Third Party Observations (TPOs) filed between January and December 2024

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 at the national phase.

<table>
<tr><td>TPO No.</td><td>238</td></tr>
<tr><td>Appl. No.</td><td>WO2023056312 (WO’312): Biologic: HIV and HCV</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023056312</td></tr>
<tr><td>Applicants</td><td>MODEX THERAPEUTICS, INC.</td></tr>
<tr><td>Priority Date</td><td>63/249,722 29.09.2021 US
63/249,794 29.09.2021 US
63/249,833 29.09.2021 US
63/249,919 29.09.2021 US
63/291,305 17.12.2021 US
63/292,382 21.12.2021 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’312 claims multispecific antigen binding polypeptides and antigen binding polypeptide complexes (IgG1 or IgG4) (up to 4 specificities on 2 chains) wherein the variable domains are arranged in a loop construct (comprising cancer, HIV or other viral epitopes) with or without GS Linkers; and the Fc region comprises modifications, including the known knob-in-hole substitutions for heterodimerization, as well as further LALA, LALA PA, LS (M428L and N424S) and YTE mutations; these molecules are claimed for treating/preventing cancer, HIV or other viral diseases.
<u>TPO filed:</u> The TPO observed through prior art documents that the multispecificity of HIV-1 antibodies with tandem constructs of single chain variable fragments were disclosed, and the loops constructs were known for better for expression than the tandem constructs for bispecificity with respect to CAR molecules for cancer, and thus, it would be obvious to use the same for HIV, and other viral diseases. The TPO also used prior art to show that the linkers used and the Fc modification of the antibodies are common knowledge and hence their use in the multispecific constructs was obvious. Thus, the Application lacked inventive step.
<u>No. of prior art documents used in No. of notes.:</u> 7 prior art documents were used in 3 notes to assail inventive step for all the claims of WO’312.
<u>Additional comment filed:</u> Yes. The Additional Comment was filed to point out the multiple applications filed by the Applicant for multispecific antigen binding polypeptides (TPO was filed for all 4 applications). The note brought out the similarities and differences in the Applications, and provided further information on the obviousness of (a) tumor epitopes as target epitopes, (b) multispecific antibody constructs, including pentaspecific and hexaspecific constructs, including some further prior art for the same; (c) the advantage of the loop construct over the tandem construct as disclosed in prior art; and (d) Fc modifications, including knob-in-hole, and the linkers previously known. Thus, lack of inventive step.
<u>Importance of Application:</u> The Application is of importance as it is the MSTAR technology by Modex therapeutics for multispecific antibodies, that has been taken ahead</td></tr>
<tr><td>Date of Filing of TPO</td><td>29/01/2024</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>Canada</td><td>19.03.2024</td><td>3232349</td><td>Published 26.03.2024</td></tr>
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Mexico	26.03.2024	MX/a/2024/003809	Published 05.07.2024
Israel	27.03.2024	311757	
Japan	28.03.204	2024519649	
Australia	02.04.2024	AU2022358512	
India	26.04.2024	202417033485	Published 29.11.2024
China	29.04.2024	202280072889.7	Published 25.06.2024
European Patent Office	29.04.2024	2022877539	Published 07.08.2024
Republic of Korea		1020247014150	Published 28.06.2024

TPO No.	**239**
Appl. No.	**WO2023056313 (WO'313): Biologic: HIV**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023056313
Applicants	MODEX THERAPEUTICS, INC.
Priority Date	63/249,722 29.09.2021 US 63/249,794 29.09.2021 US 63/249,833 29.09.2021 US 63/249,919 29.09.2021 US 63/291,305 17.12.2021 US 63/292,382 21.12.2021 US
Details	**Summary of Application:** WO'313 claims antigen binding polypeptides and antigen binding polypeptide complexes (IgG1 or IgG4) (up to 3 specificities on 2 polypeptide chains) wherein the variable domains are arranged in a loop construct (comprising cancer, HIV or other viral epitopes) with or without GS Linkers; and the Fc region (with KiH) comprises modifications, CL and CH1 regions, including the known knob-in-hole substitutions for heterodimerization, as well as further LALA, LALA PA, LS (M428L and N424S) and YTE mutations; these molecules are claimed for treating/preventing HIV-1 or other viral diseases. WO'313 sets out the trispecific NAb VRC01scFv/PGT121x10e8v4 with LS mutations in IgG1. The other antibody claimed in WO'313 includes PG16.
	TPO filed: The TPO observed through prior art documents that the multispecificity of HIV-1 antibodies with tandem constructs of single chain variable fragments were disclosed, and the loops constructs were known for better for expression than the tandem constructs for bispecificity with respect to CAR molecules for cancer, and thus, it would be obvious to use the same for HIV, and other viral diseases. The TPO also used prior art to show that the linkers used and the Fc modification of the antibodies are common knowledge and hence their use in the multispecific constructs was obvious. Thus, the Application lacked inventive step.
	No. of prior art documents used in No. of notes.: 7 prior art documents were used in 3 notes to assail inventive step for all the claims of WO'313.
	Additional comment filed: Yes. The Additional Comment was filed to point out the multiple applications filed by the Applicant for multispecific antigen binding polypeptides. The note brought out the similarities and differences in the Applications, and provided further information on the obviousness of (a) tumor epitopes as target epitopes, (b) multispecific antibody constructs, including pentaspecific and hexaspecific constructs, including some further prior art for the same; (c) the advantage of the loop construct over the tandem construct as disclosed in prior art; and (d) Fc modifications, including knob-in-hole, and the linkers previously known. Thus, lack of inventive step.
	Importance of Application: The Application is of importance as it is the MSTAR technology by Modex therapeutics for multispecific antibodies, that has been taken ahead.
Date of Filing of TPO	29/01/2024

National Phase

Office	Entry Date	National Number	National Status
Canada	19.03.2024	3232357	Published 21.03.2024
Mexico	26.03.2024	MX/a/2024/003807	Published 05.07.2024
Israel	27.03.2024	311758	
Japan	28.03.2024	2024519821	
Australia	02.04.2024	AU2022354068	
India	25.04.2024	202417032967	Published 29.11.2024
European Patent Office	29.04.2024	2022877540	Published 07.08.2024
China	28.05.2024	202280078695.8	Published 09.07.2024
Republic of Korea		1020247014151	Published 28.06.2024

TPO No.	**240**
Appl. No.	**WO2023056314 (WO'314): Biologic: HIV**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023056314
Applicants	MODEX THERAPEUTICS, INC.
Priority Date	63/249,722 29.09.2021 US 63/249,794 29.09.2021 US 63/249,833 29.09.2021 US 63/249,919 29.09.2021 US 63/291,305 17.12.2021 US 63/292,382 21.12.2021 US
Details	**Summary of Application:** WO'314 claims multispecific antigen binding polypeptides and antigen binding polypeptide complexes (IgG1 or IgG4) (up to 6 specificities on 3 chains) wherein the variable domains are arranged in a loop construct (comprising cancer, HIV or other viral epitopes) with or without GS Linkers; and the Fc region comprises modifications, including the known knob-in-hole substitutions for heterodimerization, as well as further LALA, LALA PA, LS (M428L and N424S) and YTE mutations; these molecules are claimed for treating/preventing cancer, HIV or other viral diseases.
	TPO filed: The TPO observed through prior art documents that the multispecificity (bi to pentaspecific) Nabs in ScFv tandem format, etc. including that of HIV-1 antibodies with tandem constructs of single chain variable fragments were disclosed, and the loops constructs were known for better for expression than the tandem constructs for bispecificity with respect to CAR molecules for cancer, and thus, it would be obvious to use the same for HIV, and other viral diseases. The TPO also used prior art to show that the linkers used and the Fc modification of the antibodies are common knowledge and hence their use in the multispecific constructs was obvious. Thus, the Application lacked inventive step.
	No. of prior art documents used in No. of notes.: 8 prior art documents were used in 4 notes to assail inventive step for all the claims of WO'314.
	Additional comment filed: Yes. The Additional Comment was filed to point out the multiple applications filed by the Applicant for multispecific antigen binding polypeptides. The note brought out the similarities and differences in the Applications, and provided further information on the obviousness of (a) tumor epitopes as target epitopes, (b) multispecific antibody constructs, including pentaspecific and hexaspecific constructs, including some further prior art for the same; (c) the advantage of the loop construct over the tandem construct as disclosed in prior art; and (d) Fc modifications, including knob-in-hole, and the linkers previously known. Thus, lack of inventive step.
	Importance of Application: The Application is of importance as it is the MSTAR technology by Modex therapeutics for multispecific antibodies, that has been taken ahead.

Date of Filing of TPO	29/01/2024
National Phase	

Office	Entry Date	National Number	National Status
Canada	19.03.2024	3232364	Published 26.03.2024
Mexico	26.03.2024	MX/a/2024/003808	Published 05.07.2024
Israel	27.03.2024	311765	
Japan	28.03.2024	2024519823	
Australia	02.04.2024	AU2022356387	
India	25.04.2024	202417032960	Published 29.11.2024
European Patent Office	29.04.2024	2022877541	Published 07.08.2024
China	28.05.2024	202280078666.1	Published 03.09.2024
Republic of Korea		1020247014152	Published 28.06.2024

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<tr><td>TPO No.</td><td>241:</td></tr>
<tr><td>Appl. No.</td><td>WO2023056315 (WO’315): Biologic: HIV</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023056315</td></tr>
<tr><td>Applicants</td><td>MODEX THERAPEUTICS, INC.</td></tr>
<tr><td>Priority Date</td><td>63/249,722 29.09.2021 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’315 claims multispecific antigen binding polypeptides and antigen binding polypeptide complexes (IgG1 or IgG4) (up to 6 specificities on 3 chains) wherein the variable domains are arranged in a loop construct comprising HIV epitopes with or without GS Linkers; and the Fc region comprises modifications, including the known knob-in-hole substitutions for heterodimerization, as well as further LALA, LALA PA, LS (M428L and N424S) and YTE mutations; these molecules are claimed for treating/preventing HIV.

<u>TPO filed:</u> The TPO observed through prior art documents that the multispecificity (bi to pentaspecific) of HIV-1 antibodies with tandem constructs of single chain variable fragments were disclosed, and the loops constructs were known for better for expression than the tandem constructs for bispecificity with respect to CAR molecules for cancer, and thus, it would be obvious to use the same for HIV. The TPO also used prior art to show that the linkers used and the Fc modification of the antibodies are common knowledge and hence their use in the multispecific constructs was obvious. Thus, the Application lacked inventive step.

<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 for all the claims of WO’315.

<u>Additional comment filed:</u> Yes. The Additional Comment was filed to point out the multiple applications filed by the Applicant for multispecific antigen binding polypeptides. The note brought out the similarities and differences in the Applications, and provided further information on the obviousness of (a) tumor epitopes as target epitopes, (b) multispecific antibody constructs, including pentaspecific and hexaspecific constructs, including some further prior art for the same; (c) the advantage of the loop construct over the tandem construct as disclosed in prior art; and (d) Fc modifications, including knob-in-hole, and the linkers previously known. Thus, lack of inventive step.

<u>Importance of Application:</u> The Application is of importance as it is the MSTAR technology by Modex therapeutics for multispecific antibodies, that has been taken ahead.</td></tr>
<tr><td>Date of Filing of TPO</td><td>29/01/2024</td></tr>
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<tr><td>Mexico</td><td>26.03.2024</td><td>MX/a/2024/003804</td><td>Published 05.07.2024</td></tr>
<tr><td>Israel</td><td>27.03.2024</td><td>311762</td><td></td></tr>
<tr><td>Japan</td><td>28.03.2024</td><td>2024519822</td><td></td></tr>
<tr><td>Australia</td><td>02.04.2024</td><td>AU2022357501</td><td></td></tr>
<tr><td>India</td><td>24.04.2024</td><td>202417032574</td><td>Published 29.11.2024</td></tr>
<tr><td>European Patent Office</td><td>29.04.2024</td><td>2022877542</td><td>Published 07.08.2024</td></tr>
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	China	28.05.2024	202280078694.3	Published 17.09.2024
	Republic of Korea		1020247014156	Published 28.04.2024

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<tr><td>TPO No.</td><td>242</td></tr>
<tr><td>Appl. No.</td><td>WO2023064424 (WO’424)</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023064424</td></tr>
<tr><td>Applicants</td><td>DUKE UNIVERSITY</td></tr>
<tr><td>Priority Date</td><td>63/254,867 12.10.2021 US
63/338,547 05.05.2022 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’424 claims recombinant HIV Env immunogens that are V2 optimised based on signature analysis of mature apex broadly neutralizing antibodies (bNAbs) and unmutated common ancestors (UCA). It also claims nucleic acids (mRNA) encoding the same, immunogenic compositions with lipid nano particle (LNP), and methods of inducing an immune response with prime boost administration. Importantly the V2 optimized immunogens are of CH505 trimers, and of CAP256-SU, T250, Q23 and CAM13. The optimized immunogens for the UCAs and bNAbs include mutations at positions K169R and/or Q170R (168-KKRR-171), and D167N, etc.

<u>TPO filed:</u> The TPO observed through prior art documents that positions of the mutations through the signature analysis of mature apex & UCA bNAb binding was known and disclosed earlier, for T250 and Q223 along with prime-boost administration, for CH505 and CAP256SU, along with mRNA-LNP compositions, & for CAM13. The Applicant merely introduced these identified mutations together in known immunogens based on signature analysis which is also disclosed earlier. Thus, the Application lacked inventive step.

<u>No. of prior art documents used in No. of notes.: 4</u> prior art documents were used in 3 notes to assail inventive step for all the claims of WO’424.

<u>Additional comment filed:</u> Yes. The Additional Comment was filed putting all the prior art notes together.

<u>Importance of Application:</u> The Application is of importance as Duke University has looked at multiple immunogen formats with HIV Env and the V2 optimized, which is a vaccine candidate to be initiated into clinical trials.</td></tr>
<tr><td>Date of Filing of TPO</td><td>12/02/2024</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>Canada</td><td>12.04.2024</td><td>3234955</td><td>Published 16.04.2024</td></tr>
<tr><td>European Patent Office</td><td>13.05.2024</td><td>2022881744</td><td>Published 21.08.2024</td></tr>
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TPO No.	**243**
Appl. No.	**WO2023062559 (WO'559)**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023062559
Applicants	VIIV HEALTHCARE UK (NO.5) LIMITED
Priority Date	63/255,956 13.10.2021 US 63/257,212 19.10.2021 US
Details	**Summary of Application:** WO'559 claims formulations of capsid inhibitors that contain either PEG-based formulations (water, ethanol and PEG)or poloxamer-based formulations (poloxamer338, 188, mannitol, buffer) to be administered via intramuscular or subcutaneous injection, that can be given in combination with other agents. **TPO filed:** The TPO observed through prior art documents that the excipients used in the formulations of WO'559 are known to be used for long-acting formulations, are commonly and routinely used, and the extended-release pharmacokinetic data for capsid inhibitor, PEG, ethanol, water, was known, and also known in the art, or set forth in text books. Thus, the Application lacked inventive step. **No. of prior art documents used in No. of notes.:** 5 prior art documents were used in 4 notes to assail inventive step for all the claims of WO'559. **Additional comment filed:** Yes. The Additional Comment was filed putting all the prior art notes together. **Importance of Application:** The Application is of importance as Viiv Healthcare has been looking at long-acting formulations of capsid inhibitors for treatment of HIV.
Date of Filing of TPO	13/02/2024

National Phase

Office	Entry Date	National Number	National Status
Australia	05.04.2024	2022362855	
Israel	07.04.2024	311982	
Canada	08.04.2024	3234219	Published 09.04.2024
United States of America	11.04.2024	18700402	Published 26.12.2024
India	12.04.2024	202417029733	Published 15.11.2024
Japan	12.04.2024	2024522260	
Mexico	12.04.2024	MX/a/2024/004551	Published 05.07.2024
China	15.04.2024	202280069343.6	Published 31.05.2024
Republic of Korea	03.05.2024	1020247014899	Published 28.05.2024
European Patent Office	13.05.2024	2022797493	Published 21.08.2024
Russian Federation	13.05.2024	2024112404	Published 19.08.2024

TPO No.	**244**
Appl. No.	**WO2023062066 (WO'066)**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023062066
Applicants	ARCHIVEL FARMA, S.L.
Priority Date	21382926.0 14.10.2021 EP (Priority Withdrawn 11.04.2024)
Details	**Summary of Application:** WO'066 is an application for a RUTI – a drug with the active ingredient of FCMtb that received orphan drug designation. WO'066 claims liposome formulations of RUTI, for use in a method for treating active TB, or where TB is susceptible, Rifampicin resistant, MDR, or extensive drug resistant TB. It is administered once or twice, in the absence of chemotherapy (chemo), or before or concomitant with chemo (where chemo is for 4 weeks and comprises antibiotic treatment for TB), or where the first dose is administered within 4 weeks of the first dose of chemo, and the liposome formulation is administered at a dose of 5 to 200 micrograms of FCMtb.
	TPO filed: The TPO observed through prior art documents that liposome formulations of FCMtb agent, identified as RUTI, is used for treatment of active TB, as well as latent TB, and the doses are also disclosed in the prior art. Thus, the Application lacked novelty and/ or inventive step.
	No. of prior art documents used in No. of notes.: 11 prior art documents were used in 6 notes to assail novelty and/or inventive step for all the claims of WO'066.
	Additional comment filed: Yes. The Additional Comment was filed putting all the prior art notes together.
	Importance of Application: The Application is of importance as it is with respect to RUTI and liposome formulations used for the treatment of active TB. This has been taken ahead in clinical trials.
Date of Filing of TPO	14/02/2024
National Phase	No National Phase as of 24.03.2025

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<tr><td>TPO No.</td><td>245</td></tr>
<tr><td>Appl. No.</td><td>WO2023077061 (WO’061)</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023077061</td></tr>
<tr><td>Applicants</td><td>WEINER, David and al.</td></tr>
<tr><td>Priority Date</td><td>63/273,925 28.10.2021 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’061claims nucleic acid molecule encoding one or more synthetic bispecific immune cell engager with one HIV antigen binding domain and one immune cell engaging domain (targets a cell selected from T cell, APC, NK cell, a neutrophil and a macrophage, having CD3, etc. as the T cell-specific target receptors; the synthetic bispecific immune cell engagers thereof; wherein nucleic acid is DNA/RNA and may comprise an expression vector, compositions of nucleic acid with LNP, or cells expressing the synthetic bispecific immune cell engager or a chimeric antigen receptor (CAR) thereof; method of preventing or treating a disease or disorder associated with HIV. One of the BiTE molecules disclosed in WO’061 include the anti-CD3 and anti-HIV antibody 3BNC117, with leader sequences, and 6His tag. Other BiTE molecules comprise HIV antibody PGDM1400 arm and an anti-CD3 arm. The sequences claimed in WO’061 comprise two scFvs (anti-HIV and anti-CD3) and are BiTEs. WO’061 also exemplifies Siglec7 and Siglec9 natural killer engagers, wherein one arm binds to the HIV epitope and one arm binds to Siglec.
<u>TPO filed:</u> The TPO observed through prior art documents that bispecific immune cell engager, and the nucleic acid base encoding the same were already known and prior disclosed. Further bispecific molecules, including BiTE – with one arm targeting and HIV antigen and the other arm targeting an effector arm was already known and disclosed in the art, and the dMABs technology to generate such BiTES and deliver them was also known. Further, Siglec7 and/or Siglec9 have also been disclosed in prior art for treating cancer, HIV, etc. Thus, the Application lacked inventive step.
<u>No. of prior art documents used in No. of notes.:</u> 9 prior art documents were used in 8 notes to assail inventive step for all the claims of WO’061.
<u>Additional comment filed:</u> Yes. The Additional Comment was filed putting all the prior art notes together.
<u>Importance of Application:</u> The Application is of importance as it is the Applicants are involved with Inovio Pharmaceuticals, who are taking this DMAb technology ahead for infectious diseases.</td></tr>
<tr><td>Date of Filing of TPO</td><td>03/04/2023</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>United States of America</td><td></td><td>18705388</td><td>Published 19.12.2024</td></tr>
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<tr><td>TPO No.</td><td>246</td></tr>
<tr><td>Appl. No.</td><td>WO2023114639 (WO’639)</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023114639</td></tr>
<tr><td>Applicants</td><td>The Scripps Research Institute</td></tr>
<tr><td>Priority Date</td><td>17/550,768 14.12.2021 US
17/743,762 13.05.2022 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’639 claims a method to enhance immunogenicity or responder frequency of a vaccine (increasing 2-tier nAb) comprising glycan shielded immunogenic protein from viruses such as HIV, HCV, SARS-CoV2, etc. especially HIV-1 where the immunogen is UFO gp140 trimer, for contacting the vaccine with an enzyme (Endo H) for removing or shortening the N-linked glycan chain from the protein. The Applications claims methods of treating / preventing HIV-1 infection. The examples in the Application WO’639 disclose the trimming of glycans of E2p- and I3-01-based HIV trimer vaccines and of BG505 UFO trimer vaccine, both formulated in an adjuvant. The trimer alone and present on nanoparticles were produced using ExpiCHO cells.
<u>TPO filed:</u> The TPO observed through prior art documents that the method of partial deglycosylation or glycan trimming is known and has been used earlier, including for HIV glycoproteins, influenza, SARS-CoV2, etc. The TPO also brought out that the antibody responses upon vaccination were also known. With respect to the exemplified scaffolded and non-scaffolded immunogens, the TPO used prior art documents to show obviousness. Thus, the Application lacked inventive step.
<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 for all the claims of WO’639.
<u>Additional comment filed:</u> Yes. The Additional Comment was filed putting all the prior art notes together.
<u>Importance of Application:</u> The Application is of importance as the molecules UVAX-1197 and UVAX-1107 that were covered by the Application had entered Phase I clinical trials.</td></tr>
<tr><td>Date of Filing of TPO</td><td>15/04/2024</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 24.03.2025</td></tr>
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TPO No.	**247**
Appl. No.	**WO2023114951 (WO'951)**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023114951
Applicants	VIIV HEALTHCARE COMPANY
Priority Date	63/290,758 17.12.2021 US
Details	**Summary of Application:** WO'951 claims method of treating HIB by administering temsavir or fostemsavir and at least one broadly neutralizing antibody or antigen binding fragment that binds to HIV envelope glycoprotein (HIV gp160, HIV gp120, HIV gp41), more particularly antibody N6, N6-LS, N6-DE, or N6-LAGA. It further comprises of administering a third-agent an integrase inhibitor, such a raltegravir, bictegravir, etc. more particularly cabotegravir, wherein the first agent (1mg/kg to 100 mg/kg body weight) is administered orally/ parenterally once, twice or thrice a day. WO'951 also claims combinations – dual or triple combination for use in treatment of HIV, & kits.
	TPO filed: The TPO observed through prior art documents that combination of N6 antibody with small molecule entry inhibitors are known and their synergistic effect is also known. The prior art also brought out the known Fc mutations in the antibody constant region. Thus, the Application lacked novelty and/ or inventive step.
	No. of prior art documents used in No. of notes.: 4 prior art documents were used in 3 notes to assail novelty and / or inventive step for all the claims of WO'951.
	Additional comment filed: No
	Importance of Application: The Application is of importance as Viiv Healthcare has made presentations at conferences (CROI poster) with respect to the combination as claimed in the present Application.
Date of Filing of TPO	17/04/2024

National Phase

Office	Entry Date	National Number	National Status
Australia	31.05.2024	2022409827	
Israel	03.06.2024	313306	
United States of America	12.06.2024	18718857	Published 26.12.2024
Canada	13.06.2024	3241017	Published 16.06.2024
Japan	14.06.2024	2024535995	
Mexico	14.06.2024	MX/a/2024/007429	Published 08.10.2024
China	17.06.2024	202280083606.9	Published 09.08.2024
Republic of korea	11.07.2024	1020247023208	Published 13.08.2024
European Patent Office	17.07.2024	2022850944	Published 23.10.2024
Russian Federation	17.07.2024	2024119908	Published 05.08.2024

<table>
<tr><td>TPO No.</td><td>248</td></tr>
<tr><td>Appl. No.</td><td>WO2023154761 (WO’761)</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023154761</td></tr>
<tr><td>Applicants</td><td>THE WISTAR INSTITUTE OF ANATOMY AND BIOLOGY
THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA</td></tr>
<tr><td>Priority Date</td><td>63/308,008 08.02.2022 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’761 claims compositions comprising primary human NK cells that express CD64 Fc receptor from an exogenous nucleic acid molecule, the NK cells having bound to broadly neutralizing antibodies (anti-HIV antibodies 10-1074 or its variants, 3BNC-117, etc.). WO’761 also claims a method of inducing or augmenting the ADCC comprising administering the composition by transducing NK cells ex vivo and culturing in media supplements with one or more cytokines (IL-21). The Application, WO’761, claims methods of generating such modified human NK cells, and the composition, the use of which is for treatment of HIV-1, cancer, bacterial or viral infections.

<u>TPO filed:</u> The TPO observed through prior art documents that NK cells expressing CD64 have been disclosed earlier as a platform for docking antibodies and have been explored for cancer Abs. The TPO also brought out that there was prior knowledge of NK based ADCC being effective against HIV, and therefore it would be obvious for a person skilled in the art to use the same docking platform with the anti-HIV antibodies, or any such anti-viral, anti-bacterial antibodies, etc.

<u>No. of prior art documents used in No. of notes.:</u> 6 prior art documents were used in 6 notes to assail inventive step for all the claims of WO’761. Of these 6 prior art documents, one was a Px document that also assailed novelty, and/or inventive step.

<u>Additional comment filed:</u> Yes. The Additional Comment was filed to show that the results shown in Example 3 of WO’761 were known and anticipated in the prior art.

<u>Importance of Application:</u> The Application is of importance a CROI poster presentation set the contents of the present Application WO’761 for HIV treatment. This was under the BEAT HIV collaboration program and included the work of University of Pennsylvania.</td></tr>
<tr><td>Date of Filing of TPO</td><td>31/05/2024</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 24.03.2025</td></tr>
</table>

<table>
<tr><td>TPO No.</td><td>249</td></tr>
<tr><td>Appl. No.</td><td>WO2023156505 (WO’505)</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023156505</td></tr>
<tr><td>Applicants</td><td>JANSSEN VACCINES & PREVENTION B.V.</td></tr>
<tr><td>Priority Date</td><td>22157331.4 17.02.2022 EP</td></tr>
<tr><td rowspan="5">Details</td><td><u>Summary of Application:</u> WO’505 claims recombinant HIV envelope proteins with R304V, N302M and T320L mutations and method of improving trimer folding by such mutations. According to the Applicant, such HIV Env proteins have improved folding and can induce broadly neutralising antibodies (bnAbs) and decrease binding to non-neutralising antibodies (non-nAbs). WO’505 also claims such Env protein, further comprising SOSIP and other mutations, wherein the HIV Env protein (gp140, gp160, etc.) is a clade A, B or C protein, a trimeric complex thereof, a particle (liposome or nanoparticle) thereof, nucleic acid encoding such protein, vector, host cell, method of producing such Env protein and composition thereof.</td></tr>
<tr><td><u>TPO filed:</u> The TPO observed through prior art documents that the 302M, 304V, and 320L substitutions have been disclosed earlier, and are all in the V3 region of the HIV env glycoprotein immunogen. All of these were hydrophobic, and with other substitutions that also have been disclosed earlier, reduce the binding of nNAbs. The TPO observed that use of these three substitutions with others for trimer stability and better yield was obvious and the associated effect on reduction of in non-nAbs was anticipated.</td></tr>
<tr><td><u>No. of prior art documents used in No. of notes.:</u> 5 prior art documents were used in 4 notes to assail novelty (partially) and/or inventive step for all the claims of WO’505. 2 of the patent documents cited in the TPO, were also cited in the ISR.</td></tr>
<tr><td><u>Additional comment filed:</u> Not filed</td></tr>
<tr><td><u>Importance of Application:</u> A TPO was filed because this is an application for modified HIV Env proteins that elicit reduced binding to non-nAbs.
In January 2023, Janssen had reported the discontinuation of the Phase 3 Mosaico HIV vaccine clinical trial because the “study’s independent Data and Safety Monitoring Board (DSMB) determined that the regimen was not effective in preventing HIV infection compared to placebo among study participants”.[1] At some conferences, this failure was identified as a failure of the approach to develop HIV vaccines to elicit non-nAbs. In light of this, it is expected that HIV modified Env proteins such as those that are the subject of the present application (with reduced binding to non-nAbs) may be a candidate immunogen in the future.</td></tr>
<tr><td>Date of Filing of TPO</td><td>17/06/2024</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 24.03.2025
</td></tr>
</table>

[1] “Janssen and Global Partners to Discontinue Phase 3 Mosaico HIV Vaccine Clinical Trial”, 18 January 2023, at https://www.jnj.com/media-center/press-releases/janssen-and-global-partners-to-discontinue-phase-3-mosaico-hiv-vaccine-clinical-trial

<table>
<tr><td>TPO No.</td><td>250</td></tr>
<tr><td>Appl. No.</td><td>WO2023156663 (WO’663)</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023156663</td></tr>
<tr><td>Applicants</td><td>IMMUNOCORE LIMITED</td></tr>
<tr><td>Priority Date</td><td>17/938,321 05.10.2022 US
63/312,007 20.02.2022 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’663 claimss HIV specific binding Tcell receptors which bind the HLA-A*02 restricted peptide SLYNTVATL derived from HIV Gag gene product, p17, comprising non-natural mutations, especially F50K and S96A, which result in improved stability and/or yield but retain the advantageous properties of the previously disclosed HIV TCR. It also claims nucleic acid encoding such TCR alpha and/or beta chain, an expression vector, a cell harbouring such TCR expression vector, an isolated or non-naturally occurring cell, pharmaceutical composition thereof, such molecule, etc. for use in treating HIV, and method of treating HIV. WO’663 exemplifies and provides data for IMC-M113V, a candidate that is in clinical trials.
<u>TPO filed:</u> The TPO observed through prior art documents the prior disclosure of the mutations at position 50 and 96 in the alpha chain of the HIV gag-specific T-cell receptor, and their effect. The TPO observed that it is common knowledge to try and use such mutations for enhancing stability and yield of the T-cell receptor.
<u>No. of prior art documents used in No. of notes.:</u> 6 prior art documents were used in 4 notes to assail novelty and/or inventive step for all the claims of WO’663.
<u>Additional comment:</u> Not filed.
<u>Importance of Application:</u> A TPO was filed because this is an application that relates to IMC-M113V, a candidate of Immunocore that is in Phase I clinical trials for HIV (https://www.clinicaltrialsregister.eu/ctr-search/search?query=IMC-M113V). The development of this candidate is also being funded by the Bill and Melinda Gates Foundation.</td></tr>
<tr><td>Date of Filing of TPO</td><td>20/06/2024</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>Israel</td><td>07.08.2024</td><td>314832</td><td></td></tr>
<tr><td>Australia</td><td>09.08.2024</td><td>AU23222190</td><td></td></tr>
<tr><td>China</td><td>16.08.2024</td><td>202380022429.8</td><td>Published 27.09.2024</td></tr>
<tr><td>Japan</td><td>16.08.2024</td><td>2024548572</td><td></td></tr>
<tr><td>Mexico</td><td>20.08.2024</td><td>MX/a/2024/010233</td><td>Publised 06.12.2024</td></tr>
<tr><td>New Zealand</td><td>23.08.2024</td><td>813966</td><td>Published 30.08.2024</td></tr>
<tr><td>European Patent Office</td><td>20.09.2024</td><td>2023706587</td><td>Published 25.12.2024</td></tr>
<tr><td>Republic of Korea</td><td>20.09.2024</td><td>1020247031311</td><td>Published 14.10.2024</td></tr>
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<table>
<tr><td>TPO No.</td><td>251</td></tr>
<tr><td>Appl. No.</td><td>WO2023183852 (WO’852):</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023183852</td></tr>
<tr><td>Applicants</td><td>BOARD OF REGENTS OF THE UNIVERSITY OF NEBRASKA</td></tr>
<tr><td>Priority Date</td><td>63/269,831 23.03.2022 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’852 claims long-acting lipophilic phosphate and/or phosphonate ester prodrugs of nucleoside, nucleotide, or nucleobase, or analog thereof. WO’852 also claims nanoparticles comprising one or more of the claimed prodrug compounds, and methods of treating viral infections, such as HIV, HCV, etc. and cancer, clotting disorders.

<u>TPO filed:</u> The TPO observed through prior art documents that the phosphonate ester prodrugs of nucleoside compound with anti-viral activity were known, the structural components analogous to the linkers claimed in the present Application, WO’852, were also known, similar prodrugs, and nanoparticles comprising the prodrugs for treatment were also disclosed in prior art.

<u>No. of prior art documents used in No. of notes.:</u> 7 prior art documents were used in 6 notes to assail inventive step for all the claims of WO’852. A comparative table of the compounds claimed in WO’852 and those in the prior art document was also uploaded.

<u>Additional comment filed:</u> The Additional Comments filed brought out the lack of inventive step as brought out in the TPO, and cited some additional documents showing similar concepts and combination of prodrug moieties. The Additional Comments also pointed out that the present Application, WO’852, also failed in lack of inventive step due to the insufficiency of data to support the alleged advantages and/or technical effect of the claimed prodrug compounds, and for lack of sufficiency of disclosure.

<u>Importance of Application:</u> A TPO was filed because prodrugs of nucleoside, nucleotides are constantly explored, and there appears to be such phosphonate ester prodrugs being explored for Tenofovir, in preclinical trials.</td></tr>
<tr><td>Date of Filing of TPO</td><td>23/07/2024</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 Phases as of 24.03.2025</td></tr>
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<table>
<tr><td>TPO No.</td><td>252</td></tr>
<tr><td>Appl. No.</td><td>WO2023183472 (WO’472):</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023183472</td></tr>
<tr><td>Applicants</td><td>BOARD OF REGENTS OF THE UNIVERSITY OF NEBRASKA</td></tr>
<tr><td>Priority Date</td><td>63/269,829 23.03.2022 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’472 claims long-acting lipophilic double-ester prodrugs of integrase inhibitors. The INSTI drugs are selected from DTG, BIC, CAB, EVG, RAL, BI224436, MK-2048. WO’472 claims nanoparticles comprising the prodrugs and polymer surfactant (P407), and method of treatment, by administering the claimed compounds once a month, in various intervals upto once in 12 months.

<u>TPO filed:</u> The TPO observed through prior art documents that an earlier application of the Applicants disclosed the fatty acid esters of the same INSTI, with optional substitutions as claimed in the present Application, WO’472. The role of spacers in prodrug designs and the use of esters and amides for derivatizing hydroxyl and carboxyl groups to improve lipophilicity were also known.

<u>No. of prior art documents used in No. of notes.:</u> 2 prior art documents were used in 1 note to assail novelty (to the extent of overlap) and/or inventive step for all the claims of WO’472.

<u>Additional comments filed:</u> Additional Comments were filed to show that the claims fail for lack of inventive step and lack of sufficiency of disclosure due to lack of supporting data in the accompanying description

<u>Importance of Application:</u> The application claimed prodrugs of approved known drugs. Hence it is important.</td></tr>
<tr><td>Date of Filing of TPO</td><td>23/07/2024</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 Phases as of 24.03.2025</td></tr>
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<table>
<tr><td>TPO No.</td><td>253</td></tr>
<tr><td>Appl. No.</td><td>WO2023192881 (WO’881)</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023192881</td></tr>
<tr><td>Applicants</td><td>THE UNITED STATES OF AMERICA, AS REPRESENTED BY THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES</td></tr>
<tr><td>Priority Date</td><td>63/324,152 28.03.2022 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’881 claims variants of anti-HIV monoclonal antibodies (mAb) such as VRC07-523, N6, 10E8v4 and VRC01.23 with variant variable heavy and light chain sequences, resulting in lower polyreactivity and better half-life of the mAb, and some further modifications and substitutions. WO’881 also claims mAbs that comprise the alpha-synuclein (ATS alpha) fused to the C-terminus of the light and heavy chain of the antibodies that include multispecific Abs and monoclonal Abs.

<u>TPO filed:</u> The TPO observed that modifications to the positive charged amino acids arginine and lysine to neutral amino acids, such as aspartate, glutamate, etc. in the variable regions of antibodies are already known to change the isoelectric point of the antibodies and thereby result in less polyreactive antibodies with higher half-life. Based on the prior art, the TPO also observed that such changes being implement further in the constant region are also known and exemplified. The TPO also observed that addition of the acidic tail of alpha synuclein to monoclonal antibodies has been claimed before and one effect of adding this tail resulting from stability is increased half-life.

<u>No. of prior art documents used in No. of notes.:</u> 4 prior art documents were used via 3 notes.

<u>Additional comment filed:</u> The Additional Comment filed brought forth that the WOSA document WO2019165122 (WO’122) and 2018 Kwon, et al. identify the need for reducing the autoreactivity of anti-HIV antibodies and increasing the half-life and further WO’122 also covered the sequences of the present Application, WO’881, with more than 90% identity. The additional comments also showed that the use of abYsis software for establishing the amino acids at positions and contact residues of Ag-Ab interactions is known to a person skilled in the art. Further, the additional comments showed the comparison between Kabat and EU numbering schemes using links and textbooks. The additional comments also pointed out some errors with respect to priority date of some claims and naming of variants and sequence IDs in the claims.

<u>Importance of Application:</u> The application claimed substitutions to anti-HIV antibodies that aid in reduction of polyreactivity and also increase the half-life, which have been identified as hindrances to the therapeutic application of monoclonal antibodies.</td></tr>
<tr><td>Date of Filing of TPO</td><td>29/07/2024</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>
<tr><td>United States of America</td><td>23.09.2024</td><td>18849734</td><td></td></tr>
<tr><td>European Patent Office</td><td>28.10.2024</td><td>2023718605</td><td>Published 05.02.2025</td></tr>
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<table>
<tr><td>TPO No.</td><td>254</td></tr>
<tr><td>Appl. No.</td><td>WO2023196832 (WO’832)</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023196832</td></tr>
<tr><td>Applicants</td><td>BRII BIOSCIENCES, INC.</td></tr>
<tr><td>Priority Date</td><td>63/327,839 06.04.2022 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’832 claims a method of treating HIV infection by administering once weekly dose (0.1–25 mg, particularly 1.25 mg) or a once daily dose (0.1– 5 mg, particularly 0.25 or 0.38 mg) of an adenosine derivative, i.e., compound of formula 1 (which is a medoximil carbonate or ODOL prodrug of EFdA) or EFDA, for a plurality of weeks (up to 52 weeks) as a tablet, for wild type HIV or its mutant or resistant strains. It also claims the use of these prodrug long-acting compounds for treating HIV.
<u>TPO filed:</u> The TPO observed through prior art documents that EFdA, it’s ODOL prodrugs, its doses and effective dosage regimen have already been disclosed earlier.
<u>No. of prior art documents used in No. of notes</u>.: 7 prior art documents were used in 4 notes to assail inventive step for all the claims of WO’832.
<u>Additional comment filed:</u> The Additional Comments filed brought out the lack of inventive step as brought out in the TPO, and also pointed out the lack of novelty due to prior use – and cited some additional documents thereof. The Additional Comments also pointed out the lack of inventive step, lack of technical effect, and lack of sufficiency of disclosure (WO’832 does not disclose any studies or data to show the effect of administration of the claimed prodrug to a person with reduced expression of 3 enzymes or at risk of CD4+ lymphocyte count reduction.
<u>Importance of Application:</u> A TPO was filed because Islatravir is an important drug molecule. Its prodrug BRII-732 is currently in clinical trials. Claiming doses and dosage regimen may lead to evergreening of the molecule.</td></tr>
<tr><td>Date of Filing of TPO</td><td>06/08/2024</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>
<tr><td colspan="4">No National Phase as of 24.03.2025</td></tr>
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TPO No.	**255**
Appl. No.	**WO2023196875 (WO'875)**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023196875
Applicants	GILEAD SCIENCES, INC.
Priority Date	63/328,061 06.04.2022 US 63/476,873 22.12.2022 US
Details	**Summary of Application:** WO'875 claims multiple markush formulae for bridged tricyclic carbamoylpyridone compounds, and also specific compounds with methyl substitution on the bridge as well as spirocyclic heterocyclic substituents (particularly spiro-isooxazoline ring with further substituents), methoxy, fluorine, methyl, and/or CH2F and the bridged moiety is also substituted with a methyl group. WO'875 also claimed pharmaceutical compositions, with an additional therapeutic anti-HIV agent, etc. **TPO filed:** The TPO observed through prior art documents that the main scaffold of the bridged carbamoylpyridone compounds as HIV integrase inhibitors has already been disclosed, with possible spirocyclic substituents on the bridged moiety. TPO also pointed out the known significance and biological activity of the isoxazole and isooxazoline moieties. **No. of prior art documents used in No. of notes.:** 5 prior art documents were used in 2 notes to assail inventive step for all the claims of WO'875. **Additional comment filed:** Additional Comments were filed to show that the patent family applications were filed at the EPO and USPTO, wherein the claims were narrowed down and only specific compounds were claimed. These were granted patents, and the TPO was filed focusing only on the 11 specific compounds claimed in the National Phase (patent family) applications. The Additional Comments also pointed out the lack of unity of invention. **Importance of Application:** The Applicant, Gilead Sciences, has been studying these types of compounds for the past few years. The Patent family applications have entered the national phases in some countries, and the EPO and US have already granted patents.
Date of Filing of TPO	06/08/2024

National Phase

Office	Entry Date	National Number	National Status
European Patent Office	13.10.2023	2023722475	Published 17.01.2024 Granted 12.06.2024
Israel	16.09.2024	315684	
Australia	17.09.2024	AU2023249631	
New Zealand	17.09.2024	814609	Published 27.09.2024 Divisional 06.02.2025
China	23.09.2024	202380029590.8	Published 08.11.2024
Mexico	24.09.2024	MX/a/2024/011695	Published 08.11.2024
Japan	26.09.2024	2024557160	
Philippines	02.10.2024	12024552370	
United Arab Emirates	04.10.2024	P2024-02632	
Thailand	04.10.2024	2401006659	

	Eurasian Patent Organization	09.10.2024	202492337	
	India	25.10.2024	202417081360	Published 20.12.2024
	Singapore	30.10.2024	11202406601Q	Published 30.10.2024
	Republic of Korea		1020247036569	Published 07.01.2025

<table>
<tr><td>TPO No.</td><td>256</td></tr>
<tr><td>Appl. No.</td><td>WO2023235825 (WO’825)</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023235825</td></tr>
<tr><td>Applicants</td><td>DUKE UNIVERSITY
THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA</td></tr>
<tr><td>Priority Date</td><td>63/347,838 01.06.2022 US</td></tr>
<tr><td>Details</td><td>Summary of Application: WO’825 claims recombinant HIV-1 Env polypeptide (gp160 transmembrane envelope) based on CH505 T/F Env—comprising an optimised sequence for binding to CH235 UCA (mutations G458Y and N197X(D)) and additionally other known mutations for stability (F14, etc.) at positions of interprotomer contacts within a single trimeric envelope (I535M). WO825 also claims the Env linked to a self-assembling protein (ferritin), that can self-assemble into a multimeric complex, to form fusion protein, nucleic acid (mRNA) and compositions thereof; method of inducing immune response therewith; with specific mutations, methods thereof for prime or boost administration; wherein the NA is mRNA encapsulated in an LNP. WO’825 specifically claims HIV-1 envelope CH505.w24.e5F14.SOS.GSA.L.Y712I.I535M.A316W. S306L.R308L gp160_mVHss.

TPO filed: The TPO observed through prior art documents the information that the Applicant of the present Application based their immunogen design on was already known and disclosed in prior art (involvement of the N197 glycan in affecting the binding to CH235UCA), that the additional mutations that the Applicants had added onto the CH505 Env immunogen for trimer stabilization, surface expression, etc. were already known mutations with disclosed effects and the viral isolates have also been disclosed earlier, and that such CH505 immunogens have already been expressed using self-assembling nanoparticles and mRNAs encapsulated in lipid nanoparticles.

No. of prior art documents used in No. of notes.: 10 prior art documents were used in 6 notes to assail inventive step for all the claims of WO’825.

Additional comment filed: The Additional Comments filed pointed out that the Application, WO825, is one of two identical applications filed (the other one being WO2023, claiming the HIV-1 CH505.M5.G458Y/N197D immunogen. To show that certain claims lacked inventive step, the Additional Comments also pointed out that (i) the mutations claimed in of WO825 listed in Tables 1 and 3 of the present Application are all known mutations with established effects, and (ii) the untranslated regions (UTRs) and poly A tail claimed in WO825 set out in Table 5 of the present Application, are known in the art, have been earlier explored with the SARS-CoV-2 mRNA vaccine by Duke University.

Importance of Application: A TPO was filed because this is an application by Duke University for recombinant HIV immunogens designed to elicit CH235 UCA antibodies. There is a Phase I clinical trial NCT06557785 with CH505 M5 immunogen (279K mutation) with N197D modification; it is described as an mRNA gp160 immunogen (https://clinicaltrials.gov/study/NCT06557785</td></tr>
<tr><td>Date of Filing of TPO</td><td>01/10/2024</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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	European Patent Office	02.01.2025	2023816952	Published 09.04.2025

<table>
<tr><td>TPO No.</td><td>257</td></tr>
<tr><td>Appl. No.</td><td>WO2023235823 (WO’823) : Biologic : HIV</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023235823</td></tr>
<tr><td>Applicants</td><td>DUKE UNIVERSITY</td></tr>
<tr><td>Priority Date</td><td>63/347,833 01.06.2022 Us</td></tr>
<tr><td>Details</td><td>
Summary of Application: WO’823 claims recombinant HIV-1 Env polypeptide based on CH505 T/F Env—comprising an optimised sequence for binding to CH235 UCA (mutations G458Y and N197X(D)) and additionally other known mutations (F14, etc.). WO823 also claims the Env linked to a self-assembling protein (ferritin) to form fusion protein, nucleic acid (mRNA) and compositions thereof; method of inducing immune response therewith; with specific mutations. The claims of Application WO’823 are identical to WO2023235825 except that WO’823 does not specifically claim the mRNA molecule encoding the immunogen along with its untranslated regions (UTRs) and poly A tail and compositions and methods thereof.

TPO filed: The TPO observed through prior art documents that the information that the Applicant of the present Application based their immunogen design on was already known and disclosed in prior art (involvement of the N197 glycan in affecting the binding to CH235UCA), that the additional mutations that the Applicants had added onto the CH505 Env immunogen for trimer stabilization, surface expression, etc. were already known mutations with disclosed effects and the viral isolates have also been disclosed earlier, and that such CH505 immunogens have already been expressed using nanoparticles.

No. of Prior Art documents used in No. of Notes: 10 prior art documents were used in 6 notes to assail inventive step for all the claims of WO’823

Additional Comments: Additional Comments were filed to point out that the Application, WO823, is one of two identical applications filed (the other one being WO2023235825), claiming the HIV-1 CH505.M5.G458Y/N197D immunogen. To show that certain claims lacked inventive step, the Additional Comments also pointed out that (i) the mutations claimed in of WO823 are all known mutations with established effects, and (ii) the untranslated regions (UTRs) and poly A tail claimed in WO823 are known in the art.

Importance of Application: A TPO was filed because this is an application by Duke University for recombinant HIV immunogens designed to elicit CH235 UCA antibodies. There is a Phase I clinical trial NCT06557785 with CH505 M5 immunogen (279K mutation) with N197D modification; it is described as an mRNA gp160 immunogen.
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<tr><td>Date of Filing of TPO</td><td>01/10/2024</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>02.01.2025</td><td>2023816950</td><td>Published 09.04.2025</td></tr>
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<tr><td>TPO No.</td><td>258</td></tr>
<tr><td>Appl. No.</td><td>WO2024006982 (WO’982): Small Molecule: HIV</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024006982</td></tr>
<tr><td>Applicants</td><td>GILEAD SCIENCES, INC.</td></tr>
<tr><td>Priority Date</td><td>63/357,859 01.07.2022 US</td></tr>
<tr><td>Details</td><td>Summary of Application: WO’982 claims compounds selected from Compounds of Formulae I-VI, or a pharmaceutically acceptable salt thereof that are analogues of lenacapavir, with various substituents on the pyridine and indazole moiety. The Application also claims composition comprising the claimed compounds in an amount greater than about 25, 50 or 75% by weight or in an amount lesser than about 25, 10 or 1% by weight. WO’982 also claims preparation of the said compounds with a purity greater than 95%. Further, WO982 claims pharmaceutical composition comprising the said compounds and further additional therapeutic agents, and method thereof for preventing or treating HIV as well as the use of the said compounds in preventing or treating HIV.
TPO filed: The TPO observed through prior art documents that the analogues of Lenacapavir differed in only peripheral modifications that have been disclosed or claimed earlier.
No. of prior art documents used in No. of notes.: 4 prior art documents were used in 4 notes (one document was a Px document), to assail novelty (to the extent of overlap) and/ or inventive step for all the claims of WO’982.
Additional comment filed: The Additional Comments filed highlighted the peripheral substitutions in comparison with the prior art documents to show the overlap/ similarity in the prior art and the present application, WO’982.
Importance of Application: A TPO was filed because this is an application that claims analogues of Lencapavir, a known capsid inhibitor that has entered late stages of clinical trial and has been approved in some countries. Opinion from TWN was also taken with respect to this Application, and were advised to file the TPO</td></tr>
<tr><td>Date of Filing of TPO</td><td>01/11/2024</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>03.02.2025</td><td>2023748673</td><td></td></tr>
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<tr><td>TPO No.</td><td>259</td></tr>
<tr><td>Appl. No.</td><td>WO2024015741 (WO’741): Biologic: HIV</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024015741</td></tr>
<tr><td>Applicants</td><td>GILEAD SCIENCES, INC.</td></tr>
<tr><td>Priority Date</td><td>63/384,020 16.11.2022 US
63/388,599 12.07.2022 US
63/485,122 15.02.2023 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’741 claims self-amplifying RNA (SAM or saRNA) including: polynucleotide sequence encoding polypeptide sequences for HIV-1 immunogens, joined to an adjacent polypeptide segment by one or more peptide linkers, and a promoter sequence, LNP/polymer nanoparticles, and expression vectors thereof including adenoviral vectors ChAd68; compositions, kits with additional agents and methods of eliciting immune response thereof with prime-boost administration.
<u>TPO filed:</u> The TPO observed through prior art documents that the Applicant has merely used an earlier disclosed HIV immunogen design strategy and delivered the immunogen using ChAd68/ SAM (Venezuelan equine encephalitis virus with a 26S promoter) vectored vaccine regimen, which has been disclosed earlier as effective for treating HIV.
<u>No. of prior art documents used in No. of notes</u>: 6 prior art documents were used in 4 notes to assail novelty (to the extent of overlap) and/or inventive step for all the claims of WO’741.
<u>Additional comment filed:</u> Not filed.
<u>Importance of Application:</u> A TPO was filed because a Phase 1b clinical trial relating to the claims and disclosures of the present Application was found: https://midwayresearch.org/current-open-studies/. This trial was also listed in the 2023 and 2024 TAG report for HIV.</td></tr>
<tr><td>Date of Filing of TPO</td><td>12/11/2024</td></tr>
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<tr><td>Australia</td><td>11.12.2024</td><td>AU2023307100</td><td></td></tr>
<tr><td>Republic of Korea</td><td>07.02.2025</td><td>1020257004129</td><td></td></tr>
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<tr><td>TPO No.</td><td>260</td></tr>
<tr><td>Appl. No.</td><td>WO2024023790 (WO’790): Biologic: TB</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024023790</td></tr>
<tr><td>Applicants</td><td>UNIVERSITY OF CAPE TOWN
UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY</td></tr>
<tr><td>Priority Date</td><td>2023/05862 01.06.2023 ZA
2211137.1 29.07.2022 GB</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’790 claims vaccine compositions comprising nucleic acids (NA) encoding for Wbbl1, CFP-10, PPE18 and/or PE13 antigens (Ags) of Mycobacterium tuberculosis (Mtb), the NA further with leader nucleotide sequence encoding a secretory peptide signal and linkers; NA is mRNA (capped at the 5’ end; includes one or more modified nucleotides- selected from N1 -methyl-pseudouridine and pseudouridine) comprised in a lipid nanoparticle (LNP). WO’790 claims that it is capable of eliciting a protective immune response against Mtb and use and methods thereof, with at least one NA from the stated antigens hereabove. WO’790 also claims NA construct (mRNA) encoding at least one or two Ags selected from Wbbl1, CFP-10, PPE18 and PE13 and LNP comprising the construct, and also claims vaccine composition, NA construct or LNP for use in a method of eliciting a protective immune response against Mtb.

<u>TPO filed:</u> The TPO observed through prior art documents that the (a) the strategy of identification of Mtb vaccine antigens after T cell receptor clustering by employing GLIPH2 has been explored earlier; (b) different patient Cohorts have been studies with respect to the linking of T cell receptor sequence to functional phenotype at the single-cell level and bulk level; (c) use of mRNA-LNP for the delivery of Tb antigens has been envisaged and disclosed earlier; and (d) all the antigens selected based on the clustering strategy are well-known, and fusions constructs including these antigens have also been disclosed earlier for use in tuberculosis vaccines.

<u>No. of prior art documents used in No. of notes.:</u> 12 prior art documents were used in 7 notes, to assail inventive step for all the claims of WO’790.

<u>Additional comment filed:</u> Not filed

<u>Importance of Application:</u> A TPO was filed because this is an application wherein the Universities have collaborated with BioNTech for mRNA-based vaccine constructs. Multiple presentations and posters relating to the claims of the present Application based on the development of mRNA TB vaccine incorporating antigens which are preferentially targeted in individuals who controlled tuberculosis infection. https://health.uct.ac.za/sites/default/files/media/documents/health_uct_ac_za/813/uct-satvi-annual-report-2023-digital-5-sep-2023.pdf</td></tr>
<tr><td>Date of Filing of TPO</td><td>29/11/2024</td></tr>
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<tr><td>European Patent Office</td><td>28.02.3035</td><td>2023754847</td><td></td></tr>
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TPO No.	**261**
Appl. No.	**WO2024030121 (WO'121): Small Molecule: TB**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024030121
Applicants	THE SCRIPPS RESEARCH INSTITUTE CORNELL UNIVERSITY
Priority Date	
Details	**Summary of Application:** WO'121 claims compounds of Formula I (piperidinyl ethanone scaffold) and Formula II (azabicyclo ethanone scaffold), specifically 5 compounds - mCLB073, mCIS635, mCLE299, mCLF177 and mCLF178 of Formula I, which are agonists of Mtb adenylyl cyclase Rv1625c which stimulate cAMP synthesis and inhibit cholesterol utilization by Mtb. WO'121 also claims composition (for oral administration) comprising the said compounds and additional therapeutic compounds for treating TB; and method for activating Mtb adenylyl cyclase, method of inhibiting cholesterol degradation pathway and method of preventing, ameliorating or treating TB.
	TPO filed: The TPO observed through the prior art document that the prior art document already disclosed the identical 5 compounds as claimed specifically in WO'121, and that it also disclosed analogues of V-59 (with piperidinyl ethanone scaffold = Formula I of WO'121), as Rv1625c agonists which act as inhibitors of *Mtb* cholesterol utilization.
	No. of prior art documents used in No. of notes.: 1 prior art document was used in 1 note to assail novelty (to the extent of overlap) and/ or inventive step for all the claims of WO'121.
	Additional comment filed: The Additional Comments filed brought out the lack of unity of invention, lack of sufficiency of disclosure, lack of novelty, and lack of inventive step of the claims of the Application WO'121. The Additional Comments also highlighted that the 5 specifically claimed compounds, have been disclosed earlier establishing lack novelty for claims specific to the 5 compounds, and a lack inventive step for all the claims.
	Importance of Application: A TPO was filed because it has been reported that mCLB073, an orally available, optimized version of V-59, was approximately 17 times more effective at killing *Mycobacterium tuberculosis* in vitro; and that the team of Brian VanderVen (one of the co-inventors of WO'121) has handed off mCLB073 to the Gates Foundation for safety testing and studying its efficacy in combination with other frontline tuberculosis drugs.
Date of Filing of TPO	02/12/2024
National Phase	No National Phase as of 24.03.2024

<table>
<tr><td>TPO No.</td><td>262</td></tr>
<tr><td>Appl. No.</td><td>WO2024028445 (WO’445): Biologic: TB</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024028445</td></tr>
<tr><td>Applicants</td><td>BIONTECH SE.</td></tr>
<tr><td>Priority Date</td><td>PCT/EP2022/071816 03.08.2022 EP
PCT/EP2022/087251 21.12.2022 EP</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’445 claims a composition/medical preparation comprising at least 1 mRNA molecule encoding Mycobacterium tuberculosis (Mtb) antigens (Ags) that are from the acute (Ag85A, ESAT6), latent (VapB47, Hrp1), and resuscitation (RpfA, RpfD) phases of the Mtb life cycle, with additional 2 Ags with amino acid sequences in a fusion molecule not linked by a linker, that is with M72 and HbhA Ags; either as a multiantigen construct or mRNA mixes with fusion of 2 Ags. WO’445 further claims the compositions of the mRNA that is modified and formulated in lipid nanoparticles, for use of treating/preventing tuberculosis in humans; and methods thereof.

<u>TPO filed:</u> The TPO observed through prior art documents that the same 2 Mtb Ags from each of the acute, latency and resuscitation phases of Mtb life cycle and also construct encoding all 6 Ags together, or as part of multiple vectors, with additional Ags, were already disclosed/claimed in the prior art, which also states the possibility that different or additional TB Ag inserts with known effects would increase efficacy. The TPO also brought out the obviousness to explore the mRNA vaccine platform for TB.

<u>No. of prior art documents used in No. of notes.:</u> 15 prior art documents were used in 7 notes to assail inventive step for all the claims of WO’445.

<u>Additional comment files:</u> Filed to bring out that there is another identical Application, being WO2024027910 that has been filed by the Applicant. The Additional Comments also brought out the lack of inventive step of the claims of the present Application.</td></tr>
<tr><td>Date of Filing of TPO</td><td>03/12/2024</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>Israel</td><td>21.01.2025</td><td>318534</td><td></td></tr>
<tr><td>Australia</td><td>22.01.2025</td><td>AU2023317822</td><td></td></tr>
<tr><td>India</td><td>31.01.2025</td><td>202547008246</td><td>Published 14.02.2025</td></tr>
<tr><td>European Patent Office</td><td>03.03.2025</td><td>2023753870</td><td></td></tr>
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TPO No.	**263**
Appl. No.	**WO2024027910 (WO'910): Biologic: TB**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024027910
Applicants	BIONTECH SE
Priority Date	
Details	**Summary of Application:** WO'910 is the first priority document of the Application WO2024028445 (WO'445). WO'910 claims a composition/medical preparation comprising at least 1 mRNA molecule encoding *Mycobacterium tuberculosis* (Mtb) antigens (Ags) that are from the acute (Ag85A, ESAT6), latent (VapB47, Hrp1), and resuscitation (RpfA, RpfD) phases of the Mtb life cycle, with additional 2 Ags with amino acid sequences in a fusion molecule not linked by a linker, that is with M72 and HbhA Ags; either as a multiantigen construct or mRNA mixes with fusion of 2 Ags. WO'910 further claims the compositions of the mRNA that is modified and formulated in lipid nanoparticles, for use of treating/preventing tuberculosis in humans; and methods thereof.
	TPO filed: The TPO used the same prior art used for the identical Application WO'445. The TPO observed through prior art documents that the same 2 Mtb Ags from each of the acute, latency and resuscitation phases of Mtb life cycle and also construct encoding all 6 Ags together, or as part of multiple vectors, with additional Ags, were already disclosed/claimed in the prior art, which also states the possibility that different or additional TB Ag inserts with known effects would increase efficacy. The TPO also brought out the obviousness to explore the mRNA vaccine platform for TB.
	No. of prior art documents used in No. of notes.: 15 prior art documents were used in 7 notes to assail inventive step for all the claims of WO'445.
	Additional comment filed: Filed to bring out that there is another identical Application, being WO2024028445 that has been filed by the Applicant. The Additional Comments also brought out the lack of inventive step of the claims of the present Application.
	Importance of Application: A TPO was filed because the vaccine is in Phase 1/ 2 clinical trials and is also included in the 2023 TAG reports.
Date of Filing of TPO	03/12/2024
National Phase	No National Phase as of 24.03.2024

TPO No.	**264**
Appl. No.	**WO2024036217 (WO'217): Biologic: HIV**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024036217
Applicants	FRED HUTCHINSON CANCER CENTER
Priority Date	63/370,910 09.08.2022 US
Details	**Summary of Application:** WO217 claims a method of eliciting antibodies that bind full length glycosylated HIV 426c envelope (Env) immunogen (multimerized form) in a person in need thereof, the method comprising administering to the person an HIV Env immunogen that binds germline B cell receptors (specifically of VRC01), with/without a boost, to an envelope immunogen having glycosylation site at position 276, and discontinuing ART in HIV-infected persons, allowing natural viral rebound to guide antibody maturation.
	TPO filed: The TPO observed through prior art documents that eliciting antibodies with engineered HIV 426c Env immunogen, and identical adjuvants was known and disclosed. Prior art documents also disclosed viral rebound due to ART interruption that initiates antibody maturation, thereby showing that a method of administering germline targeting immunogen (with or without booster dose), combined with ART interruption for maturing antibodies via viral rebound is obvious.
	No. of prior art documents used in No. of notes.: .: 2 prior art documents in 2 notes assailed inventive step.
	Additional comment filed: Filed to point out some inadvertent errors in the Application WO'217, to show a table of comparison of the sequences of the one's disclosed in the Application WO'217 and the prior art, through BLAST analysis and the observation of the results of the BLAST, and to point out the insufficiency of disclosure.
	Importance of Application: A Phase I clinical trial has commenced to study the germline targeting HIV-1 Env derived immunogens – titled 426c.Mod.Core-C4b Adjuvanted With 3M-052-AF + Alum Immunization in Combination With an Antiretroviral Analytical Treatment Interruption (ATI) in People Living With HIV for Elicitation of VRC01-lineage Antibodies; available at https://www.clinicaltrials.gov/study/NCT06006546, that appears to be linked to the Application WO'217.
Date of Filing of TPO	08/12/2024
National Phase	No National Phase as of 24.03.2024

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<tr><td>TPO No.</td><td>265</td></tr>
<tr><td>Appl. No.</td><td>WO2024035618 (WO’618): Small Molecule: TB</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024035618</td></tr>
<tr><td>Applicants</td><td>MERCK SHARP & DOHME LLC
WERTHENSTEIN BIOPHARMA GMBH</td></tr>
<tr><td>Priority Date</td><td>63/396,929 10.08.2022 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO’618 claims crystalline forms of and processes for preparing oxazolidinone compounds (specifically compound of Formula I) useful for the treatment of TB infection. WO’618 also claims processes for preparing and intermediates used in the process for preparing crystalline forms of Compound of Formula I. It also claims compositions of crystalline form of the compound. WO’618 further claims Amorphous dispersion formulation comprising polymer and prepared using hot melt extrusion (HME).
<u>TPO filed:</u> The TPO observed through prior art documents that identical compounds as WO’618 have been the subject matter of an earlier patent Application by the Applicant, Merck. The synthesis scheme was prior disclosed for synthesizing oxazolidinone compounds and hence it is obvious to employ similar scheme to synthesize an already known compound. Also, the TPO observed that making crystalline forms, and amorphous solid dispersion using HME is routine and already known.
<u>No. of prior art documents used in No. of notes.:</u> 5 prior art documents were cited in 5 notes to assail inventive step.
<u>Additional comment filed:</u> Not filed.
<u>Importance of Application:</u> The compound appears on the TAG reports – TB treatment 2023, and that it has entered Phase Ia/b clinical trials, available at https://clinicaltrials.gov/study/NCT05824091 , and that the compound – called MK7762 – TBD09 is funded by BMGMRI, NIH, etc. – available at https://www.newtbdrugs.org/pipeline/compound/tbd09-mk7762 that discloses the oxazolidinone compound.</td></tr>
<tr><td>Date of Filing of TPO</td><td>10/12/2024</td></tr>
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<tr><td>European Patent Office</td><td>10.03.2025</td><td>2023853241</td><td></td></tr>
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TPO No.	**266**
Appl. No.	**WO2024044684 (WO'684): Biologic: HIV**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2024044684
Applicants	INTERNATIONAL AIDS VACCINE INITIATIVE, INC. THE SCRIPPS RESEARCH INSTITUTE
Priority Date	63/373,414 24.08.2022 US
Details	**Summary of Application:** WO'684 claims improved HIV antigens, including germline-targeting designs, trimer stabilization designs, combinations of those two, trimers designed with modified surfaces helpful for immunization regimens and other types of trimer modifications (additional trimer modifications that add functionality) and claims a non-naturally occurring protein, which is multimeric, has additional cysteines; a nucleic acid encoding the same formulated in lipid nanoparticle; and method of eliciting immune response by administering to animal (mammal-human) an effective amount of protein/nucleic acid along with an additional booster dose from HIV pseudo virus.
	TPO filed: The TPO observed through prior art documents that the immunogens as claimed in WO'684 have been claimed earlier.
	No. of prior art documents used in No. of notes.: 4 prior art documents were used in 2 notes to assail novelty (to the extent of overlap) and inventive step.
	Additional comment filed: The Additional comments brought forth the similarity of the immunogens disclosed in the prior art cited by the TPO, the claim-to-claim disclosure to claim comparison between the prior art document and the Application WO'684, and disclosure of some proteins/ immunogens in other prior art documents.
	Importance of Application: Multiple immunogens claimed in WO'684 were found to be part of clinical trials.
Date of Filing of TPO	24/12/2024
National Phase	No National Phase as of 24.03.2024