5) LIMITED.</td></tr>
<tr><td>Priority Date</td><td>63/421,737 02.11.2022 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’690, claims a bispecific anti-HIV gp120-binding protein comprising an anti-V3 broadly neutralizing antibody (bNAb) comprising two heavy chains and two light chains; and at least one CD4 domain, wherein the CD4 domain is attached directly or by a linker to the N-terminus or C-terminus of the anti-V3 bNAb heavy chains (one or both) and/or light chains (one or both); pharmaceutical composition, method, use thereof; kit comprising in separate containers: an anti-HIV gp120-binding protein and an anti-viral drug that inhibits cellular entry, replication, or transcription of HIV in a human; nucleic acids, vector, host cell and method of production thereof; a thermostable soluble CD4 domain; and a bispecific anti-HIV gp120-binding protein comprising an anti-V3 bNAb or an antigen-binding Fab’ or F(ab’)2 fragment thereof; and at least one CD4 domain, wherein the C-terminus of the CD4 domain is attached directly or by a linker to the N- terminus of the anti-V3 heavy chain variable region or light chain variable region.
<u>TPO filed:</u> The TPO observed through the prior art documents that the single domain CD4 and polypeptide modifications in D1 domain for improved soluble expression, thermal stability, specificity, as well as the fusion protein construct was known. The single domain CD4-G4S linker-Antibody or fragments thereof, that binds to HIV gp120, for inhibiting HIV was already known. Also, it was shown through prior art that synergistic activity between anti-V3 loop Abs and soluble CD4 domain was already disclosed. The prior art documents brought out the significance of linker length. The TPO through the prior art documents showed that the claims of WO’690 lacked inventive step.
<u>No. of prior art documents used in No. of notes.:</u> 6 prior art documents through 4 notes to assail inventive step.
<u>Additional comment filed:</u> to point out that (a) the use of computational simulation tool for designing additional stabilizing mutations to generate thermally stable soluble CD4 molecules as disclosed in the present Application, WO’690 and (b) certain (likely inadvertent) errors in Claim 48 of WO’690.
<u>Importance of Application:</u> WO’690 relates to a bispecific construct comprising the V3-bnab and CD4 domains. VH4527079 (VH-079) is a bispecific molecule in clinical trials (NCT06652958, Phase I) and is disclosed in the ViiV Healthcare pipeline.</td></tr>
<tr><td>Date of Filing of TPO</td><td>03/03/2025</td></tr>
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<tr><td>Israel</td><td>21.04.2025</td><td>320413</td><td></td></tr>
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Thailand	30.04.2025	2501002841	
Japan	01.05.2025	2025525326	
India	02.05.2025	202517042728	Published 27.06.2025
Algeria	21.05.2025	DZP2025000586	
Eurasian Patent Organization	30.05.2025	202591370	
Singapore	30.05.2025	11202502180S	Published 30.05.2025
European Patent Office	02.06.2025	2023800776	Published 10.09.2025
Russian Federation	02.06.2025	2025114747	Published 03.07.2025
Republic of Korea		1020257017658	Published 02.07.2025

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<tr><td>TPO No.</td><td>269</td></tr>
<tr><td>Appl. No.</td><td>WO2024138121 (WO'121): Biologic: TB</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024138121</td></tr>
<tr><td>Applicants</td><td>AKAGERA MEDICINES, INC.</td></tr>
<tr><td>Priority Date</td><td>63/476,916 22.12.2022 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO'121 claims lipid nanoparticle composition comprising specific lipids and nucleic acid: (i) the lipids: ionizable cationic lipid, ICL (KC3-OA, KC4-OA, etc), phospholipids (DSPC, HSPC, DPPC), anionic phospholipids (DPPS, DSPS, DSPG, DPPG), PEG2000-DMG, cholesterol, each lipid in a specific mol% ratio to that of total lipids, (ii) nucleic acid, mRNA (3'- and 5'-UTR, modified pseudo-uridine, polyA tail, 5'-cap, signal peptide) encoding the Mycobacterium tuberculosis (Mtb) antigens, LNP composition as a vaccine, and method of administration therewith to induce an immune response against Mycobacterium Tuberculosis (Mtb) infection. The mRNA encoding MTb proteins selected from the group consisting of CFP10/Rv3874, ESAT-6/Rv3875, Mtb32A/Rv0125, Mtb39A/Rv1196, Ag85B/Rv1886c, EsxW/Rv3620c, EsxV/Rv3619c, PE13/Rv1195, PPE30/Rv1802, PPE40/Rv2356c and TB10.4/Rv0288. T cell epitopes or MTb antigens recognized by T cells, or MHC- Class I epitopes or a concatenated sequence.

<u>TPO filed:</u> The TPO observed through the prior art documents that (a) the identical or similar LNP composition was already known, (b) sequences for the Mtb T-cell epitopes were already known, (c) the claimed Mtb proteins or antigens were already disclosed and a fusion protein construct comprising the antigens and the epitopes as well as the connecting linkers were already known, (d) tools for predicting the order of the construct was also known.

<u>No. of prior art documents used in No. of notes.:</u> 11 prior art documents through 8 notes to assail inventive step.

<u>Additional comment filed:</u> to point out that (a) an earlier Application by Akagera Medicines, WO2022115645 [attached as Citation 1 in TPO], already disclosed identical or similar lipid nanoparticle components and mRNA vaccine for tuberculosis (TB); (b) the epitope sequences claimed in WO121 are already covered in the prior art document Lindestam Arlehamn, et al. [Citations 2 and 2A] and WO2011063263 [Citation 2B].

<u>Importance of Application:</u> WO'121 relates to LNP composition as a vaccine, the LNPs comprising Mtb antigens, T cell epitopes thereof, or nucleic acid (mRNA) encoding the same. WO'121 possibly relates to m-RNA based prophylactic vaccine in the pipeline of Akagera, AKG-200 for M. tuberculosis preclinical stage; presentation at the TB vaccine forum by Ross Fulton.</td></tr>
<tr><td>Date of Filing of TPO</td><td>22/04/2025</td></tr>
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	India	17.07.2025	202517068248	Published 14.11.2025
	China	22.07.2025	202380092150.7	Published 17.10.2025
	European Patent Office	22.07.2025	2023908620	Published 29.10.2025

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<tr><td>TPO No.</td><td>270</td></tr>
<tr><td>Appl. No.</td><td>WO2024163262 (WO’262): Small Molecule: HIV</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024163262</td></tr>
<tr><td>Applicants</td><td>MERCK SHARP & DOHME LLC</td></tr>
<tr><td>Priority Date</td><td>63/482,133 30.01.2023 US
63/607,595 08.12.2023 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’262 claims prodrugs of nucleoside reverse transcriptase inhibitors of Formulae I–VI, comprising the 4-amino-2-chloro-pyrrolopyrimidine nucleobase attached to THF substituted with 2-ethynyl, 2-CH2-OH and 3-OH groups, that include several prodrugs (including ester, carbonate esters, phosphoramidate, amide, carbamate, etc) explored at position 4 of nucleobase and 3’- or 5’- position on THF; certain specific compounds; compositions and methods thereof; claimed compound and composition for use, in the treatment or prophylaxis of HIV, or delay in onset of AIDS.
<u>TPO filed:</u> The TPO observed through the prior art documents that (a) identical categories of prodrugs including ester, carbonate ester, phosphoramidate, amide, carbamate, etc. comprising alkyl, hetero/aryl, hetero/ cycloalkyl (e.g. odol, adamantly) groups as terminal groups were known. In fact, these prodrugs, as disclosed in the prior art, were for identical nucleoside analogues of pyrrolopyrimidine attached to 2-ethynyl-THF (including MK-8527) and islatravir. The prior art also disclosed the compositions, and methods thereof.
<u>No. of prior art documents used in No. of notes.:</u> 5 prior art documents through 3 notes to assail novelty (to the extent of overlap) and inventive step.
<u>Additional comment filed:</u> to point out (a) the nomenclature of the nucleoside compounds that are used interchangeably; (b) to assert the similarity of the identical categories of prodrugs claimed and/or disclosed in the Application and the prior art documents through Tables of comparison; and (c) the priority date of the claims relating to variable W – on the pyrrolopyrimidine ring and di-substituted or carbamate prodrugs as exemplified, would be the second priority document dated 08.12.2023 and not the first priority document dated 30.01.2023.
<u>Importance of Application:</u> WO’262 relates to prodrugs of Compound A, which is now identified as MK-8527. MK-8527 is being clinically investigated as an alternative to islatravir, as a NNRTI.</td></tr>
<tr><td>Date of Filing of TPO</td><td>30/05/2025</td></tr>
<tr><td>National Phase</td><td>
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<tr><td>New Zealand</td><td>16.07.2025</td><td>823415</td><td>Published 25.07.2025</td></tr>
<tr><td>Australia</td><td>24.07.2025</td><td>AU2024213822</td><td></td></tr>
<tr><td>Israel</td><td>27.07.2025</td><td>322370</td><td></td></tr>
<tr><td>Mexico</td><td>29.07.2025</td><td>MX/a/2025/008847</td><td>Published 02.09.2025</td></tr>
<tr><td>Thailand</td><td>29.07.2025</td><td>2501004996</td><td></td></tr>
<tr><td>United Arab Emitates</td><td>30.07.2025</td><td>P2025-02367</td><td></td></tr>
<tr><td>India</td><td>21.08.2025</td><td>202517079406</td><td>Published 12.09.2025</td></tr>
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	Eurasian Patent Organization	28.08.2025	202592261	
	Singapore	29.08.2025	11202504953U	Published 29.08.2025
	China	26.09.2025	CN2024800224165	
	European Patent Office		2024709908	Published 10.12.2025

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<tr><td>TPO No.</td><td>271</td></tr>
<tr><td>Appl. No.</td><td>WO2024160956 (WO’956): Biologic: TB</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024160956</td></tr>
<tr><td>Applicants</td><td>INSTITUT NATIONAL DE LA SANTÉ ET DE LA RECHERCHE MÉDICALE,
ASSISTANCE PUBLIQUE-HÔPITAUX DE PARIS (APHP),
UNIVERSITÉ PARIS-EST CRÉTEIL VAL DE MARNE,
BAYLOR RESEARCH INSTITUTE</td></tr>
<tr><td>Priority Date</td><td>23305134.1 02.02.2023 EP</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’956 claimed antibody directed against CD40, comprising the CD40 heavy chain, fused to the TB polyepitope polypeptide comprising Ag85B, ESAT6 and Rv1980, and CD40 light chain; VH and VL domains, heavy chain and/or light chain; (b) such antibody, wherein the polyepitope polypeptide (Mtb Antigens conjugated via linkers L1 or L2, selected from FlexV1, f1, f2, f3 or f4), specifically “Ag85B-f1-ESAT-6-f4-Mpt64”, is fused via FlexV1 linker to the heavy chain of the 12E12 antibody and comprising a light chain; (c) the antibody is fused to the antigen directly or via a linker (FlexV1); (d) vaccine composition (CD40.TB) thereof; (e) polynucleotide, vector and host cell thereof; (f) method for vaccinating against Mtb.
<u>TPO filed:</u> The TPO observed through the prior art documents that Ab-antigen complex comprising an antigenic polypeptide (Ag85B–f2–ESAT-6–f4–Rv1980) fused to the heavy chain of an anti-CD40 12E12 Ab were already disclosed. NCBI BLAST analysis of the sequences claimed in WO956 with the corresponding sequences in the prior art documents showed that the sequences showed 100% sequence identity, only with a slight difference in the VH and VL domains, which, however, was disclosed in another prior art document claiming the similar anti-CD40 antibody construct comprising SARS-CoV-2 antigens.
<u>No. of prior art documents used in No. of notes.: 4</u> 3 prior art documents were filed through 3 notes to assail novelty (to the extent of overlap) and inventive step.
<u>Additional comment filed:</u> to highlight that all the sequences and the constructs claimed in the present Application have been already claimed and/or disclosed.
<u>Importance of Application:</u> The molecules based on the platform comprising the anti-CD40 12E12 Ab are in clinical trials.</td></tr>
<tr><td>Date of Filing of TPO</td><td>02/06/2025</td></tr>
<tr><td>National Phase</td><td>
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<tr><td>European Patent Office</td><td></td><td>2024703023</td><td>Published 10.12.2025</td></tr>
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TPO No.	**272**
Appl. No.	**WO2024196661 (WO'661): Small Molecule: HIV**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024196661
Applicants	EXAVIR THERAPEUTICS, INC.
Priority Date	63/490,999 17.03.2023 US
Details	**Summary of Application:** WO661 claims crystalline forms 1, 2 and 4 and mixture of crystalline forms 1 and 4 of the compound M2CAB (Cabotegravir stearate), characterized by a XRPD pattern (Cu Kα radiation) showing characteristic peaks (in degrees 2θ) at 17.8, 5.6, 21.6 and 21.6, respectively, and a DSC profile having a characteristic endotherm; and method of treating, inhibiting, and/or preventing a viral (retroviral, HIV) infection by administering a crystalline form or mixture thereof. **TPO filed:** The TPO observed through prior art documents that M2CAB is a known compound and that its crystal forms along with their biological activity and characterization is already known. Also, several crystallization techniques (parameters-solvent, temperature, mixing, etc are important), and different characterization methods (XRPD, DSC) are already known and are also regarded important for regulatory approval process. **No. of prior art documents used in No. of notes.:** 11 prior art documents were used in 7 notes to assail inventive step. **Additional comment filed:** Yes. The Additional Comments were filed to highlight that the claimed crystal forms of M2CAB did not show any technical advance, advantage or effect over those forms already known in the prior art. **Importance of Application:** The application relates to crystal forms of compound M2CAB, the LA stearate ester prodrug of cabotegravir, being developed as XVIR-110 and VH-310.
Date of Filing of TPO	17/07/2025

National Phase

Office	Entry Date	National Number	National Status
Mexico	12.09.2025	MX/a/2025/010833	
Israel	14.09.2025	323337	
Japan	16.09.2025	2025554208	
Australia	29.09.2025	AU2024238583	
India	03.10.2025	202517095215	Published 14.11.2025
European Patent Office	17.10.2025	2024775382	Published 21.01.2026
Republic of Korea	17.10.2025	1020257034827	Published 23.01.2026
Russian Federation	17.10.2025	2025128350	Published 01.11.2025

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<tr><td>TPO No.</td><td>273</td></tr>
<tr><td>Appl. No.</td><td>WO2024196662 (WO’662): Small Molecule: HIV</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024196662</td></tr>
<tr><td>Applicants</td><td>EXAVIR THERAPEUTICS, INC.L.</td></tr>
<tr><td>Priority Date</td><td>63/491,002 17.03.2023 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’662 claims (i) a pharmaceutical composition comprising 25–45 w/w% of (a) either a crystalline form of compound (Cabotegravir Stearate; M2CAB), or a mixture of crystalline forms thereof, (b) cryoprotectant (sugar-trehalose), (c) surfactant (d) PEG, (e) phosphate buffer (pH 7.0); (ii) composition comprising plurality of nanoparticles comprising the crystalline form or mixture thereof, surfactant and/or PEG; nanoparticles within defined range of particle size distribution, z-average, PDI; (iii) composition where the mixture comprises 10–30% w/w of 1 form and 70–90% w/w of the other form; the mixture of forms is characterized by characteristic peaks in XRPD pattern; (iv) Process of preparing the said compositions; (v) Method of treating, inhibiting and/or preventing HIV by intramuscularly administering the composition.
<u>TPO filed:</u> The TPO observed through prior art documents that the pharmaceutical composition comprising the known prodrug M2CAB was already disclosed, also its nanoparticles and excipients used in the formulation are already known. Further, it was shown that XRPD characterization of M2CAB, and its use for treating/preventing HIV was already known.
<u>No. of prior art documents used in No. of notes.:</u> 8 prior art documents were used in 4 notes to assail inventive step.
<u>Additional comment filed:</u> Additional comments were filed to bring out that the claimed crystal forms of M2CAB did not show any technical advance, advantage or effect over those forms already known in the prior art.
<u>Importance of Application:</u> The application relates to composition comprising the crystal forms, mixture thereof, of compound M2CAB, the LA stearate ester prodrug of cabotegravir, being developed as XVIR-110 and VH-310.</td></tr>
<tr><td>Date of Filing of TPO</td><td>17/07/2025</td></tr>
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<tr><td>India</td><td>03.10.2025</td><td>202517095283</td><td></td></tr>
<tr><td>European Patent Office</td><td>17.10.2025</td><td>2024775383</td><td>Published 21.01.2026</td></tr>
<tr><td>Republic of Korea</td><td>17.10.2025</td><td>1020257034852</td><td>Published 23.01.2026</td></tr>
<tr><td>Russian Federation</td><td>17.10.2025</td><td>2025128346</td><td>Published 07.11.2025</td></tr>
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<tr><td>TPO No.</td><td>274</td></tr>
<tr><td>Appl. No.</td><td>WO2024215947 (WO’947): Biologic: HIV)</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024215947</td></tr>
<tr><td>Applicants</td><td>DUKE UNIVERSITY,
TRIAD NATIONAL SECURITY, LLC,
THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA</td></tr>
<tr><td>Priority Date</td><td>63/495,528 11.04.2023 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The Application, WO’947, claims recombinant HIV envelope immunogens which are V2 optimized for unmutated common ancestor binding, and nucleic acids (mRNA) encoding the same, immunogenic compositions with lipid nanoparticles, etc. and methods of inducing immune response.

<u>TPO filed:</u> The TPO observed through prior art documents that similar V2 optimized immunogens were already known, as well as the immunogen stabilizing mutations identified through signature analysis was already known; and the use of these immunogens in a mRNA-LNP vaccine was also obvious.

<u>No. of prior art documents used in No. of notes.:</u> 6 prior art documents were used in 4 notes to assail inventive step. One of the documents used in the TPO was published after the priority date but before the filing date of WO’947 to assail novelty (to the extent of overlap), and/or inventive step.

<u>Additional comment filed:</u> Yes. The Additional Comments were filed to highlight that the immunogens claimed (Claim 1- Table 5; Fig.21/22) can validly claim the filing date as the priority date, and that there is insufficiency of disclosure due to lack of technical effect data for the immunogens. It also pointed out that a readable format of the sequence listing file was unavailable.

<u>Importance of Application:</u> The application relates to an earlier application for which TPO was filed (WO2023064424, TPO NO: 242) that related to V2 optimization of HIV Env being explored by Duke University as one of the strategies for immunogen development.</td></tr>
<tr><td>Date of Filing of TPO</td><td>11/08/2025</td></tr>
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<tr><td>European Patent Office</td><td>11.11.2025</td><td>2024789480</td><td>Published 18.02.2026</td></tr>
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<tr><td>TPO No.</td><td>275</td></tr>
<tr><td>Appl. No.</td><td>WO2024214041 (WO’041): Biologic: HBV</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024214041</td></tr>
<tr><td>Applicants</td><td>GLAXOSMITHKLINE INTELLECTUAL PROPERTY DEVELOPMENT LIMITED</td></tr>
<tr><td>Priority Date</td><td>63/495,613 12.04.2023 US
63/580,470 05.09.2023 US
63/595,033 01.11.2023 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> Secondary Application for Hepatitis B virus (HBV). WO’041 claims methods for treating chronic hepatitis B (CHB), by administering sequentially an antisense oligonucleotide (ASO) compound (eg. Bepirovisen, AHB-137, AUS-1493, etc.) and interferon (PEG-IFN-alpha-2a), in specific dosing regimen, after determining the HBsAg baseline as not greater than the threshold level of 1000 IU/ml to 3000 IU/ml, and the HBeAg levels.
<u>TPO filed:</u> The TPO observed through prior art documents that the compounds Bepirovirsen and PEG-IFN-alpha-2a, and sequential administration of these was already disclosed in prior art, and the stratification of the patients based on the baseline antigen levels of HBsAg and HBeAg were known, and the endpoints and quantification methods were known. The dosing regimens were also disclosed earlier.
<u>No. of prior art documents used in No. of notes.:</u> 12 prior art documents were used in 8 notes to assail novelty (to the extent of overlap) and/or inventive step.
<u>Additional comment filed:</u> Additional comments were filed to highlight that i) the first filed priority document dated 12.04.2023 is unavailable on the patentscope portal; (ii) Claims 38, 40 and 41 can only validly claim a later priority date of 01.11.2023; (iii) all claims lack novelty to the extent of overlap and inventive step.
<u>Importance of Application:</u> The application relates to the sequential combination of Bepirovirsen and PEG-IFN-alpha-2a which is in Phase 2 clinical trials. Also, AHB-137 is in clinical trials and is reported to be better compared to Bepirovirsen.</td></tr>
<tr><td>Date of Filing of TPO</td><td>12/08/2025</td></tr>
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<tr><td>Republic of Korea</td><td>07.11.2025</td><td>KR1020257037432</td><td></td></tr>
<tr><td>European Patent Office</td><td>12.11.2025</td><td>2024722722</td><td>Published 18.02.2026</td></tr>
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<tr><td>TPO No.</td><td>276</td></tr>
<tr><td>Appl. No.</td><td>WO2024213776 (WO’776): Biologic: TB</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024213776</td></tr>
<tr><td>Applicants</td><td>BIONTECH SE, THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY, UNIVERSITY OF CAPE TOWN</td></tr>
<tr><td>Priority Date</td><td>63/496,141 14.14.2023 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’776 claims RNA encoding antigens of Mycobacterium tuberculosis namely WbbL1, PPE18 and PE13, which are altered, pharmaceutical compositions thereof wherein RNA molecules formulated in a lipid formulation, such as in lipid nanoparticles or liposomes, kits, use and methods thereof.

<u>TPO filed:</u> The TPO observed through prior art documents that the PPE, PE and WbbL1 antigens and immunogenic constructs thereof with the signal peptide, transmembrane domain and mRNA; compositions thereof were already disclosed as TB vaccines.

<u>No. of prior art documents used in No. of notes.:</u> 11 prior art documents were used in 7 notes to assail novelty (to the extent of overlap) and/or inventive step.

<u>Additional comment filed:</u> Additional comments were filed to highlight that the sequences for signal peptide, trafficking signal as well as the RNA construct encoding Mtb antigens and the LNP formulations thereof were already known. Also, it was observed that another application, WO2024216214, was filed by the Applicants of WO’776 on the same day

<u>Importance of Application:</u> The TB vaccine construct- mRNA-LNP vaccine comprising the three TB antigens WbbL1, PPE18 and PE13 is being developed by BioNTech in collaboration with University of Capetown. BiontechSe already has mRNA vaccines for tuberculosis in clinical trials.</td></tr>
<tr><td>Date of Filing of TPO</td><td>14/08/2025</td></tr>
<tr><td>National Phase</td><td><table><tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr></table>No National Phase as of 24 February 2026</td></tr>
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<tr><td>TPO No.</td><td>277</td></tr>
<tr><td>Appl. No.</td><td>WO2024216214 (WO’214): Biologic: TB</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024216214</td></tr>
<tr><td>Applicants</td><td>BIONTECH SE, THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY, UNIVERSITY OF CAPE TOWN</td></tr>
<tr><td>Priority Date</td><td>63/496,147 14.04.2023 US
63/496,149 14.04.2023 US
63/512,681 10.07.2023 US
63/512,683 10.07.2023 US
63/586,839 29.09.2023 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’214 claims RNA encoding a chimeric protein comprising T cell epitopes of three or more (four to seven) different Mycobacterium tuberculosis antigens selected from Wbbl1, PPE18, PE13, EsxA, EsxB, EsxG, EsxH, EsxI, EsxJ, EsxK, EsxL, EsxM, EsxN, EsxV and EsxW or immunogenic variants thereof, pharmaceutical compositions thereof wherein RNA molecules formulated in a lipid formulation, such as in lipid nanoparticles or liposomes, kits, use and methods thereof.
<u>TPO filed:</u> The TPO filed observed through prior art documents that (i) the Esx, PE and PPE antigens of Mtb and immunogenic constructs thereof with signal peptide and trafficking domain; (ii) string constructs of these multiple antigens; (iii) mRNA-LNP vaccine, were already known.
<u>No. of prior art documents used in No. of notes.:</u> 17 prior art documents were used in 9 notes to assail inventive step for all the claims.
<u>Additional comment filed:</u> to highlight that (i) the sequences for signal peptide, trafficking signal as well as the RNA construct encoding Mtb antigens and the LNP formulations thereof were already known; (ii) another application, WO2024213776, was filed by the Applicants of WO’214 on the same day; and (iii) the string constructs claimed in Claims 19–33 can only validly claim a priority date of 29.09.2023.
<u>Importance of Application:</u> The TB vaccine construct - mRNA-LNP vaccine comprising the TB antigens and fusion/string construct comprising the multiple TB antigens and T-cell epitopes is being developed by BioNTech in collaboration with University of Capetown, etc. BiontecSe already has mRNA vaccines with tuberculosis antigens in clinical trials.</td></tr>
<tr><td>Date of Filing of TPO</td><td>14/08/2025</td></tr>
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<tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr>
<tr><td>India</td><td>13.11.2025</td><td>202517110855</td><td>Published 26.12.2025</td></tr>
<tr><td>European Patent Office</td><td>14.11.2025</td><td>2024725309</td><td>Published 18.02.2026</td></tr>
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<tr><td>TPO No.</td><td>278</td></tr>
<tr><td>Appl. No.</td><td>WO2024220624 (WO’624): Small Molecule: HIV</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024220624</td></tr>
<tr><td>Applicants</td><td>GILEAD SCIENCES, INC.</td></tr>
<tr><td>Priority Date</td><td>63/497,168 19.04.2023 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’624 claims the oral and subcutaneous (SC) dosing regimen for Lenacapavir – comprising an initiation dose and a maintenance dose, and for patients who miss or anticipate missing a SC injection within the scheduled time and window period, may receive an oral bridging dosage (250–650 mg, once per week), until they can receive their next SC injection. The Application, WO’624 claims the dosing regime, dose and composition of the oral and SC dosage forms; wherein the HIV-infection is caused by multidrug resistant HIV-1 mutants.
<u>TPO filed:</u> The TPO observed through prior art documents that the claimed dosing regimen for lenacapavir comprising the initiation, maintenance and oral bridging dose was already known.
<u>No. of prior art documents used in No. of notes.:</u> 12 prior art documents were used in 8 notes to assail novelty (to the extent of overlap), and/ or inventive step.
<u>Additional comment filed:</u> Not filed
<u>Importance of Application:</u> The dosing regimens claimed in the present Application WO’624 are the same as that disclosed in the label-prescribing information for Sunlenca.</td></tr>
<tr><td>Date of Filing of TPO</td><td>19/08/2025</td></tr>
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<tr><td>European Patent Office</td><td>19.11.2025</td><td>2024724892</td><td>Published 25.02.2026</td></tr>
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<tr><td>TPO No.</td><td>279</td></tr>
<tr><td>Appl. No.</td><td>WO2024223943 (WO’943): Biologic: TB</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024223943</td></tr>
<tr><td>Applicants</td><td>IMCHECK THERAPEUTICS, COMMISSARIAT A L'ENERGIE ATOMIQUE ET AUX ENERGIES ALTERNATIVES</td></tr>
<tr><td>Priority Date</td><td>23170412.3 27.04.2023 EP</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’943 is a secondary application. WO’943 claims a BTN3A-activating antibody for use in treating multidrug resistant (MDR) bacterial infectious disorder, preferably selected from MDR Mtb infections or active TB, wherein the antibody (i) binds to human PBMC (EC50 less than 50 mcg/ml), induces in vitro (EC50 below 5 mcg/ml; degranulation assay), in vivo activation of Vg9Vd2 T cells; (ii) comprises specific sequences of HCDRs 1–3 and LCDRs 1–3, VH and VL polypeptide, heavy and light chains; (iii) mutant IgG1 – triple mutant with FES mutations and PE double mutant; (iv) is administered in combination with 2nd therapeutic agent; (v) administered intravenously at a unit dose of 0.1 mg to 1 g; the treatment decreases Vg9Vd2 T cells in blood, reduces relapse, etc.
<u>TPO filed:</u> The TPO observed through prior art documents that similar BTN3A-activating isolated antibodies, for use in treating infectious diseases including Mtb, which binds to human BTN3A polypeptide and induces activation of Vg9Vd2 T cells, and comprises an IgG1 constant region with triple FES or IgG4 with double PE mutations. Also, identical HCDR and LCDR and VH and VL sequences were already disclosed.
<u>No. of prior art documents used in No. of notes.:</u> 7 prior art documents were used in 5 notes to assail inventive step.
<u>Additional comment filed:</u> to highlight that the priority date of the mAb3 variant CDR sequences claimed in Claim 3 (SEQ ID NOs: 35–40) is the filing date, and the relevant prior art is before the “filing date” of the present Application WO’943. The additional comments also highlighted the insufficiency of disclosure with respect to the use of the claimed mAbs for treating a disorder caused by MDR bacteria, including MDR TB.
<u>Importance of Application:</u> Research on ImCheck’s ICT41, an antibody related to antibodies of the present Application, is supported by French government funding.</td></tr>
<tr><td>Date of Filing of TPO</td><td>27/08/2025</td></tr>
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<tr><td>European Patent Office</td><td>27.11.2025</td><td>2024723116</td><td>Published 04.03.2026</td></tr>
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<tr><td>TPO No.</td><td>280</td></tr>
<tr><td>Appl. No.</td><td>WO2024249573 (WO’573) – Small Molecule - HIV</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024249573</td></tr>
<tr><td>Applicants</td><td>GILEAD SCIENCES, INC.</td></tr>
<tr><td>Priority Date</td><td>63/505,226 31.05.2023 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The Application, WO’573, claims the solid forms, including the crystalline forms, the solvate forms and the co-crystal forms of the lenacapavir prodrug, wherein the promoiety is (oxobutanyl-(5-methyl-3-(phosphonooxy)phenyl)acetic acid, i.e. the nitrogen of the sulphonamido moiety is attached to -C(O)-(CH2-CH(CH2)2)-phenyl and wherein phenyl is substituted with -OP(O)(OH)2 and -CH2C(O)OH at meta positions and methyl at para position. The solid forms characterized using XRPD, DSC, TGA. WO’573 further claims the pharmaceutical composition comprising the solid form of the said prodrug, method of treating or preventing HIV in heavily treatment experienced patients, and the compound or composition for use in therapy or for use in method of treating or preventing HIV.

<u>TPO filed:</u> The TPO observed through prior art documents that TML based prodrugs were already known in the art, polymorphs, crystalline forms, solvates, co-crystals are routinely explored, characterised, analysed for several active pharmaceutical ingredients.

<u>No. of prior art documents used in No. of notes.:</u> 11 prior art documents were used in 7 notes to assail inventive step. One of the documents used in the TPO was a patent application published after the priority date but before the filing date of WO’573, was used to assail inventive step.

<u>Additional comment filed:</u> Yes. The Additional Comments were filed to highlight (i) that the prodrug of WO’573 was structurally identical to the prodrug moiety of the prior art cited – WO2023102239 (“P” document), (ii) lack of inventive step or obviousness of solid forms claimed in WO’573, and (iii) lack of sufficiency of disclosure.

<u>Importance of Application:</u> The application relates to the crystalline forms, solvates, and co-crystals for a TML-based prodrug of lenacapavir, which is now known as lenacapavir pacfosacil. It appears to be an application that covers Lenacapavir prodrug (possibly GS-4182); currently in trials in combination with GS-1720.</td></tr>
<tr><td>Date of Filing of TPO</td><td>30/09/2025</td></tr>
<tr><td>National Phase</td><td>
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<tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr>
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<tr><td>India</td><td>03.12.2025</td><td>202517121165</td><td>Published 26.12.2025</td></tr>
<tr><td>European Patent Office</td><td>02.01.2026</td><td>2024736184</td><td></td></tr>
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<tr><td>TPO No.</td><td>281</td></tr>
<tr><td>Appl. No.</td><td>WO2024249517 (WO’517): Small molecule: HIV</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024249517</td></tr>
<tr><td>Applicants</td><td>GILEAD SCIENCES, INC.</td></tr>
<tr><td>Priority Date</td><td>63/470,139 31.05.2023 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’517 claims protease inhibitors of formulae I-XI (compounds of WO’517 represent carboxylate ester prodrugs of elunonavir – which is an atazanavir analogue), wherein the -OH group is linked to the TML-containing promoieties; OH and -CH3 substitution on phenyl group further derivatized to a phosphonooxy group and a substituted amide group (particularly amino acid or modified amino acid group), respectively. WO’517 further claims pharmaceutical composition thereof along with additional therapeutic agents (e.g., lenacapavir), method of treating/preventing HIV therewith, use thereof, etc.
<u>TPO filed:</u> The TPO observed through prior art documents that the TML-based prodrugs, wherein the substituents methyl and hydroxyl on the TML-phenyl was further derivatized with amino acids, etc is already known in the art.
<u>No. of prior art documents used in No. of notes.:</u> 11 prior art documents were used in 5 notes to assail inventive step.
<u>Additional comments filed:</u> to highlight that the Application claimed multiple Markush formulae, differing in peripheral modifications, that cannot form a single inventive concept. There was lack of unity of invention. All claims of WO’517 lack inventive step.
<u>Importance of Application:</u> The application claimed the prodrugs of the protease inhibitor elunonavir, which is an atazanavir analogue.</td></tr>
<tr><td>Date of Filing of TPO</td><td>30/09/2025</td></tr>
<tr><td>National Phase</td><td>
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<tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr>
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<tr><td>New Zealand</td><td>29.10.2025</td><td>826544</td><td></td></tr>
<tr><td>Israel</td><td>03.11.2025</td><td>324431</td><td>Published 01.12.2025</td></tr>
<tr><td>India</td><td>20.11.2025</td><td>202517114308</td><td>Published 19.12.2025</td></tr>
<tr><td>Mexico</td><td>20.11.2025</td><td>MX/a/2025/013861</td><td>Published 07.01.2026</td></tr>
<tr><td>Eurasian Patent Organization</td><td>18.12.2025</td><td>202593377</td><td></td></tr>
<tr><td>Singapore</td><td>30.12.2025</td><td>11202507606Y</td><td>Published 30.12.2025</td></tr>
<tr><td>European Patent Office</td><td>02.01.2026</td><td>2024735430</td><td></td></tr>
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TPO No.	**282**
Appl. No.	**WO2024254226 : Cervical Cancer : Biologic**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024254226
Applicants	MERCK SHARP & DOHME LLC
Priority Date	63/507,269 09.06.2023 US
Details	**Summary of Application:** The Application, WO'226, claims a composition comprising: (a) virus-like particles (VLPs) of at least one type of human papillomavirus (HPV) selected from the group consisting of HPV types: 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 55, 56, 58, 59, 66, 68, 69, 70, 73, and 82; (b) a squalene nanoemulsion (SNE) adjuvant, wherein the SNE adjuvant comprises sorbitan trioleate (SPAN-85); polysorbate-20 (PS-20) or polysorbate-80 (PS-80); and squalene; wherein SNE further comprises a cationic lipid (13Z,16Z)-N,N-dimethyl-3-nonyldocosa-13,16-dien-1-amine (CLA); (c) buffer (histidine), salt (NaCl) and optionally aluminium adjuvant. WO'226 claims a method of preventing infection of or reducing the likelihood of infection of a human patient by a human papillomavirus (HPV); use and kit thereof.
	TPO filed: The TPO observed through prior art documents that the same adjuvant system (CLA-SNE) has been previously claimed for multivalent HPV vaccines comprising Land similar cationic lipid-based adjuvant systems have also been used for HPV vaccines. The TPO also disclosed the general state-of-the-art of squalene-based adjuvants.
	No. of prior art documents used in No. of notes.: 5 prior art documents were used in 3 notes to assail inventive step.
	Additional comment filed: Yes. The Additional Comments were filed to highlight the similarity between the claims and disclosures of the prior art document (WO2022169789; Citation 1) and the claims and disclosures of the present Application.
	Importance of Application: The application relates to a different adjuvant system for multivalent vaccines like GARDASIL®9 HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58, that provide enhanced immunogenicity over the current aluminium ones.
Date of Filing of TPO	08/10/2025

National Phase

Office	Entry Date	National Number	National Status
Israel	04.12.2025	325148	Published 01.01.2026
Thailand	04.12.2025	2501008310	
New Zealand	05.12.2025	827955	Published 19.12.2025
Eurasian Patent Organization	8.12.2025	202593245	
United Arab Emirates	9.12.2025	P2025-03974	
Australia	22.12.2025	AU2024284242	
Algeria	08.01.2026	DZP2026000020	
Republic of Korea	08.01.2026	1020267000689	
European Patent Office	09.01.2026	2024738109	
Singapore	30.01.2026	11202508311X	Published 30.01.2026

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<tr><td>TPO No.</td><td>283</td></tr>
<tr><td>Appl. No.</td><td>WO2024263918 (WO’918): HBV: Biologic</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024263918</td></tr>
<tr><td>Applicants</td><td>BRII BIOSCIENCES, INC.</td></tr>
<tr><td>Priority Date</td><td>63/522,851 23.03.2023 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’918 claims method for treating Chronic Hepatitis B infection, comprising: (a) administering HBV surface Antigen (HBsAg) (BRII-179; 20 to 100 mcg), to identify responders on the basis of certain anti-HBs antibody levels, and (b) HBV therapy (including anti-HBsAg siRNA, IFN-alpha, PEG-IFN-alpha, etc) at least 4 weeks after an initial HBsAg dose; wherein the subject is virally suppressed with a NRTI prior to administration of the HBsAg (Claims 1–61; pp.31–43; Exs.1–8). WO918 discloses that the administered HBsAg contains the S, Pre-S1 and Pre-S2 proteins and an aluminium phosphate adjuvant (p.18 of WO918).
<u>TPO filed:</u> The TPO observed through prior art documents that therapeutic vaccines BRII-179, and its potential use in combination with other agents was known for enhanced immune response. The TPO also observed through prior art documents that the anti-HBs antibody levels are an indicator for identifying responders to HBV therapy.
<u>No. of prior art documents used in No. of notes</u>.: 11 prior art documents were used in 6 notes to assail inventive step.
<u>Additional comment filed:</u> to highlight the erroneous Claims numbers in the Application WO’918.
<u>Importance of Application:</u> The application relates to therapeutic vaccine BRII-179 which is already being studied in clinical trials, in combination with siRNA VIR-2218 and/or PEG-IFN-alpha - the clinical trials related to the Application WO’918 are NCT04749368 and NCT06650852.</td></tr>
<tr><td>Date of Filing of TPO</td><td>18/10/2025</td></tr>
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<tr><td>TPO No.</td><td>284</td></tr>
<tr><td>Appl. No.</td><td>WO2025006586 (WO’586): HIV: Small Molec</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2025006586</td></tr>
<tr><td>Applicants</td><td>GILEAD SCIENCES, INC.</td></tr>
<tr><td>Priority Date</td><td>63/523,505 27.06.2023 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’586 claims i) the crystalline forms II– V of the bis (phenylacetate) ester prodrug of islatravir (EFdA), i.e., Compound 1, characterized by XRPD, DSC, etc.; (ii) the solvate forms (with solvents acetone, methyl ethyl ketone solvate, dichloromethane, tetrahydrofuran, toluene, n-butyl acetate, methyl acetate, xylene, heptane, butanol, p-dioxane, DMAc, ethyl acetate, dimethylacetamide) of Compound 1; (iii) pharmaceutical composition comprising the crystalline form or its co-crystal or salt form, or comprising the claimed solvate form; (iv) method for treating/preventing HIV therewith, and these solid forms for use [Claims 1–46]. WO’586 discloses that the claimed crystalline forms II–IV can be obtained by drying the several solvates under vacuum at 50degC or air drying and form V can be prepared by heating form II or III at a particular temperature, i.e., by solid-phase transformation [Exs.1–5; pp.28–34; Table 6]..
<u>TPO filed:</u> The TPO observed through prior art documents that polymorphism, polymorph screening is routinely explored for pharmaceuticals and that the crystallization methods, preparation of solvates using the solvents claimed, and desolvated forms thereof, and the analytical techniques used in the present Application are already known in the art; also, it is shown that the ICH guidelines set out the flowcharts that recommend polymorph screening and characterization for regulatory purposes.
<u>No. of prior art documents used in No. of notes.:</u> 11 prior art documents were used in 8 notes to assail inventive step.
<u>Additional comment filed:</u> Not filed.
<u>Importance of Application:</u> The Application claims the crystalline forms, solvates, desolvated forms and co-crystals for bis (phenylacetate) ester prodrug of islatravir (EFdA).</td></tr>
<tr><td>Date of Filing of TPO</td><td>27/10/2025</td></tr>
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<tr><td>TPO No.</td><td>285</td></tr>
<tr><td>Appl. No.</td><td>WO2025002280 (WO’280): Cervical Cancer: Biologic</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2025002280</td></tr>
<tr><td>Applicants</td><td>MERCK SHARP & DOHME LLCTHE TRUSTEES OF THE UNIVERSITY OF SICHUAN KELUN-BIOTECH BIOPHARMACEUTICAL CO., LTD.</td></tr>
<tr><td>Priority Date</td><td>PCT/CN2023/105367 30.06.2023 CN</td></tr>
<tr><td>Details</td><td>Summary of Application: WO’280 claims a method of treating a cancer in a patient, comprising administering to the patient: (a) an anti-human PD-1 antibody (Pembrolizumab, etc.; 200/400 mg) and (b) an Immunoconjugate (5 mg/kg) which is an antibody-drug conjugate (ADC) comprising anti-Trop-2 antibody (Sacituzumab) to treat ovarian cancer, cervical cancer, prostate cancer, or urothelial cancer and pharmaceutical compositions and kits thereof.

TPO filed: The TPO observed through prior art documents that the claimed ADC of Formula I claimed in WO280 is the same as ADC SKB264 (sacituzumab tirumotecan) and was already disclosed to be used in combination with pembrolizumab for the same cancers, in similar dosing regimen. Further, the combination was already in clinical trial and the combination has been proposed for multiple cancers. The TPO also had a P document claiming a similar combination for assailing novelty and/or inventive step of all claims.

No. of prior art documents used in No. of notes.: 8 prior art documents were used in 4 notes to assail novelty and /or inventive step.

Additional comment filed: to highlight that immunoconjugate claimed in the methods of the present Application was a known antibody-drug conjugate, with various nomenclature, non-availability of the sequences in a searchable/readable format, and to link all the prior art documents used in the TPO.

Importance of Application: The Application relates to the combination of ADC and pembrolizumab, which is already in clinical trial - NCT05642780, for the treatment of solid tumors, including cervical cancer, urothelial cancer, ovarian cancer and prostate cancer. The additional comments also brought forth the various nomenclature, non-availability of the sequences in a searchable/ readable format, and the additional comments highlighted the prior art documents used in the TPO.</td></tr>
<tr><td>Date of Filing of TPO</td><td>30/10/2025</td></tr>
<tr><td>National Phase</td><td>
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<tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr>
<tr><td>European Patent Office</td><td>30.01.2026</td><td>2024830912</td><td></td></tr>
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TPO No.	**286**
Appl. No.	WO2025042394 **(WO'394): HIV: Small Molecule**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2025042394
Applicants	GILEAD SCIENCES, INC.
Priority Date	
Details	**Summary of Application:** The Application, WO'394, claims method of treating and preventing HIV by administering Lenacapavir (LEN)or it's sodium salt (Na) in dosing regimens comprising (i) initiation dosage in the first period of time, and maintenance dosage in the second period of time, and if the maintenance dose is missed for more than 28 weeks, then re-start from the initiation dose; the dosing is administered subcutaneously (SC solution) and/or orally (film-coated tablet), with oral loading (Day 2 or 8) dosage; (ii) the SC is about 927 mg LEN, oral is about 600 mg of LEN (300 mg tablet x2); (iii) each SC solution comprises water, PEG300, and sodium salt of LEN, whereas the tablet. prepared by spray dried dispersion technology, comprises sodium salt, copovidone, poloxamer 407, microcrystalline cellulose, mannitol, croscarmellose sodium, magnesium stearate, and one or more pharmaceutical excipients. (iv) LEN/Na is administered in heavily treatment experienced patients infected with MDR HIV-1, wherein the specific HIV-1 mutants are resistant to multiple drugs of different ARV classes (NRTI, NNRTI, PI, INSTI), the patient is failing the current ARV regimen, and administration of LEN decreases viral load; (v) event-driven administration as Pre-exposure prophylaxis, or post-exposure prophylaxis, etc. The Application claims the resistant mutants of HIV-1, combination therapy with LEN, monotherapy, and also claims the compound with the stereochemistry of the compound defined. **TPO filed:** The TPO observed through prior art documents that the dosing regimen for LEN comprising the initiation, maintenance dosing, and alternative dosing in case of missed maintenance dose, was already disclosed in the regulatory documents by the US FDA, and the EMA. The prior art documents also disclosed the resistant mutants of HIV, the monotherapy, the combination therapy, etc. **No. of Prior Art documents used in No. of Notes:** 5 prior art documents were used in 5 notes to assail novelty(to the extent of overlap) and/ or inventive step. **Additional Comments:** Not filed. **Importance of Application:** The application relates to dosing regimens of Lenacapavir, approved in some countries.
Date of Filing of TPO	24/11/2025
National Phase	No National Phase as of 24.02.2026

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<tr><td>TPO No.</td><td>287</td></tr>
<tr><td>Appl. No.</td><td>WO2025029247 (WO’247): HIV: Small Molecule</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2025029247</td></tr>
<tr><td>Applicants</td><td>GILEAD SCIENCES, INC.</td></tr>
<tr><td>Priority Date</td><td></td></tr>
<tr><td>Details</td><td>Summary of Application: WO’247 claims method for treating or preventing HIV by administering oral dosage regimens in people exposed to or at risk of exposure to HIV as pre-exposure or post exposure prophylaxis, in heavily treatment experience patients with MDR HIV, as monotherapy, comprising weekly dosing regimen for LEN (i.e., Compound Ia/Ib) comprising an oral initiation dosage (oral 600 mg, on Days 1 and 2), followed by maintenance dosage (oral 300 mg once weekly), and if 1 or 2 maintenance dosages are missed then orally administering 300 mg or 600 mg respectively, 1–14 days after the missed dose. The Application also claims the mutant resistant HIV wherein the patient is resistant to some antiretroviral (ARV) therapy, LEN can be administered as a combination therapy too with other ARVs, etc.
TPO filed: The TPO observed through prior art documents that the oral dosing regimens for LEN comprising the initiation, maintenance, and missed dose regimens was known, and the dependant claims of the mutant resistant HIV, event-driven administration for PrEP and PEP, etc. combination therapy and monotherapy, etc. was already known for LEN.
No. of prior art documents used in No. of notes.: 11 prior art documents were used in 7 notes to assail novelty, and /or inventive step.
Additional comment filed: YES. The Additional comments were filed to to highlight (i) the number of Applications filed by Gilead Sc. claiming dosing regimens for lenacapavir, (ii) the similarity in the dependent claims in the Applications and the prior art (iii) the lack of novelty, and/ or inventive step (iv) the insufficiency of disclosure.
Importance of Application: The application relates to the oral regimen of lenacapavir.</td></tr>
<tr><td>Date of Filing of TPO</td><td>28/11/2025</td></tr>
<tr><td>National Phase</td><td>
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<tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr>
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<tr><td>TPO No.</td><td>288</td></tr>
<tr><td>Appl. No.</td><td>WO2025038715 (WO’715): HIV: Small Molecule</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2025038715</td></tr>
<tr><td>Applicants</td><td>GILEAD SCIENCES, INC.</td></tr>
<tr><td>Priority Date</td><td>23201068.6 29.09.2023 EP
63/519,675 15.08.2023 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The Application, WO’715, claims a monolayer, bilayer, or multilayer tablet comprising lenacapavir and bictegravir, the release profile and use in the treatment of HIV.
<u>TPO filed:</u> The TPO observed through prior art documents that combination of lenacapavir and bictegravir using the same dosing regimen was already known. The formulations claimed in WO’715 were already known for lenacapavir and bictegravir oral formulations. The dissolution parameters that were claimed in WO’715, were already known in the art.
<u>No. of prior art documents used in No. of notes</u>: 10 prior art documents were used in 6 notes to assail novelty(to the extent of overlap) and/ or inventive step.
<u>Additional comment filed:</u> Filed to highlight (a) lenacapavir and bictegravir are known drugs, and the combination and dosing regimen of the two said drugs is also already known; (b) oral dosage forms of lenacapavir and bictegravir including in monlayer or multilayer tablets comprising the same excipients was also known; (c) dissolution studies are routinely conducted using known methods.
<u>Importance of Application:</u> The application relates to fixed dose combination of lenacapavir and bictegravir, the dosing regimen, and combination – which is in clinical trials.</td></tr>
<tr><td>Date of Filing of TPO</td><td>13/12/2025</td></tr>
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<tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr>
<tr><td>European Patent Office</td><td>23.08.2024</td><td>2024755477</td><td>Published 09.04.2025
Granted 31.12.2025</td></tr>
<tr><td>Australia</td><td>29.01.2026</td><td>AU2024325153</td><td></td></tr>
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<tr><td>TPO No.</td><td>289</td></tr>
<tr><td>Appl. No.</td><td>WO2025039059 (WO’059): Cervical Cancer: Biologic</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2025039059</td></tr>
<tr><td>Applicants</td><td>IMUNOTERA SOLUÇÕES TERAPÊUTICAS LTDA</td></tr>
<tr><td>Priority Date</td><td>1020230169902 23.08.2023 BR</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’059 claims hybrid protein comprising an extender portion linked to the N- and/or C-terminal region of a modified portion of HSV-1 glycoprotein D fused to HPV oncoprotein E7 [SEQ ID NO: 2/3], hybrid nucleotide sequence [DNA SEQ ID NO: 5/6; RNA SEQ ID NO: 17/18], nucleic acid molecule and vector, use for preparing a medicament for the treatment of lesions and/or HPV infection [HPV16]; therapeutic vaccine and medicament for use, formulation 1 µg to 70 µg for administration via nasal, intramuscular, subcutaneous or intradermal routes and process of producing formulation, method for treating lesions and/or cancer caused by HPV infection.

<u>TPO filed:</u> The TPO observed through prior art documents that hybrid protein comprising fusion of HSV-1 gD and HPV 16 E7 was already known and used for the treatment of cancer caused by HPV 16, the N/C terminal tags, with identical sequences, associated with pET28 vector were already known.

<u>No. of prior art documents used in No. of notes.:</u> 11 prior art documents were used in 5 notes to assail inventive step.

<u>Additional comment filed:</u> YES. The Additional comments were filed to highlight that fusion protein of HSV-1 gD and HPV 16 E7 generated using pET28 vectors are known, the extender regions used as N/C terminal tags are known, strategy of adding linkers in between fusion proteins is known.

<u>Importance of Application:</u> The application relates to the Terah-7 therapeutic vaccine for HPV associated cervical cancer was found to be an important molecule about to enter clinical trials</td></tr>
<tr><td>Date of Filing of TPO</td><td>23/12/2025</td></tr>
<tr><td>National Phase</td><td>
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<tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr>
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No National Phases as of 10 February 2026
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TPO No.	**290**
Appl. No.	**WO2025043094 (WO'094): HBV / HDV: Small Molecule**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2025043094
Applicants	ASSEMBLY BIOSCIENCES, INC.
Priority Date	63/534,255 23.08.2023 US
Details	**Summary of Application:** WO'094 claims benzothia(dia)zepine compounds of Formula I, wherein (i) M is NRx (NCH3)/CRyRz (CHF), (ii) R4 is F-substituted alkyl (-$CH_2CH_2CF_2CH_3$, etc.) (iii) R5 is optionally-substituted (with F) phenyl/cycloalkyl, (iv) X is NH/CH, (v) R3 is haloalkyl (CF3), alkylthio (S-CH3), (vi) R1 is phenyl/monocycloheteroaryl (e.g., N-containing 5/6-membered moieties), substituted with R2 (-C(O)OH, -C(O)OC1-6alkyl, -P(O)(OH)2, -S(O)2OH, tetrazole, etc); composition thereof, method therewith for treatment of HBV/HDV infections.
	TPO filed: The TPO observed through prior art documents that the benzothia(dia)zepine compounds of identical scaffold with similar substituents are already disclosed for the treatment of HBV/HDV. Also, the use of aryl moieties as substituents on the benzothia(dia)zepine compounds are known.
	No. of prior art documents used in No. of notes.: 7 prior art documents were used in 5 notes to assail inventive step.
	Additional comment filed: YES. The Additional comments were filed to highlight the similarity in the structures of the benzothia(dia)zepine compounds claimed in the present Application WO'094 and the prior art documents used in the TPO.
	Importance of Application: The application relates to Anti HBV and HDV compounds in the pipeline of Assembly Biosciences who has collaborated with Gilead Sciences for compounds to treat HBV/ HDV.
Date of Filing of TPO	23/12/2025
National Phase	No National Phase as of 10.02.2026