Third Party Observations (TPOs) filed between January and December 2023

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 (in early 2024). 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>206</td></tr>
<tr><td>Appl. No.</td><td>WO2021250648 (WO’648)</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2021250648</td></tr>
<tr><td>Applicants</td><td>PFIZER INC.</td></tr>
<tr><td>Priority Date</td><td>03.09.2020 US
29.01.2021 US
02.04.2021 US
28.05.2021 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> Pfizer’s application WO’648 was for peptidomimetic inhibitors of SARS-CoV-2 3Cl-pro or Mpro. The inhibitor compounds specifically claimed nitrile warhead (P1’), gamma-lactam (P1), and cyclic moiety (P2)(e.g., azabicyclohexane). WO’648 also made claims various physical forms of the inhibitor compounds, pharmaceutical compositions, combination with ritonavir & oral administration twice daily.

<u>TPO filed:</u> The TPO observed that the compounds claimed in WO’648 were similar to known compounds (a table of comparison was also filed), such as Boceprevir, & Narlaprevir, and minor modifications were made at the periphery to reach the compounds claimed in the present Application, WO’648. The TPO brought out that the modifications made were obvious to a person skilled in the art, and thus the Application WO’648 lacked inventive step.

<u>No. of prior art documents used in No. of notes.:</u> 11 prior art documents were used in 8 notes to show that the Application lacked inventive step.

<u>Additional comment filed:</u> An additional comment was also filed to show how several other companies/ teams have asserted the importance of azabicyclohexane (P2) and tert-leucine (P3) for potent SARS-CoV-2 Mpro inhibition activity & suggested further optimization of HCV NS3/4A pro-inhibitors Boceprevir and Narlaprevir, having these structural scaffolds for repurposing as SARS-CoV-2 Mpro inhibition. The Additional comment also brought about the observation of obviousness of having SARS-CoV-2 protease inhibitors with boceprevir scaffold with suitable modifications by pointing out the multiplicity of applications (Pardes Biosciences, Enanta Pharmaceuticals, Stanford University) with priority dates within a span of few months, claiming peptidomimetic inhibitors with the scaffold of boceprevir and the substituents as those claimed for nirmatrelvir

Importance of Application: This Application relates to Pfizer’s oral drug Paxlovid, a combination of Nirmatrelvir [PF-07321332; Compound E61 in WO648] and Ritonavir, used to treat COVID-19. Paxlovid has received EUA from FDA for treatment of mild-to-moderate COVID-19.</td></tr>
<tr><td>Date of Filing of TPO</td><td>03/01/2023</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>Canada</td><td>05.11.2021</td><td>3137824</td><td>Published 02.03.2022
Granted 08.11.2022</td></tr>
<tr><td>Costa Rica</td><td>05.11.2021</td><td>CR2021-000558</td><td>Published 24.01.2022</td></tr>
<tr><td>Israel</td><td>07.11.2021</td><td>299071</td><td>Divisional 13.12.2022</td></tr>
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Brazil	08.11.2021	122023004755	Divisional 11.04.2023
Japan	08.11.2021	2021566159	
Mexico	08.11.2021	MX/a/2021/013679	Published 09.02.2022 Granted 04.04.2024
Nicaragua	08.11.2021	2021-000104 I	
Peru	08.11.2021	001591-2024	Divisional 11.07.2024 Granted 22.07.2024 Published 29.03.2022
Australia	09.11.2021	2021266232	
Dominican Republic	09.11.2021	DOP2021000232	Published 15.02.2022
United Arab Emirates	10.11.2021	P6002051/2021	
Cuba	10.11.2021	D2021093	
Eurasian Patent Organization	10.11.2021	202192798	
India	10.11.2021	202117051620	Published 16.09.2022
New Zealand	10.11.2021	782196	Published 26.11.2021 Divisional 24.08.2022 Granted 29.11.2022
Russian Federation	10.11.2021	2021132570	Granted 26.12.2022
European Patent Office	11.11.2021	2021758144	Published 16.02.2022 Granted 12.10.2022
Thailand	11.11.2021	2101007038	
Singapore	12.11.2021	11202112508R	Published 29.09.2022 Granted 29.09.2022
China	19.11.2021	202180003440.0	Published 10.05.2022 Granted 02.05.2023
Republic of Korea	30.11.2021	1020217039289	Published 12.04.2022 Granted 09.12.2022
Georgia	11.04.2022	15927/1	
Chile	18.07.2022	2021002965	Published 27.01.2023 Granted 28.04.2023
Serbia	04.11.2022	P-2022/1020	Granted 30.11.2022
Philippines	04.04.2023	12023550925	
Saudi Arabia	26.07.2024	521430792	

TPO No.	207
Appl. No.	**WO2022059023 (WO'023)**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022059023
Applicants	BHARAT BIOTECH INTERNATIONAL LIMITED
Priority Date	202041036825 15.09.2020 IN
Details	**Summary of Application:** The Applicant, Bharat Biotech, claims a SARS-CoV-2 vaccine formulation against viral infections comprising a vaccine antigen (SARS-CoV-2 & its variants, JEV, HBV, VLP, etc)- inactivated, using β-propiolactone (BPL)/formaldehyde as vaccine antigen; the formulation further comprises of excipients, including a specific Algel-IMDG (imidazoquinoline) adjuvant (TLR agonist adsorbed onto Al hydroxide gel). The vaccine formulation provides long term protective immunity to the virus and is used for prophylactic or therapeutic purposes.
	TPO filed: The TPO observed that the SARS-CoV-2 virus has been inactivated and used in vaccines with BPL, and formulated with Algel & Algel-IMDG TLR7/8 adjuvants adsorbed on aluminium hydroxide gel, has been disclosed prior to the priority date of the Applicant of WO'023. The clinical trials too with the vaccine disclosing the vaccine and the formulation were disclosed prior to priority date. Prior art disclosing the use of imidazoquinoline TLR7/8 agonists was used, and earlier application of the Applicant for Zika vaccine using inactivated whole virion, and similar adjuvants, & methods as used for Japanese Encephalitis vaccine inactivated were also used in the TPO.
	No. of prior art documents used in No. of notes.: 14 prior art documents via 8 notes was used to show that the Application lacked novelty, and/or inventive step.
	Additional comment filed: An Additional comment was filed to bring out (1) the variants of SARS-CoV-2 claimed in WO'023 were not disclosed in the priority document, hence the date of filing would be the priority date vis-à-vis the claims with the variants. Documents disclosing the variants were referred to. (2) The adjuvant Algel-IMDG, also known as Alhydroxyquim-II was admittedly licensed by BBIL from ViroVax LLC USA; whereas ViroVax LLC had filed an application WO2021226088 for this adjuvant with a priority date earlier than that of WO'023. (3) The Imidazoquinoline TLR 7/8 agonist with the same scaffold has been studied by teams at the University of Kansas, University of Minnesota, etc.
	Importance of Application: This application is Bharat Biotech COVID-19 inactivated vaccine Covaxin (BBV152), which got EUA and marketing approval in India as it's first indigenous COVID-19 vaccine.
Date of Filing of TPO	16/01/2023

National Phase

Office	Entry Date	National Number	National Status
Brazil	15.03.2023	112023004799	
United States of America	15.03.2023	18026404	Published 30.11.2023
European Patent Office	17.04.2023	2021868893	Published 16.07.2023

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<tr><td>TPO No.</td><td>208</td></tr>
<tr><td>Appl. No.</td><td>WO2022067010 (WO’010)</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022067010</td></tr>
<tr><td>Applicants</td><td>MODERNATX, INC.</td></tr>
<tr><td>Priority Date</td><td>63/083,779 25.09.2020 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The Applicant, ModernaTX filed an application claiming an mRNA vaccine comprising an ORF encoding a SARS-CoV-2 S protein variant with at least 3, and up to 6 proline substitutions; the mRNA (with 5’ & 3’-UTRs & 1-methylpseudouridine chemical modification) formulated in a lipid nanoparticle, and a method of inducing immune response in humans through administration of the mRNA. It specifically claims Combo47 (also known as hexapro) with 6 proline substitutions at positions F817, A892, A899, A942, K986, & V987. (The earlier mRNA vaccine of ModernaTX had two proline substitutions)

<u>TPO filed:</u> The TPO observed through prior art documents that multiple proline substitutions were known, including hexapro, and combination variant Combo47, prefusion stabilization techniques known, and the use of the variants, the same composition of the lipid nanoparticles, etc. was brought out to show that the Application lacked inventive step.

<u>No. of prior art documents used in No. of notes.:</u> 13 prior art documents were used via 8 notes to show that the Application lacked inventive step.

<u>Additional comment filed:</u> An Additional comment was filed to assert that the ionizable cationic lipid, Compound 1 in WO’010 is identical to the proprietary lipid SM-102 used in the lipid nanoparticle composition for encapsulating mRNA-1273 and also has been disclosed earlier in several prior art documents as a component of the LNP composition.

Importance of Application: This is ModernaTX’s mRNA vaccine encoding SARS-CoV-2 variant with proline substitutions (at 3 to 6 positions).</td></tr>
<tr><td>Date of Filing of TPO</td><td>25/01/2023</td></tr>
<tr><td>National Phase</td><td>
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<tr><td>European Patent Office</td><td>25.04.2023</td><td>2021795094</td><td>Published 02.08.2023
Withdrawn06.11.2023</td></tr>
<tr><td>United States of America</td><td></td><td>18028126</td><td>Published 09.11.2023</td></tr>
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<tr><td>TPO No.</td><td>209</td></tr>
<tr><td>Appl. No.</td><td>WO2022079303</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022079303</td></tr>
<tr><td>Applicants</td><td>INSTITUT PASTEUR
THERAVECTYS</td></tr>
<tr><td>Priority Date</td><td>20306236.1 16.10.2020 EP</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The application claimed recombinant lentiviral vector genome and a LV particle thereof, comprising a polynucleotide encoding a fusion polypeptide: first with a multimerization scaffold fused with antigenic polypeptide (Mtb antigen, influenza virus or a coronavirus such as SARS-CoV-2 or a tumoral antigen) comprising at least one collectin (SPD, etc.), and second comprising a CD40L ectodomain; a pharmaceutical composition thereof for use in the elicitation of a prophylactic immune response and/or cellular and/or humoral response against the antigenic polypeptide or immunogenic fragments thereof, for preventing or treating an infection, wherein the immune response involves the induction of MHC-II restricted presentation of the antigenic polypeptide or immunogenic fragments thereof, by an antigen-presenting cell, in particular a dendritic cell, and the induction of a CD4-mediated cellular immune response. It also claims a method of production of the lentiviral vector.
<u>TPO filed:</u> The TPO observed that the lentiviral vectors have been used for multiple antigens, and the construct of the vectors was known. The TPO brought out that the obviousness in the of use lentiviral vectors constructs for treating viral diseases.
<u>No. of prior art documents used in No. of notes.:</u> 13 prior art documents were used in 8 notes to show that the Application lacked novelty and/or inventive step.
<u>Additional comment filed:</u> An additional comment was also filed to show that the priority date of one claim – claim 11 with respect to pFlap-SP1 beta2m-GFP-WPREm construct that was not claimed in the priority document, and thus the priority for this claim would be date of filing. The comment also brought out that the multimerization scaffold (SPD-Ag-CD40L) with lentiviral vectors and MTB antigens was known, and that its use resulted in CD4 mediated cellular immune response via the MHCII pathway. The priority documents were read together to point out obviousness of the present application.
<u>Importance of Application</u>: This Application relates to platform technology for viral infection; that has entered clinical trials for HIV. It has also been looked at as a booster for TB following the BCG vaccine.</td></tr>
<tr><td>Date of Filing of TPO</td><td>16/02/2023</td></tr>
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<tr><td>Canada</td><td>14.04.2023</td><td>3195830</td><td>Published 17.05.2023</td></tr>
<tr><td>Japan</td><td>17.04.2023</td><td>2023523523</td><td></td></tr>
<tr><td>New Zealand</td><td>27.04.2023</td><td>799434</td><td>Published 28.04.2023</td></tr>
<tr><td>Republic of Korea</td><td>15.05.2023</td><td>1020237016375</td><td>Published 16.06.2023</td></tr>
<tr><td>European Patent Office</td><td>16.05.2023</td><td>2021805380</td><td>Published23.08.2023</td></tr>
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	Singapore	31.05.2023	11202302912P	Published 31.05.2023
	China	16.06.2023	202180085160.9	Published 19.09.2023
	United States of America		18030102	Published 16.11.2023

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<tr><td>TPO No.</td><td>210</td></tr>
<tr><td>Appl. No.</td><td>WO2022084333</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022084333</td></tr>
<tr><td>Applicants</td><td>JANSSEN VACCINES & PREVENTION B.V.</td></tr>
<tr><td>Priority Date</td><td>20202762.9 20.10.2020 EP
20207201.3 12.11.2020 EP</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The Applicant, claims a vaccine administration combination regimen for HIV treatment, comprising a first composition comprising a poxvirus vector (MVA) comprising a polynucleotide that encodes at least one HIV envelope (Env) antigen & a second composition comprising a human adenovirus vector (Ad26) comprising a polynucleotide that encodes at least one HIV Env antigen, administered to induce a broad T-cell immune response.
<u>TPO filed:</u> The TPO observed that the functioning of the MVA prime and Ad26 boost regimen, and its effect on CD4+, CD8+ T cell responses, in addition to the neutralizing antibody responses, was known and obvious.
<u>No. of prior art documents used in No. of notes.:</u> 6 prior art documents via 4 notes was used to show that the Application lacked inventive step.
<u>Additional comment filed:</u> NA
<u>Importance of Application:</u> This application is for the MVA prime and AD26 boost regimen that has been explored earlier for other organisms. Janssen has explored this combination for Ebola and may explore for HIV.</td></tr>
<tr><td>Date of Filing of TPO</td><td>20/02/2023</td></tr>
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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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TPO No.	211
Appl. No.	**WO2022101469**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022101469
Applicants	BIONTECH SE
Priority Date	63/114,478 16.11.2020 US 63/115,588 18.11.2020 US
Details	**Summary of Application:** The application claimed formulations (dry and frozen) comprising lipid nanoparticles (LNPs), which comprise mRNA payloads & the lipids (ALC-0135, ALC-0159, DSPC & Cholesterol at specified quantity & relative mass ratio); the formulation also comprising sucrose/trehalose, buffer (Tris/ PBS/ HEPES) comprising or free of NaCl; Method of preparing the LNPs & a method of preparing & administering the dosage form of claimed formulation; Method of delivering nucleic acid or inducing immune response against viral antigen (SARS-CoV-2 S-protein) or epitope thereof, encoded by the mRNA; Claimed formulation or method thereof, with its percent of water after drying & during storage, modified/non-modified mRNA, size & polydispersity of LNPs during storage, percent of encapsulation & expression of mRNA. **TPO filed:** The TPO observed that there was no inventive step in method of producing LNPs comprising the mRNA, and referred to prior art that disclosed the lipid components, buffers (first and second), excipients, etc. – all the formulation components, and the process for lyophilization and freeze-drying, & reconstituted, that have been used earlier in mRNA vaccines. **No. of prior art documents used in No. of notes.:** 14 prior art documents were used in 8 notes to show that the Application lacked inventive step. **Additional comment filed:** NA **Importance of Application:** This Application relates to the Pfizer vaccine, Comirnaty vaccine product with the purple and orange cap that comprise the lyophilized product to be reconstituted and the ready to use product, respectively.
Date of Filing of TPO	16/03/2023

National Phase

Office	Entry Date	National Number	National Status
Brazil	28.04.2023	112023008158	
Israel	08.05.2023	302770	
New Zealand	08.05.2023	799723	Published 26.05.2023
Canada	10.05.2023	3198311	Published 06.06.2023
Japan	15.05.2023	2023528665	
Mexico	15.05.2023	MX/a/2023/005697	Published 11.09.2023
United Arab Emirates	16.05.2023	P6001152/2023	
India	12.06.2023	202347039994	Published 30.06.2022
Republic of Korea	15.06.2023	1020237020260	Published 20.07.2023

		European Patent Office	16.06.2023	2021814751	Published 20.09.2023
		Russian Federation	16.06.2023	2023115651	
		Singapore	28.06.2023	11202303768W	Published 28.06.2023
		China	14.07.2023	202180090672.4	Published 10.11.2023
		Saudi Arabia	21.07.2024	523440776	
		United States of America		18036679	Published 08.02.2024

TPO No.	212
Appl. No.	**WO2022101470**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022101470
Applicants	BIONTECH SE
Priority Date	63/114,478 16.11.2020 US 63/115,128 18.11.2020 US 63/115,588 18.11.2020 US 63/135,723 10.01.2021 US 63/149,372 15.02.2021 US PCT/EP2020/082602 18.11.2020 EP PCT/EP2021/059460 12.04.20201 EP
Details	**Summary of Application:** The Applicant, claims composition comprising LNPs dispersed in an aqueous phase (buffer system- Tris, TEA, etc and their protonated form, monovalent anion- chloride, acetate, glycolate, lactate and anion of MES, MOPS, HEPES); aqueous phase free of anions of inorganic phosphate, citrate, EDTA, sulfate, carbonate, etc; buffer system, pH, osmolarity, water/solvent content, RNA encoding SARS-CoV-2 S protein of composition; LNP composition; method thereof (preparing RNA & ethanolic lipid solution, mixing, filtration, dispersion in final buffer, dilution; optionally freezing); Composition in liquid/frozen form; method of storing composition; method for preparing ready-to-use formulation; use of composition in therapy & for inducing immune response; mRNA integrity, Z-avg, PDI before and after storage **TPO filed:** The TPO observed that the Application lacked inventive step as the formulation with the buffer, etc. & its methods of preparation have been disclosed earlier. **No. of prior art documents used in No. of notes.:** 6 prior art documents were used in 4 notes to assail inventive step. **Additional comment filed:** NA **Importance of Application:** This application relates to the formulation with Tris buffer, which is frozen and ready to use after thawing. WO'470 relates to the Comirnaty grey cap product.
Date of Filing of TPO	16/03/2023

National Phase

Office	Entry Date	National Number	National Status
Brazil	28.04.2023	112023008166	
Israel	08.05.2023	302771	
New Zealand	08.05.2023	799720	Published 26.05.2023
Canada	12.05.2023	3198742	Published 08.06.2023
Japan	15.05.2023	2023528666	
Mexico	15.05.2023	MX/a/2023/005696	Published 12.06.2023
United Arab Emirates	16.05.2023	P6001153/2023	
European Patent Office	16.06.2023	2021807117	Published 20.09.2023
Russian Federation	16.06.2023	2023115649	

	Singapore	28.06.2023	11202303779U	Published 28.06.2023
	China	12.07.2023	202180090335.5	Published 29.09.2023
	Saudi Arabia	09.06.2024	523440778	
	Republic of Korea		1020237020261	Published 21.08.2023
	United States of America		18036677	Published 28.12.2023

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<tr><td>TPO No.</td><td>213</td></tr>
<tr><td>Appl. No.</td><td>WO2022120217</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022120217</td></tr>
<tr><td>Applicants</td><td>GRITSTONE BIO, INC.</td></tr>
<tr><td>Priority Date</td><td>63/121,164 03.12.2020 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The application claims a method for delivering a composition comprising a chimpanzee adenovirus (ChAdV) vector (ChAdV68) to humans, plurality of doses of the composition, a composition thereof (at least 27 weeks interval), encoding epitopes of tumor cells (KRAS and TP53) or infected cells (HIV gag) with immune modulators (anti-CTLA4), etc., further comprises administering a self-amplifying alphavirus-based expression system with one or more vectors RNA alphavirus backbone encoding the antigen and lipid nanoparticle formulations. The regimen in WO’217 comprises of SAM is administered at weeks 4 and 17 between the plurality of ChAdV 68 vectored vaccines (week 0 and week 33).
<u>TPO filed:</u> The TPO observed that the application was not novel or inventive, as there were prior art documents that discloses and/or claimed the same or similar heterologous antigen expression system, compositions and method for delivery thereof, for the HIV and cancer antigens. Prior art documents also disclosed similar heterologous ChAd prime-SAM boost regimens.
<u>No. of prior art documents used in No. of notes.: 8</u> prior art documents were used in 6 notes to show that the Application lacked novelty, and/or inventive step.
<u>Additional comment filed:</u> NA
<u>Importance of Application:</u> This technology has been in trials for cancer, & the ChAd based prime-boost regimen is used for cancer & HIV. Gritstone has a partnership with Gilead Sciences for utilizing the Gritstone vaccine platform technology for HIV cure. https://gritstonebio.com/platforms/; https://www.gilead.com/news-and-press/press-room/press-releases/2021/2/gilead-sciences-and-gritstone-announce-collaboration-utilizing-gritstones-vaccine-platform-technology-for-hiv-cure</td></tr>
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<tr><td>Israel</td><td>29.05.2023</td><td>303298</td><td></td></tr>
<tr><td>Canada</td><td>01.06.2023</td><td>3200935</td><td>Published 01.09.2023</td></tr>
<tr><td>China</td><td>05.06.2023</td><td>202180081878.0</td><td>Published 29.08.2023</td></tr>
<tr><td>Japan</td><td>05.06.2023</td><td>2023534100</td><td></td></tr>
<tr><td>Australia</td><td>21.06.2023</td><td>2021391921</td><td></td></tr>
<tr><td>European Patent Office</td><td>03.07.2023</td><td>2021901562</td><td>Published 11.10.2023</td></tr>
<tr><td>Republic of Korea</td><td></td><td>1020237021567</td><td>Published 07.08.2023</td></tr>
<tr><td>United States of America</td><td></td><td>18272087</td><td>Published 21.03.2024</td></tr>
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<tr><td>TPO No.</td><td>214</td></tr>
<tr><td>Appl. No.</td><td>WO2022119384</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022119384</td></tr>
<tr><td>Applicants</td><td>GENEXINE, INC.
KOREA DISEASE CONTROL AND PREVENTION AGENCY</td></tr>
<tr><td>Priority Date</td><td>10-2020-0168502 04.12.2020 KR</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The Applicant, claims The application claims fusion protein comprising a fusion polypeptide (linked by GS linker), derived from Mtb, e.g., Ag85A, TB10.4, Mtb32b & PstS3, further comprising polypeptide selected from PPE39, GlcB, RipA; fusion protein comprises signal peptide (TPA, herpes simplex virus glycoprotein DS (HSV gDS), growth hormone) polynucleotide thereof; recombinant vector (plasmid/viral vector) thereof, pharmaceutical composition for preventing/treating TB comprising fusion protein/ polynucleotide/ recombinant vector; composition further comprising adjuvant (IL-12, IL-21, Mip-1a protein).
<u>TPO filed:</u> The TPO observed that the Application lacked inventive step as fusion constructs for TB that use multiple TB antigens in different stages of the TB lifecycle have been prior disclosed. Prior art disclosed that the adjuvant construct BD121A was known to improve the immune response when used in a vaccine for infectious diseases like TB.
<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.
<u>Additional comment filed:</u> NA
<u>Importance of Application:</u> This application is fusion construct with TB antigens, polypeptides connected via linkers and an adjuvant construct. Since multiple companies/universities are working on such fusion constructs for TB, this seems to be the way ahead.</td></tr>
<tr><td>Date of Filing of TPO</td><td>04/04/2023</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>India</td><td>04.07.2023</td><td>202317044727</td><td>Published 23.08.2024</td></tr>
<tr><td>Philippines</td><td>04.07.2023</td><td>12023551823</td><td></td></tr>
<tr><td>China</td><td>02.08.2023</td><td>202180092760.8</td><td>Published 22.09.2023</td></tr>
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<tr><td>TPO No.</td><td>215</td></tr>
<tr><td>Appl. No.</td><td>WO2022125378</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022125378</td></tr>
<tr><td>Applicants</td><td>VIIV HEALTHCARE COMPANY</td></tr>
<tr><td>Priority Date</td><td>63/122,031 07.12.2020 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The application claims a combination comprising cabotegravir or a pharmaceutically acceptable salt thereof and a gp120 binding protein (N6LS antibody) wherein the gp120 binding protein neutralizes HIV-1, with CDR sequences and variable heavy and light chain sequences of the antibody, wherein the recombinant domain is an IgG1 constant domain comprising M428L and N434S mutations, which is administered to a human once every month, 2 months or 3 months; a method of treating HIV in a human in need thereof; a combination thereof for use; use in the manufacture of a medicament for use in the treatment of HIV and a kit comprising the integrase strand transfer inhibitor cabotegravir and a gp120 binding protein that neutralizes HIV-1.

<u>TPO filed:</u> The WOSA in this Application cited several documents as prior art. The TPO was filed to point out some additional aspects and documents that were missed by the WOSA. The TPO used prior art to show that the compositions of cabotegravir were known and its use in combination with gp120 binding proteins was also known and disclosed in prior art.

<u>No. of prior art documents used in No. of notes.:</u> 5 prior art documents were used in 4 notes to show that the Application lacked novelty and/or inventive step.

<u>Additional comment filed:</u> Yes. The Additional comment pointed out the documents used in the WOSA and the TPO used as prior art to assail novelty and inventive step.

<u>Importance of Application:</u> The combination is in clinical trials already. https://clinicaltrials.gov/ct2/show/NCT03739996</td></tr>
<tr><td>Date of Filing of TPO</td><td>11/04/2023</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>Japan</td><td>06.06.2023</td><td>2023534373</td><td></td></tr>
<tr><td>European Patent Office</td><td>07.07.2023</td><td>2021830880</td><td>Published 11.10.2023</td></tr>
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<tr><td>TPO No.</td><td>216</td></tr>
<tr><td>Appl. No.</td><td>WO2022125412</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022125412</td></tr>
<tr><td>Applicants</td><td>MERCK SHARP & DOHME LLC</td></tr>
<tr><td>Priority Date</td><td>63/123,846 10.12.2020 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The Application relates to Tetrahydroquinazoline derivatives (with defined stereochemistry) of formula I with specific substituents defined or its salts and pharmaceutical composition or method thereof for treatment/prophylaxis of HIV for eliciting GAG-POL dimerization in HIV-infected cells & selectively killing the HIV-infected GAG-POL expressing cells & augmenting suppression of HIV viremia by administering the compounds in combination with other anti-HIV agents & use thereof in therapy.
<u>TPO filed:</u> The TPO filed used prior art that disclosed NNRTIs (e.g., efavirenz or derivatives thereof) that selectively kill Gag-pol expressing HIV-infected cells, & compounds with the scaffold (dihydroquinazoline) and derivatives thereof with similar substitutions as anti-HIV drugs.
<u>No. of prior art documents used in No. of notes.:</u> 7 prior art documents used in 4 notes to show lack of inventive step.
Additional comment filed: NA
<u>Importance of Application:</u> It’s a long-acting drug for HIV, and a therapy that maybe used to selectively kill the viremia.</td></tr>
<tr><td>Date of Filing of TPO</td><td>11/04/2023</td></tr>
<tr><td>National Phase</td><td>
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<tr><td>United States of America</td><td>30.05.2023</td><td>18254917</td><td>Published 08.02.2024</td></tr>
<tr><td>European Patent Office</td><td>10.07.2023</td><td>2021904168</td><td>Published 18.10.2023</td></tr>
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<tr><td>TPO No.</td><td>217</td></tr>
<tr><td>Appl. No.</td><td>WO2022152818</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022152818</td></tr>
<tr><td>Applicants</td><td>VIROXIS
INSTITUT PASTEUR
CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE
INSTITUT GUSTAVE ROUSSY (IGR)</td></tr>
<tr><td>Priority Date</td><td>21305032.1 13.01.2021 EP
21305033.9 13.01.2021 EP</td></tr>
<tr><td>Details</td><td>Summary of Application: The application claims measles virus vectors, especially Schwarz strain, in the form of cDNA comprising polynucleotides expressing HIV or HTLV antigens such as gag, pol, env, nef, etc. inserted within ATUs located between the various MV genes (nef gene in additional transcription unit (ATU)1, gag-pol, & env genes in ATU 2 & 3) in a vaccine thereof, specifically to be used for a paediatric population for prevention of HIV, SIV and HTLV.
TPO filed: The TPO observed that the application was not novel or inventive, as there were prior art documents that discloses and/or claimed the MV strain vector vaccines with the antigens inserted within the ATU locations upstream and downstream, that would stimulate a humoral and cellular immune response.
No. of prior art documents used in No. of notes.: 12 prior art documents were used in 8 notes to show that the Application lacked novelty, and/or inventive step.
Additional comment filed: No
Importance of Application: The Pasteur Institut is working on the MV vaccine as claimed in the present application. See https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8536681/</td></tr>
<tr><td>Date of Filing of TPO</td><td>15/05/2023</td></tr>
<tr><td>National Phase</td><td>
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<tr><td>Australia</td><td>24.06.2023</td><td>2022208199</td><td></td></tr>
<tr><td>Canada</td><td>05.072023</td><td>3204201</td><td>Published 28.07.2023</td></tr>
<tr><td>India</td><td>06.07.2023</td><td>202317045368</td><td>Published 23.08.2024</td></tr>
<tr><td>United States of America</td><td>11.072023</td><td>18261051</td><td>Published 23.03.2024</td></tr>
<tr><td>Israel</td><td>12.07.2023</td><td>304441</td><td></td></tr>
<tr><td>Japan</td><td>12.07.2023</td><td>2023542871</td><td></td></tr>
<tr><td>European Patent Office</td><td>14.08.2023</td><td>2022700774</td><td>Published 22.11.2023</td></tr>
<tr><td>China</td><td>13.09.2023</td><td>202280021281.1</td><td>Published 02.02.2024</td></tr>
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<tr><td>TPO No.</td><td>218</td></tr>
<tr><td>Appl. No.</td><td>WO2022155530</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022155530</td></tr>
<tr><td>Applicants</td><td>MODERNATX, INC.</td></tr>
<tr><td>Priority Date</td><td>63/138,228 15.01.2021 US
63/140,920 24.01.2021 US
63/161,433 15.03.2021 US
63/173,979 12.04.2021 US
63/193,547 26.05.2021 US
63/222,925 16.07.2021 US
63/241,963 08.09.2021 US
63/283,905 29.11.2021 US
63/284,570 30.11.2021 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The Applicant, claims a method comprising administering mRNA vaccine that encode a 2P stabilized spike protein encoding various antigens of SARS-CoV2 including the first circulating virus, and further variants or strains of the virus & compositions thereof. The claims relate to Moderna’s mRNA-1273 vaccine for SARS-CoV2 & variants. It may be noted that Moderna’s mRNA-1273 has already received emergency use approval (EUA) in the United States of America in December 2020.
<u>TPO filed:</u> The TPO observed that the Application lacked novelty/ and/or inventive step, as the mRNA vaccines comprising the ORFs encoding one or more beta coronavirus antigen (particularly Spike protein), with stabilising mutations, the 2P substitutions, the 5’, 3’ UTRs, and the LNP compositions were all known.
<u>No. of prior art documents used in No. of notes.:</u> 11 prior art documents were used in 6 notes to assail novelty, and/ or inventive step.
<u>Additional comment filed:</u> The additional comment was filed with respect to the strains and their disclosure and associated priority documents, and additional prior art documents that would be valid in some countries as they were published after the priority date of WO’530 but before its filing date.
<u>Importance of Application:</u> This application relates to the variants of SARS-CoV2 that are encoded in mRNA-1273 and are in clinical trials.</td></tr>
<tr><td>Date of Filing of TPO</td><td>15/05/2023</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>Australia</td><td>13.07.2023</td><td>2022207495</td><td></td></tr>
<tr><td>Japan</td><td>14.07.2023</td><td>2023543035</td><td></td></tr>
<tr><td>European Patent Office</td><td>16.08.2023</td><td>2022702382</td><td>Published 22.11.2023</td></tr>
<tr><td>Canada</td><td></td><td>3208303</td><td>Published 15.08.2023</td></tr>
<tr><td>United States of America</td><td></td><td>1827496</td><td>Published 02.05.2024</td></tr>
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TPO No.	219
Appl. No.	**WO2022155524**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022155524
Applicants	MODERNATX, INC.
Priority Date	63/138,228 15.01.2021 US 63/140,921 24.01.2021 US 63/161,439 15.03.2021 US 63/173,972 12.04.2021 US 63/193,558 26.05.2021 US 63/222,930 16.07.2021 US 63/241,944 08.09.2021 US 63/283,795 29.11.2021 US 63/284,565 30.11.2021 US
Details	**Summary of Application:** The application claims a nucleic acid (mRNA) encoding an antigen of a second or third circulating SARS-CoV-2 virus strain (with a mutation), specifically the antigen is RBD, NTD, or a combination of RBD and NTD joined by linkers, or S1 subunit; the amino acid mutation in the antigen is described with respect to their function. It may be noted that Moderna's mRNA-1283 has already received emergency use approval (EUA) in the United States of America. **TPO filed:** The TPO observed that the Application lacked inventive step as the prior art recommended the inclusion of NTD in vaccines for SARS-CoV2, and showed that it is easy to incorporate the circulating strain of the virus in the mRNA vaccines, and showed that the LNP used in the present Application was also known. **No. of prior art documents used in No. of notes.:** 12 prior art documents were used in 7 notes to show that the Application lacked novelty and/or inventive step. **Additional comment filed:** No **Importance of Application:** The variants of mRNA-1283 are in clinical trials.
Date of Filing of TPO	15/05/2023
National Phase	

Office	Entry Date	National Number	National Status
Australia	13.07.2023	2022208057	
Japan	14.07.2023	2023543034	
European Patent Office	16.08.2023	2022703172	Published 22.11.2023
Canada		3208486	Published 16.08.2023
United States of America		18272512	Published 28.03.2024

TPO No.	220
Appl. No.	**WO2022159811**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022159811
Applicants	ESPERVITA THERAPEUTICS, INC.
Priority Date	63/141,273 25.01.2021 US 63/285,876 03.12.2021 US
Details	**Summary of Application:** The Application relates to a combination of adenosine derivative prodrug and a capsid inhibitor that can be used for the treatment and prevention of HIV, multi-drug resistant HIV, or combination thereof.
	TPO filed: The TPO filed was over and above the WOSA documents. The TPO referred to prior art showing the combination and composition of HIV capsid inhibitors, including lenacapavir, in combination with EFdA for prevention and treatment of HIV.
	No. of prior art documents used in No. of notes.: 2 prior art documents used in 1 note to show lack of novelty, and /or inventive step.
	Additional comment filed: NA
	Importance of Application: It's a combination treatment for HIV.
Date of Filing of TPO	
National Phase	No National Phase as of now

TPO No.	221
Appl. No.	**WO2022086364**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022086364
Applicants	FEDERAL STATE BUDGETARY INSTITUTION "NATIONAL RESEARCH CENTRE FOR EPIDEMIOLOGY AND MICROBIOLOGY NAMED AFTER THE HONORARY ACADEMICIAN N.F. GAMALEYA" OF THE MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION
Priority Date	2021103101 10.02.2021 RU
Details	**Summary of Application:** The applications claim an agent for inducing specific immunity against severe acute respiratory syndrome virus SARS-CoV-2, in lyophilized (freeze-dried), which contains a single active component, comprising the expression vector based on the genome of the recombinant strain of human adenovirus (Ad) serotype 26, human Ad5 or simian Ad25 (E1 and E3 regions are deleted for all 3 expression vectors and the ORF6 region of AD26 is replaced by ORF6 of Ad5) with an integrated expression cassette selected from SEQ ID NOs: 1-4; the composition of the reconstituted lyophilized (freeze-dried) buffer solution and the use of the agent for inducing immune response against the SARS-CoV-2 virus with intramuscular, intranasal or concomitant intramuscular and intranasal administration of in a dose of $5x10^{10}$-$5x10^{11}$ viral particles.
	TPO filed: The TPO observed that the application was not novel, and/ or inventive.
	No. of prior art documents used in No. of notes.: 16 prior art documents were used in 9 notes to show that the Application lacked novelty, and/or inventive step.
	Additional comment filed: Yes. Additional comment pointed out the previous applications of the Applicant
	Importance of Application: The Application is with respect to Sputnik Light & intranasal forms of the vaccine in lyophilized form.
Date of Filing of TPO	01/06/2023
National Phase	

Office	Entry Date	National Number	National Status
European Patent Office	01.03.2022	2021859329	Published 15.06.2022
Eurasian Patent Organization	04.03.2022	202290517	Published 30.09.2022 Granted 31.03.2023
Israel	13.03.2022	291330	
Republic of Korea	14.03.2022	1020227008465	Published 19.08.2022 Refused 17.06.2024
Brazil	15.03.2022	122023002765	Divisional 21.03.2023 Refused 04.07.2023
China	15.03.2022	202180005352.4	Published 19.03.2024
India	15.03.2022	202227014073	Published 16.09.2022
Japan	15.03.2022	2022516677	
Mexico	15.03.2022	MX/a/2022/003163	
Iran	28.03.2022	140150140003000095	

	United Arab Emirates	29.03.2022	P6000562/2022	
	Canada	06.04.2022	3156252	Published 24.07.2022
	Philippines	08.04.2022	12022550863	
	Saudi Arabia	07.01.2023	522432104	Withdraw 08.07.2024

TPO No.	222
Appl. No.	**WO2022086365**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022086365
Applicants	FEDERAL STATE BUDGETARY INSTITUTION "NATIONAL RESEARCH CENTER FOR EPIDEMIOLOGY AND MICROBIOLOGY NAMED AFTER THE HONORARY ACADEMICIAN N.F. GAMALEYA" OF THE MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION
Priority Date	2021103099 09.02.2021 RU
Details	**Summary of Application:** The applications claim an agent for inducing specific immunity against severe acute respiratory syndrome virus SARS-CoV-2, in liquid form, which contains a single active component, comprising the expression vector based on the genome of the recombinant strain of human adenovirus (Ad) serotype 26, human Ad5 or simian Ad25 (E1 and E3 regions are deleted for all 3 expression vectors and the ORF6 region of AD26 is replaced by ORF6 of Ad5) with an integrated expression cassette selected from SEQ ID NOs: 1-4; the composition of the liquid form buffer solution and the use of the agent for inducing immune response against the SARS-CoV-2 virus with intramuscular, intranasal or concomitant intramuscular and intranasal administration of in a dose of $5x10^{10}$-$5x10^{11}$ viral particles.
	TPO filed: The TPO observed that the Application lacked novelty/ and/or inventive step.
	No. of prior art documents used in No. of notes.: 16 prior art documents were used in 9 notes to assail novelty, and/ or inventive step.
	Additional comment filed: The additional comment was filed with respect to the previous applications of the Applicant.
	Importance of Application: This application relates to Sputnik Light and intranasal form of the vaccine in liquid form.
Date of Filing of TPO	02/06/2023
National Phase	

Office	Entry Date	National Number	National Status
Eurasian Patent Organization	01.03.2022	202290467	Published 30.0.2022 Granted 30.04.2023
European Patent Office	01.03.2022	2021859328	Published 22.06.2022
Mexico	11.03.2022	MX/a/2022/003069	Published 12.08.2022
Israel	13.03.2022	291334	
Republic of Korea	14.03.2022	1020227008478	Published 17.08.2022 Refused 03.07.2024
Brazil	15.03.2022	122023000010	Refused 07.02.2023 Divisional 23.02.2023
China	15.03.2022	202180005353.9	Published 18.10.2022
India	15.03.2022	202227014104	Published 16.09.2022
Japan	15.03.2022	2022516698	

United Arab Emirates	29.03.2022	P6000563/2022	
Iran	30.03.2022	140150140003000131	
Canada	04.04.2022	3156263	Published 08.08.2022
Philippines	08.04.2022	12022550866	
Saudi Arabia	07.01.2023	522432109	Withdraw 08.07.2024

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<tr><td>TPO No.</td><td>223</td></tr>
<tr><td>Appl. No.</td><td>WO2022170394</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022170394</td></tr>
<tr><td>Applicants</td><td>JAMES COOK UNIVERSITY
KRISHNAMOORTHY, Gopinath
HUSAIN, Aliabbas A.</td></tr>
<tr><td>Priority Date</td><td>2021900320 10.02.2021 AU</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The application claims a recombinant strain of M. bovis BCG comprising a heterologous nucleic acid encoding a fusion protein: a polypeptide that is at least about 80% identical to an ESAT-6 protein & a secretion peptide YXXXD/E for enabling secretion of the polypeptide via an ESX-5 secretion system of M. bovis BCG; nucleic acid encoding the same; vector & host cell (BCG) (Claims 14–16); vaccine; method for inducing an immune response to Mtb/treating Mtb infection, use of the recombinant strain.
<u>TPO filed:</u> The TPO observed that the Application lacked inventive step as the prior art disclosed the ESAT-6 mediated cytosolic translocation, and general secretion signal that is present in known mycobacterial T7S substrates, etc.
<u>No. of prior art documents used in No. of notes.:</u> 6 prior art documents were used in 5 notes to show that the Application lacked inventive step.
<u>Additional comment filed:</u> NA
<u>Importance of Application:</u> Relevant Vaccine for Mtb https://www.aithm.jcu.edu.au/promising-new-jcu- tuberculosis-research-funded/, https://www.jcu.edu.au/this-is- uni/health-and-medicine/articles/taking-down-tuberculosis</td></tr>
<tr><td>Date of Filing of TPO</td><td>12/06/2023</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>05.09.2023</td><td>202327059673</td><td>Published 05.01.2024</td></tr>
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<tr><td>TPO No.</td><td>224</td></tr>
<tr><td>Appl. No.</td><td>WO2022171182</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022171182</td></tr>
<tr><td>Applicants</td><td>THERAPEUTICS CO., LTD.</td></tr>
<tr><td>Priority Date</td><td>202110184680.7 10.02.2021 CN
202110184684.5 10.02.2021 CN</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The Application claims a polypeptide comprising the S1 subunit and the S2 subunit of the SARS-CoV-2 S protein from the N-terminus to the C-terminus, wherein the S1 subunit comprises an inactivated furin cleavage site with amino acid sequence of QSAQ; and in comparison to seq ID no: 1, amino acids 986 and 987 are proline; 383 and 985 are cysteine; amino acid 817, 892, 899 and 942 are proline; 614 is glycine; other mutations and sequences with percent identity; a polynucleotide (DNA/RNA) encoding the polypeptide with modified nucleobases, 1-methylpseudouracil; sequences of the RNA, 5’cap, 5’ and 3’ UTR and poly A tail; a composition comprising lipid encapsulating said polynucleotide with M5, DSPC, PEG-DMG and cholesterol (LNP/LPP); vaccine preparation and pharmaceutical composition and use of the pharmaceutical composition in the preparation of medicines for preventing and/or treating SARS-CoV-2 infection.
<u>TPO filed:</u> The TPO filed observed that prior art documents revealed mRNA-LNP variant vaccine with D614 mutation, and the 6P – hexapro substitutions, LNP components, etc. were all known in the art.
<u>No. of prior art documents used in No. of notes.:</u> 12 prior art documents used in 7 notes to show lack of novelty, and /or inventive step. One prior art document was a PX document.
<u>Additional comment filed:</u> Yes. Additional comment brought out the variant mRNA vaccines.
<u>Importance of Application:</u> It is an approved vaccine. Mainly in China.</td></tr>
<tr><td>Date of Filing of TPO</td><td>12/06/2023</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>China</td><td>14.10.2022</td><td>202280003537.6</td><td>Published 02.12.2022</td></tr>
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TPO No.	225
Appl. No.	**WO2022177465**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022177465
Applicants	FEDERAL STATE BUDGETARY INSTITUTION "NATIONAL RESEARCH CENTER FOR EPIDEMIOLOGY AND MICROBIOLOGY NAMED AFTER THE HONORARY ACADEMICIAN N.F. GAMALEYA" OF THE MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION
Priority Date	2021104430 21.02.2021 RU
Details	**Summary of Application:** The Application claims the use of an agent containing (a) two components, i.e. expression vectors hAd26 & hAd5, simian (s) Ad25 & hAd26 or sAd25 & hAd5, or (b) a single component (hAd26, hAd5 or sAd25); each with integrated expression cassette selected from SEQ ID NOs: 1–4—for inducing specific immunity against SARS-CoV-2 virus in subjects above 60 years of age and/or having chronic diseases; E1 and E3 regions of all the expression vectors are deleted, and ORF6-Ad26 is replaced by ORF6-Ad5; such use via IN and/or IM administration; wherein the components are administered sequentially at time interval of more than one week; in liquid or lyophilized form; wherein components 1 and 2 of the agent are in separate containers. **TPO filed:** The TPO filed prior art documents to show lack of novelty and inventive step. **No. of prior art documents used in No. of notes.:** 13 prior art documents used in 7 notes to show lack of novelty, and /or inventive step. **Additional comment filed:** NA **Importance of Application:** Related to Gamaleya Sputnik V and Sputnik Light vaccine and use in elderly population in clinical trial.
Date of Filing of TPO	21/06/2023
National Phase	

Office	Entry Date	National Number	National Status
Brazil	29.03.2022	112022005920	
Japan	30.02.2022	2022520003	
China	01.04.2022	202280000638.8	Published 21.10.2022
Mexico	01.04.2022	MX/a/2022/004060	Published 20.10.2022
Philippines	01.04.2022	12022550800	
India	05.04.2022	202227020557	Published 17.02.2023
Canada	06.04.2022	3156448	Published 21.08.2022
Iran	06.04.2022	140150140003000279	
European Patent Office	08.04.2022	2022713845	Published 27.12.2023
United Arab Emirates	18.04.2022	P6000695/2022	
Saudi Arabia	07.01.2023	522432310	Withdraw 08.07.2024
Eurasian Patent Organization		202290451	Published 30.09.2022 Granted 31.03.2023

		Republic of Korea		1020227010867	Published 29.12.2023

TPO No.	226
Appl. No.	**WO2022177466**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022177466
Applicants	FEDERAL STATE BUDGETARY INSTITUTION "NATIONAL RESEARCH CENTER FOR EPIDEMIOLOGY AND MICROBIOLOGY NAMED AFTER THE HONORARY ACADEMICIAN N.F. GAMALEYA" OF THE MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION
Priority Date	2021104437 21.02.2021 RU
Details	**Summary of Application:** The Application claims the use of an agent containing (a) two components, i.e., expression vectors hAd26 & hAd5, simian (s) Ad25 & hAd26 or sAd25 & hAd5, or (b) a single component (hAd26, hAd5 or sAd25); each with integrated expression cassette selected from SEQ ID NOs: 1–4—for revaccination against disease caused by SARS-CoV-2 virus; E1 and E3 regions of all the expression vectors are deleted, and ORF6-Ad26 is replaced by ORF6-Ad5. WO'466 also claims such use wherein the components are in liquid or lyophilized form & in separate containers. **TPO filed:** The TPO filed was filed to show lack of novelty and inventive step. **No. of prior art documents used in No. of notes.:** 8 prior art documents used in 5 notes to show lack of novelty, and /or inventive step. **Additional comment filed:** NA **Importance of Application:** Related to Gamaleya Sputnik V and Sputnik Light vaccine and use for revaccination.
Date of Filing of TPO	21/06/2023

National Phase

Office	Entry Date	National Number	National Status
Eurasian Patent Organization	01.03.2022	202290464	Published 31.10.2022 Granted 30.04.2023
Brazil	29.03.2022	112022005967	
Japan	31.03.2022	2022520201	
Mexico	31.03.2022	MX/a/2022/003963	Published 13.12.2022
China	01.04.2022	202280000620.8	Published 02.12.2022
Philippines	01.04.2022	12022550807	
India	05.04.2022	202227020558	Published 25.11.2022
Canada	06.04.2022	3156456	Published 26.07.2022
Iran	06.04.2022	140150140003000277	
United Arab Emirates	18.04.2022	P6000696/2022	
European Patent Office	21.09.2023	2022713844	Published 27.12.2023
Saudi Arabia	29.04.2024	523450347	Withdrawn 08.07.2024
Republic of Korea		1020227010868	Published 19.10.2023

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<tr><td>TPO No.</td><td>227</td></tr>
<tr><td>Appl. No.</td><td>WO2022192262</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022192262</td></tr>
<tr><td>Applicants</td><td>DUKE UNIVERSITY</td></tr>
<tr><td>Priority Date</td><td>63/158,074 08.03.2021 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The application claims a recombinant fusion protein sequence comprising V3 glycopeptide, a peptide linker (LPXTGG or glycine-serine) and a self-assembling protein (particularly ferritin), wherein the fusion protein is comprised in a multimeric protein complex (particularly ferritin nanoparticle), further comprising a T helper epitope, a multimeric protein complex thereof; mRNA encoding the same; a composition with adjuvant [LNP, TLR7/8 agonist (see Additional Comments), alum, or a combination]; VLP/host cell comprising the fusion protein/nucleic acid; an immunogenic composition and a method of inducing an immune response to HIV-1 in a subject, by administration as a boost. WO’262 discloses that the immunogen is a minimal V3 immunogen and these glycopeptide immunogens present subsets of glycans found at positions 295, 301, 332, 339, 386 and 392.
<u>TPO filed:</u> The TPO observed that the application was not novel, and/ or inventive.
<u>No. of prior art documents used in No. of notes.:</u> 5 prior art documents were used in 4 notes to show that the Application lacked novelty, and/or inventive step.
<u>Additional comment filed:</u> Yes. Additional comment pointed out that the TLR7/8 were referred to as antagonist adjuvants in the claims, but in the disclosures, they were referred to as agonists.
<u>Importance of Application:</u> The Applicant has published multiple articles for the minimal immunogen and glycoengineering.</td></tr>
<tr><td>Date of Filing of TPO</td><td>10/07/2023</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>Canada</td><td>07.09.2023</td><td>3211186</td><td>Published 08.09.2023</td></tr>
<tr><td>European Patent Office</td><td>09.10.2023</td><td>2022767805</td><td>Published 17.01.2024</td></tr>
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<tr><td>TPO No.</td><td>228</td></tr>
<tr><td>Appl. No.</td><td>WO2022189656</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022189656</td></tr>
<tr><td>Applicants</td><td>INSTITUT PASTEUR
THERAVECTYS</td></tr>
<tr><td>Priority Date</td><td>21305317.6 12.03.2021 EP</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The application claims a recombinant lentiviral vector genome comprising a polynucleotide encoding a fusion polypeptide, comprising a first polypeptide comprising an MHC-II-associated li chain or TfR, and at least one antigenic polypeptide of a pathogen (mono or poly antigenic), wherein pathogen is a bacterial [Mycobacterium tuberculosis (Mtb)], parasite or viral pathogen (an influenza virus or a coronavirus such as SARS-CoV-2); recombinant lentiviral vector wherein the genome is obtained from pFLAP vector plasmid with promoter (CMV, b2m, SP-1-b2m, or composite BCUAG), WPRE element; recombinant lentiviral vector particle; a host cell, HEK-293T; a pharmaceutical composition (vaccine composition) with adjuvant; for use in the elicitation of a protective, preferentially prophylactic, the induction of MHC-I and MHC-II restricted presentation by an APC (DC) and the induction of a CD4- and CD8-mediated cellular immune response; or for treatment.
<u>TPO filed:</u> The TPO observed that the Application lacked inventive step.
<u>No. of prior art documents used in No. of notes.:</u> 9 prior art documents were used in 6 notes to assail inventive step.
<u>Additional comment filed:</u> No
<u>Importance of Application:</u> This application was important for tuberculosis based on the work done by the same team of inventors, for which TPO was filed.</td></tr>
<tr><td>Date of Filing of TPO</td><td>12/07/2023</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>Canada</td><td>22.08.2023</td><td>3209285</td><td>Published 27.08.2023</td></tr>
<tr><td>Australia</td><td>05.09.2023</td><td>2022233021</td><td></td></tr>
<tr><td>New Zealand</td><td>05.09.2023</td><td>803413</td><td>Published 29.09.2023</td></tr>
<tr><td>Japan</td><td>11.09.2023</td><td>2023555798</td><td></td></tr>
<tr><td>China</td><td>12.09.2023</td><td>202280020948.6</td><td>Published 31.10.2023</td></tr>
<tr><td>Republic of Korea</td><td>11.10.2023</td><td>1020237034817</td><td>Published 14.11.2023</td></tr>
<tr><td>European Patent Office</td><td>12.10.2023</td><td>2022714999</td><td>Published 17.01.2024</td></tr>
<tr><td>Singapore</td><td>31.10.2023</td><td>11202306773V</td><td>Published 31.10.2023</td></tr>
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<tr><td>TPO No.</td><td>229</td></tr>
<tr><td>Appl. No.</td><td>WO2022197624</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022197624</td></tr>
<tr><td>Applicants</td><td>MODERNATX, INC.</td></tr>
<tr><td>Priority Date</td><td>63/161,429 15.03.2021 US
63/281,021 18.11.2021 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The application claims method comprising administering (intramuscularly) a therapeutic dose (2.5, 10, 30, 50 & 100 mcg; at least 5–30 mcg), of a composition comprising an mRNA comprising an ORF that encodes a fusion protein [at least 2 domains of a SARS-CoV-2 S protein], wherein the mRNA is in LNP comprising, as prime boost vaccine (dose interval of 28 days to one year) administered to humans (aged 18–54 years, immunocompromised, etc.). WO’624 claims the composition that comprises 0.5 mg/ml of mRNA and Tris buffer, sucrose and sodium acetate & such method characterised by GMT and GMFR of nAbs against the D614G and B.1.351 variants. It also claims composition comprising specific dose & dose ranges of mRNA encoding a domain of S protein in LNP, and method comprising administering it to stimulate an immune response. WO’624 discloses that the fusion protein in SEQ ID NO. 92 is the NTD-RBD-TMD construct, mRNA-1283.
<u>TPO filed:</u> The TPO observed that the Application lacked novelty and/ or inventive step as the prior art disclosed mRNA-1283 and composition disclosures.
<u>No. of prior art documents used in No. of notes.:</u> 14 prior art documents were used in 9 notes to show that the Application lacked novelty, and/or inventive step.
<u>Additional comment filed:</u> Yes. The Additional comment pointed out the priority dates of some of the claims for the measurement of titres against the variants of SARS-CoV2
<u>Importance of Application:</u> The Application is important as it claims the dose forms of Moderna’s mRNA-1283 vaccine, against variants of SARS-CoV2, which is also in clinical trials.</td></tr>
<tr><td>Date of Filing of TPO</td><td>17/07/2023</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>Australia</td><td>10.09.2023</td><td>2022237382</td><td></td></tr>
<tr><td>Japan</td><td>14.09.2023</td><td>2023556841</td><td></td></tr>
<tr><td>European Patent Office</td><td>16.10.2023</td><td>2022714665</td><td>Published 24.01.2024</td></tr>
<tr><td>United States of America</td><td></td><td>18282097</td><td>Published 12.09.2024</td></tr>
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TPO No.	230
Appl. No.	**WO202218503 (WO'503) : Biologic : COVID**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022218503
Applicants	BIONTECH SE.
Priority Date	
Details	**Summary of Application:** The application claims a composition comprising lipid nanoparticles dispersed in an aqueous phase [buffer system, 25 mM= buffer (Tris 10-20 mM, TEA, etc. and their protonated form) and monovalent anion (chloride, acetate, glycolate, lactate and anion of MES, MOPS, HEPES)]; aqueous phase free of anions of inorganic phosphate, citrate, EDTA, sulphate, carbonate, etc; buffer system, pH, osmolarity, water/solvent content, RNA (encoding SARS-CoV-2 S protein) of composition; LNP composition; method thereof (preparing RNA & ethanolic lipid solution, mixing, filtration, dispersion in final buffer, dilution; optionally freezing); composition in liquid/frozen form; method of storing composition; method for preparing ready-to-use formulation; use of composition in therapy & for inducing immune response; mRNA integrity, Z-avg & PDI before and after storage
	TPO filed: The Application WO'503 appeared to be the same/ identical as application WO2022101470 for which TPO was filed (TPO212). The TPO observed that the application was not inventive, and re-used the notes that were filed in the earlier application.
	No. of prior art documents used in No. of notes.: 6 prior art documents were used in 4 notes to show that the Application lacked inventive step.
	Additional comment files: Yes. Additional comment pointed out the present
Date of Filing of TPO	12/08/2023
National Phase	No National Phase as of now

<table>
<tr><td>TPO No.</td><td>231</td></tr>
<tr><td>Appl. No.</td><td>WO2022221335 (WO’335) : Biologic : COVID</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022221335</td></tr>
<tr><td>Applicants</td><td>MODERNATX, INC.</td></tr>
<tr><td>Priority Date</td><td>63/174,463 13.04.2021 US
63/175,011 14.04.2021 US
63/241,959 08.09.2021 US
63/322,121 21.03.2022 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The application claims combination and multivalent mRNA vaccines, comprising antigens from 3 to 8 different viruses, specifically influenza A and B, coronavirus (SARS-CoV-2, etc.) and viral family Paramyxoviridae, subfamily Pneumovirinae (RSV and/or hMPV) or genus or subfamily Paramyxovirus (parainfluenza) or Morbillivirus, and methods of producing and using it. It also similarly claims a combination and multivalent mRNA comprising 2 to 6 different antigens from different viruses and methods thereof. The combinations that have been set out in the examples of WO’335 are of mRNA-1273+mRNA-1010+mRNA-1345, mRNA-1273+mRNA-1020+mRNA-1345, mRNA-1273+mRNA-1010, mRNA-1273+mRNA1020, etc. (pp.91-2, Example 1, Table 1)
<u>TPO filed:</u> The TPO observed that the Application lacked novelty, and/or inventive step. It observed that combination vaccines against influenza, SARS-CoV2, RSV, etc. were being planned & anticipated, and LNPs formulated multivalent mRNA vaccines.
<u>No. of prior art documents used in No. of notes.:</u> 10 prior art documents were used via 6 notes to assail novelty and/or inventive step. One document was also referred in the TPO.
Additional comment filed: No
<u>Importance of Application:</u>, The Application relates to Moderna’s combination vaccines in clinical trials (SARS-CoV-2+RSV+Flu and SARS-CoV-2+Flu)</td></tr>
<tr><td>Date of Filing of TPO</td><td>14/08/2023</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>Japan</td><td>13.10.2023</td><td>2023563061</td><td></td></tr>
<tr><td>Australia</td><td>09.11.2023</td><td>2022258335</td><td></td></tr>
<tr><td>European Patent Office</td><td>13.11.2023</td><td>2022720218</td><td>Published 21.02.2024</td></tr>
<tr><td>China</td><td>11.12.2023</td><td>202280041649.0</td><td>Published 22.03.2024</td></tr>
<tr><td>United States of America</td><td></td><td>18666087</td><td>Published 04.07.2024</td></tr>
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<tr><td>TPO No.</td><td>232</td></tr>
<tr><td>Appl. No.</td><td>WO2022221440 (WO’’440) : Biologic : COVID</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022221440</td></tr>
<tr><td>Applicants</td><td>MODERNATH, INC</td></tr>
<tr><td>Priority Date</td><td>63/175,007 04.04.2021 US
63/242,346 09.09.2021 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The application claims combination and multivalent mRNA vaccines, comprising antigens from two different viruses (from different viral families), specifically influenza A and B and coronavirus (SARS-CoV-2, etc.) and methods of producing and using it. The combinations that have been set out in the examples of WO’440 are of mRNA-1273+mRNA-1010 and mRNA-1273+mRNA1020.
<u>TPO filed:</u> The TPO observed that the Application lacked novelty and/ or inventive step as Moderna’s mRNA-1273 for COVID was already being explored as a combination vaccine with influenza and other unrelated respiratory.
<u>No. of prior art documents used in No. of notes.:</u> .: 8 prior art documents were used in 5 notes to show that the Application lacked novelty, and/or inventive step.
<u>Additional comment filed:</u> Not filed.
<u>Importance of Application:</u> The Application relates to Moderna’s combination vaccines in clinical trials (SARS-CoV-2+Flu).</td></tr>
<tr><td>Date of Filing of TPO</td><td>14/08/2023</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>Japan</td><td>13.10.2023</td><td>2023563063</td><td></td></tr>
<tr><td>Australia</td><td>09.11.2023</td><td>2022258463</td><td></td></tr>
<tr><td>European Patent Office</td><td>14.11.2023</td><td>2022720863</td><td>Published 21.02.2024</td></tr>
<tr><td>China</td><td>08.12.2023</td><td>202280041534.1</td><td>Published 22.03.2024</td></tr>
<tr><td>United States of America</td><td></td><td>18555130</td><td>Published 11.07.2024</td></tr>
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<tr><td>TPO No.</td><td>233</td></tr>
<tr><td>Appl. No.</td><td>WO2022256516 (WO’516) : BIOLOGIC : HIV</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022256516</td></tr>
<tr><td>Applicants</td><td>TEMPLE UNIVERSITY - OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION.</td></tr>
<tr><td>Priority Date</td><td>63/196,045 02.06.2021 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> The application claims a composition for preventing or treating retroviral infection in vitro or in vivo, with at least two isolated nucleic acids (NAs): (1) encoding CRISPR associated endonuclease and at least one guide RNA (gRNA) complementary to HIV-1 LTR1 & GagD, (2) encoding CRISPR associated endonuclease & at least 1 gRNA complementary to CCR5, variants, combinations, etc. further administering a therapeutically effective amount of at least one ARV agent (LASER ART), methods, synthetic NA sequences for gRNA. WO’516 discloses a 3-step treatment regimen: ART followed by AAV6-CRISPR-Cas-9 targeting CCR5, followed by AAV9-CRISPR-Cas-9 targeting HIV-1 LTR1 & GagD in pre-clinical setting (in humanised mice).
<u>TPO filed:</u> The TPO observed with prior art documents that the claims of WO’516, including the 3-step regimen were already disclosed in the prior art. The TPO filed was complementary to the WOSA documents.
<u>No. of prior art documents used in No. of notes.:</u> 3 prior art documents were used in 3 notes to show that the Application lacked novelty and/ or inventive step for all the claims.
<u>Additional comment filed:</u> Not filed.
<u>Importance of Application:</u> The Application is of importance as Temple University (Applicant) has stated in a press release that the compositions as claimed in the present Application, Wo’516, are candidates for clinical trials.</td></tr>
<tr><td>Date of Filing of TPO</td><td>30/09/2023</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>18566468</td><td>Published 08.08.2024</td></tr>
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TPO No.	234
Appl. No.	**WO2022272275 (WO'275) : Biologic : HCV**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022272275
Applicants	JANSSEN VACCINES & PREVENTION B.V. BETH ISRAEL DEACONESS MEDICAL CENTER
Priority Date	63/202,808 25.06.2021 US
Details	**Summary of Application:** The application WO'275 claims (1) methods of inducing an immune response by administering to people living with HIV & undergoing ART treatment, by administering (intramuscularly) an Ad26/MVA prime boost vaccine, with the Ad26 (four vectors in a 1:1:1:1 ratio; 5x10^9 to about 1x10^11 vp; 5 x10^10 vp) and MVA vectors (one or more; preferably one, 1x10^7 to 5x10^8 IU, 2x10^8 IU), encoding HIV immunogens of SEQ ID NOS: 1 to 4. The Application also claims administering (intravenously) two or more, preferably three, broadly neutralising antibodies (bnAbs) (preferably PGT121, PGDM1400, and VRC07-523LS) (10–20 mg/kg of each). (2) The Application claims the method wherein the person has undergone ART 48 weeks prior to administration of prime vaccine, continues to undergo ART during treatment and ART is stopped after administration of bnAbs; & (3) method of treating HIV by using ART, the claimed method and discontinuing ART.
	TPO filed: The TPO observed that the method was obvious, and the prior art referred to in the TPO brought out that therapeutic vaccine Ad26/MVA regimen and immunogen were known, the combination of at least 3 bNAbs could be combined with the therapeutic vaccines &/ or other agents for prevention & treatment of HIV was also envisaged earlier, & it would be obvious to analyse treatment (ART) interruption following discontinuation of ART.
	No. of prior art documents used in No. of notes.: 6 prior art documents were used in 4 notes to show that the Application lacked inventive step for all the claims.
	Additional comment filed: Filed, to show insufficiency of disclosure in the Application with respect to the actual working of the prime-boost vaccine regimen plus bNAb combination for ART treatment interruption.
	Importance of Application: The Application is of importance as it has entered clinical trials. The clinical trial NCT04983030 (https://classic.clinicaltrials.gov/ct2/show/NCT04983030) is with respect to the Application WO'275.
Date of Filing of TPO	20/10/2023
National Phase	No National Phase as of now

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<tr><td>TPO No.</td><td>235</td></tr>
<tr><td>Appl. No.</td><td>WO2023283576 (WO’576) : Biologic : HCV</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023283576</td></tr>
<tr><td>Applicants</td><td>THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA</td></tr>
<tr><td>Priority Date</td><td>63/218,685 06.07.2021 US</td></tr>
<tr><td>Details</td><td><u>Summary of Application:</u> WO2023283576 is an application for a lineage vaccine composition wherein at least one nucleoside modified RNA molecule encoding a p7 viral protein and further encoding at least one HCV antigen from Core, E1, E2, and further comprises an RNA encoding an adjuvant, and the RNA is encapsulated in a liponanoparticle (LNP). It claims methods of administering an effective amount to induce an immune response against HCV.
<u>TPO filed:</u> The TPO observed through prior art documents that the vaccine composition and the claims of the application, WO’576, were not novel and/or inventive.
<u>No. of prior art documents used in No. of notes.:</u> 5 prior art documents were used in 4 notes to assail novelty and/ or inventive step.
<u>Additional comment filed:</u> Not Filed.
<u>Importance of Application:</u> The Application is of importance as this is an application for an mRNA lineage vaccine for HCV. One of the listed inventors is Drew Weissman, one of the scientists whose background work on mRNAs led to the development of SARS-CoV-2 mRNA vaccines, for which he recently received the Noble prize.</td></tr>
<tr><td>Date of Filing of TPO</td><td>06/11/2023</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>Canada</td><td>04.01.2024</td><td>3224943</td><td>Published 12.01.2024</td></tr>
<tr><td>Japan</td><td>05.01.2024</td><td>2024500303</td><td></td></tr>
<tr><td>Australia</td><td>24.01.2024</td><td>2022307932</td><td></td></tr>
<tr><td>European Patent Office</td><td>06.02.2024</td><td>2022838562</td><td>Published 15.05.2024</td></tr>
<tr><td>China</td><td>05.03.2024</td><td>202280060200.9</td><td>Published 19.04.2024</td></tr>
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TPO No.	236
Appl. No.	**WO2023034801 (WO'801) : Biologic : HIV**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023034801
Applicants	VIR BIOTECHNOLOGY, INC
Priority Date	63/329,298 31.08.2021 US 63/356,386 28.06.2022 US
Details	**Summary of Application:** WO2023034801 (WO'801) is for a vaccine for HIV. It claims a recombinant HCMV vector, with TR3 backbone, with UL18, UL128, UL130, UL146, UL147 and UL82 or UL78 genes deleted, and with micro-RNA response elements (MREs), encoding a heterologous Ag, specifically fusion antigen (exemplified by HIV Ags; fusion protein of conserved HIV gag, nef and pol episensus; SEQ ID NOs: 3 & 4), pharmaceutical and immunogenic compositions, to elicit MHC-E & MHC-II restricted responses; methods of generating immune response, method of treating diseases, use. WO'801 also claims method of generating CD8+ T cells and using transfected CD8+ T cells for treating a disease, etc.
	TPO filed: The TPO observed through prior art documents that the vaccine composition and the claims of the application, WO'801, were not novel and/or inventive. The TPO also added a table of comparison of claims of one of the prior art documents with the present Application, WO'801 to bring out the similarity in the Applications.
	No. of prior art documents used in No. of notes.: 5 prior art documents were used in 5 notes to assail novelty and/ or inventive step.
	Additional comment filed: Yes. The Additional Comment was filed to bring out clearly the obviousness of using the hCMV vector and the elicitation of the MHC responses as known, the obviousness of the use of the fusion antigen; the lack of technical effect; and the formulation, though not claimed in WO'801, but disclosed was obvious. The Additional Comment also pointed out the insufficiency of disclosure in the Application, WO'801.
	Importance of Application: The Application is of importance as the construct relates to those in clinical trials, such as VIR1111, and VIR1388.
Date of Filing of TPO	30/12/2023

National Phase

Office	Entry Date	National Number	National Status
Australia	09.01.2024	2022339765	
Canada	12.01.2024	3226699	Published 24.01.2024
New Zealand	16.01.2024	807408	Published 26.01.2024
Israel	05.02.2024	310663	
Mexico	12.02.2024	MX/a/2024/001962	Published 11.04.2024
Thailand	13.02.2024	2401000912	
United States of America	27.02.2024	18687050	
United Arab Emirates	28.02.2024	P2024-00474	

		Japan	28.02.2024	2024513410	
		Philippines	28.02.2024	12024550537	
		Eurasian Patent Office	29.02.2024	202490367	
		Singapore	28.03.2024	11202401156Y	Published 28.03.2024
		European Patent Office	02.04.2024	2022777537	Published 10.07.2024
		Republic of Korea		1020247006599	Published 17.04.2024

TPO No.	237
Appl. No.	**WO2023034783 (WO'783) : Biologic : TB**
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2023034783
Applicants	VIR BIOTECHNOLOGY, INC
Priority Date	63/239,278 31.08.2021 US 63/392,778 27.07.2022 US
Details	**Summary of Application:** WO2023034783 (WO'783) claims a vaccine for tuberculosis (TB). WO'783 claims fusion protein comprising or consisting of Ag85A-ESAT6-Rv3407-Rv2626c-RpfA-RpfD (that is 2 antigens each from the acute, latency and resuscitation stage of TB – Fusion 6), and Ral2, TbH9, Ra35 (that is fusion protein MTB72F and its mutated version Mtb72Fmut SA) – (claims cover 6, 7, 8, and up to 9 fusion antigens) or fragments thereof, with a poly His tag and Met and HA tag; a nucleic acid encoding the same and a vector encoding the nucleic acid which may be a HCMV vector with a TR3 backbone and pharmaceutical or immunogenic composition of fusion protein, nucleic acid, vector. WO'783 claims method of generating immune response, use and method of treating or preventing tuberculosis, even in persons who have earlier been administrated BCG, or who is HIV positive and on ART treatment. WO'783 also claims method, use in manufacture, or use wherein tuberculosis infection is latent, pulmonary, recurrent; wherein in an amount effective for CD4+ T cell response/CD8+ T cell response restricted by MHC-II restricted/MHC-Ia. The application also claims methods of generating CD4+ T cells and CD8+ T cells and uses and methods of the CD8+ T cell thereof for treating a disease. **TPO filed:** The TPO observed through prior art documents that the vaccine composition and the claims of the application, WO'783, were not inventive. **No. of prior art documents used in No. of notes.:** 9 prior art documents were used in 5 notes to assail inventive step. **Additional comment filed:** Yes. The Additional comment was filed to show obviousness of the use of the fusion antigen (Fusion 6 Ag – known previously) with the M72 Ag (Mtb72f, & its mutated version with the S to A mutation); the obviousness to use HCMV vectors and the known conventional MHC responses elicited. The Additional Comment also brought out the obviousness of using the formulation disclosed, but not claimed in the Application WO'783. Insufficiency of disclosure was also pointed out in the Additional Comment. **Importance of Application:** The Application is of importance as it relates to pre-clinical candidate VIR-2020 TB vaccine.
Date of Filing of TPO	02/01/2024

National Phase

Office	Entry Date	National Number	National Status
Canada	18.01.2024	3226978	Published 26.01.2024
Australia	19.01.2024	2022339918	
New Zealand	23.01.2024	807561	Published 26.01.2024
India	02.02.2024	202417007297	Published 08.03.2024
Israel	05.02.2024	310667	

Thailand	09.02.2024	2401000867	
Mexico	12.02.2024	MX/a/2024/001964	Published 11.04.2024
Japan	27.02.2024	2024513275	
United Arab Emirates	28.02.2024	P2024-00475	
Philippines	28.02.2024	12024550541	
United States of America	28.02.2024	18687463	
Singapore	29.02.2024	11202400682U	Published 29.02.2024
Eurasian Patent Organization	15.03.2024	202490499	
European Patent Office	02.04.2024	2022777533	Published 10.07.2024
Republic of Korea		1020247005374	Published 17.04.2024